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Findings of not authorised substances in food and feed certified as organic

European Food Safety Authority (EFSA)

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Abstract

The European Commission requested EFSA to prepare a technical report on 21 active substances not authorised for use but detected more frequently in organic food/feed products according to notifications in the EU Organic Farming Information System (OFIS) between 2021 and 2022: fosetyl-Al, glyphosate, cypermethrin, imidacloprid, boscalid, tebuconazole, folpet, pirimiphos-methyl, azoxystrobin, fluopyram, lambda-cyhalothrin, acetamiprid, chlormequat, pendimethalin, spirotetramat, cyprodinil, chloridazon, pyriproxyfen, fludioxonil, difenoconazole and deltamethrin. The report focuses on organic food/feed of plant origin and apiculture products. It assesses the possible reasons behind the findings based on a broad spectrum of data sources: EFSA scientific Outputs, Member State reports, the EU OFIS, pesticides, biocides, veterinary medicines and chemical occurrence databases, food/feed and environmental monitoring data from the Information Platform for Chemical Monitoring, data from the EU Sustainable Plant Protection Transition project, industrial emissions portal and the literature. The report integrates inputs from a Technical Support Group composed of experts from the Joint Research Centre, European Chemicals Agency, European Environmental Agency and EFSA. None of the active substances occurs naturally. For each substance, several possible sources of residues were identified. When residues are quantified in organic products, investigation to confirm/exclude active unauthorised use of the substance is recommended. When phosphonic acid (metabolite of fosetyl and phosphonates), boscalid, fluopyram and difenoconazole are quantified in organic products, analysis of the soil where the plants were grown is recommended. When glyphosate, boscalid, azoxystrobin, fluopyram and spirotetramat are quantified in organic products, analysis of the water used to irrigate the plants is recommended. To confirm/exclude possible drift from conventional crops in the vicinity of organic crops, investigation of pesticide use around the area of the organic production site is recommended. Long/medium-range aerial transport of residues, transfer via water pathways or cross-contamination are other potential sources of residues in plants. Transfer of residues from industrial activity is unlikely.

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Keywords: organic products, residues, IPCHEM, plants, food, feed, environment

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Summary

According to Article 29(4) of Regulation (EU) 2018/848 of the European Parliament and of the Council on organic production and labelling of organic products, “by 31 December 2025, the Commission shall present a report to the European Parliament and the Council on the implementation of this Article [Article 29], on the presence of products and substances not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production and on the assessment of the national rules referred to in paragraph 5 of this Article. That report may be accompanied, where appropriate, by a legislative proposal for further harmonisation”.

To support the preparation of said report, a Service Level Agreement was concluded between the European Commission’s Directorate-General for Agriculture and Rural Development (DG AGRI), Directorate-General for Health and Food Safety (DG SANTE) and EFSA.

As one input into said report, the Agreement requests EFSA to develop a technical report on 21 active substances not authorised for use in organic production but detected more frequently according to notifications of suspicions of non-compliance with the organic legislation in the EU Organic Farming Information System (OFIS) between 2021 and 2022: fosetyl aluminium (or fosetyl-Al), glyphosate, cypermethrin, imidacloprid, boscalid, tebuconazole, folpet, pirimiphos-methyl, azoxystrobin, fluopyram, lambda-cyhalothrin, acetamiprid, chlormequat, pendimethalin, spirotetramat, cyprodinil, chloridazon, pyriproxyfen, fludioxonil, difenoconazole and deltamethrin. Since almost all findings were on organic food/feed commodities of plant origin and apiculture products, only these food/feed categories were considered in the EFSA report.

For each of the abovementioned active substances, possible reasons for their presence in organic crops were investigated based on a broad spectrum of data sources: EFSA scientific Outputs and Member State reports, EU databases on pesticides, biocides, veterinary medicines and chemicals, food/feed monitoring results from the EU OFIS and the EFSA’s chemical occurrence database, environmental monitoring data from Land Use/Cover Area frame statistical Survey Soil (LUCAS soil) and the water databases WATERQUALITY, EMPODAT and NAIADES, available on the EC’s Information Platform for Chemical Monitoring (IPCHEM), data from the EU Sustainable Plant Protection Transition project (EU SPRINT project), the EU Industrial Emissions Portal and other literature sources. EU Reference Laboratories, Member State national authorities and data providers were consulted on a case-by-case basis to collect relevant information. Only results from IPCHEM were considered for environmental occurrence.

Inputs from a Technical Support Group composed of experts from the Joint Research Centre, the European Chemicals Agency, the European Environmental Agency and EFSA were also considered.

None of the active substances assessed occurs naturally and all are or have been approved for use in plant protection products. Among these and their transformation products, ten are approved for biocidal use, five have been registered under REACH for different applications and five are authorised for veterinary medicinal use. These active substance applications may result in residues in organic plant commodities due to direct use on organic plant produce (unauthorised use) or indirectly, due to their transfer to the environment (air, soil and water) and from the environment to plants. This report investigates both the direct and indirect routes of plant exposure to these active substances.

Multi-residue methods are available for the analysis of most active substances and their residues in most matrices according to the residue definition for enforcement set in Regulation (EC) No 396/2005. Since results from food, feed and environmental samples collected between 2020 and 2022 were used in this report (unless otherwise stated), the applicable residue definitions for pesticide active substance monitoring in plants between 2020 and 2022 were considered. A wide range of analytical sensitivities has been reported, with limits of quantification (LOQ) ranging from 0.0005 mg/kg for fludioxonil to 20 mg/kg for phosphonic acid (a plant metabolite of fosetyl-Al and other phosphonate substances). Many of the available methods of analysis quantify residues at concentrations as low as 0.001 mg/kg and most of them at the default LOQ of 0.01 mg/kg.

To investigate possible active use of a substance in organic crops (unauthorised use), results from residue trials carried out to support plant protection product (PPP) applications in conventional crops were considered. Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use. Residues within the ranges derived from residue trials submitted to EFSA to support active use of a substance might be associated with active use of the substance according to the most critical conditions of use (i.e. conditions of use generating the highest residues). For less critical conditions of use, lower concentrations may also indicate active use.

Monitoring results on food and feed samples that are not labelled as organic were also integrated into the report to give a more realistic perspective on the levels of residues expected in products of conventional agriculture. These results support the statement that lower concentrations than those found in the residue trials may indicate active use.

The monitoring results on residues of pesticides in food and feed used in this report were generated through the EU multiannual control programme (EU MACP) and the national control programmes (MANCP). Results from the control activities of veterinary medicinal product residues (VMPR) in honey and feed commodities were also considered. Both pesticide residues and VMPR data collections cover 'labelled as organic' and 'not labelled as organic' food and feed commodities, processed and unprocessed.

A comparison of monitoring results between 'labelled as organic' and 'not labelled as organic' commodities shows that the occurrence of residues of pesticides in organic products is less likely than in their respective conventional commodities. For the 21 active substances considered in this report, the quantification of residues ranged from 0.04 to 3.95% in commodities labelled as organic (175,809 analytical results), and from 0.18 to 17.5% in commodities not labelled as organic (1,927,198 analytical results). Based on the above considerations, when residues of the substances considered in this report are quantified in organic commodities, the possibility of active use should be investigated.

For hydrolytically stable substances, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This is the case for fosetyl-Al, phosphonic acid (a transformation product of fosetyl and other phosphonates), glyphosate, imidacloprid, boscalid, tebuconazole, azoxystrobin, fluopyram, acetamiprid, chlormequat, pendimethalin, spirotetramat-enol, spirotetramat-monohydroxy, cyprodinil, chloridazon, chloridazon-desphenyl, pyriproxyfen, fludioxonil and difenoconazole.

For substances that may degrade under some food/feed processing conditions, the potential formation of degradation products would not be captured by the analytical methods if these products are not included in the residue definition for monitoring and, therefore, are not analysed. This would be expected to result in a decrease in the measured residues in the processed commodity when compared with the raw commodity. On the other hand, some processes such as drying may result in higher concentrations of residues in the processed commodities. Therefore, both possibilities (decrease or increase of residues) are plausible, depending on the process and the hydrolytic stability of the substance. This is the case of cypermethrin, folpet, phthalimide (a transformation product of folpet), deltamethrin, pirimiphos-methyl, lambda-cyhalothrin, spirotetramat, spirotetramat-ketohydroxy, and spirotetramat-enol-glucoside.

To investigate the possible transfer of residues of the active substances to organic commodities due to their presence in the environment, EFSA used data on the occurrence of residues of pesticides in soil, air and water sources in the EU. Most of the data come from the databases available on IPCHEM but occurrence data from the literature were also considered.

Fosetyl-Al, glyphosate, cypermethrin, tebuconazole, folpet, phthalimide, lambda-cyhalothrin, acetamiprid, chlormequat, spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, chloridazon and pyriproxyfen are not expected to accumulate in soil and plant uptake of residues from soil under organic farming systems is unlikely. Phosphonic acid, imidacloprid, boscalid, azoxystrobin, fluopyram, pendimethalin, cyprodinil, chloridazon-desphenyl, fludioxonil, difenoconazole and deltamethrin indicate a potential for accumulation in soil and a likely continued presence after discontinued use of the active substances. Occurrence data on pesticides in European soil were available from LUCAS soil on IPCHEM. Overall, 4,856 analytical results from soil monitoring in the EU for glyphosate, imidacloprid, boscalid, tebuconazole, azoxystrobin, fluopyram, pendimethalin, cyprodinil, chloridazon, fludioxonil and difenoconazole were available. In LUCAS soil, the lack of information on the agricultural use history of the sites where soil was sampled precluded knowing whether the reported quantified findings were related to recent active use or historical levels in soil. Information from studies carried out under the EU SPRINT project gave limited but relevant information on the presence of residues of glyphosate, tebuconazole, fluopyram, lambda-cyhalothrin, fludioxonil and difenoconazole in soil from organic produce production sites.

The accumulation of residues in soil cannot by itself constitute evidence for plant uptake. Based on studies assessed by EFSA on the nature and magnitude of residues of pesticides in rotational crops (i.e. crops planted after the harvest of a pesticide-treated crop), plant uptake of azoxystrobin, pendimethalin, cyprodinil, fludioxonil and deltamethrin from soil containing these active substances is unlikely. Uptake from soil that may contain residues of phosphonic acid, boscalid, fluopyram, and difenoconazole cannot be excluded.

Considering the above, when residues of phosphonic acid, boscalid, fluopyram and difenoconazole are quantified in organic commodities, analysis of the soil where the plants were grown is recommended.

The possible transfer of residues from water sources used for irrigation to plant commodities was also investigated based on monitoring results for pesticide residues in water samples from IPCHEM, and more specifically from the EEA-WATERQUALITY, EMPODAT and NAIADES databases, being the databases covering the timeframe 2020 to 2022 for most substances. In these databases, 1,056,687 analytical results are available for the 21 active substances and

some transformation products. The most monitored active substance was chloridazon (127,938 results), followed by imidacloprid (119,188 results) and glyphosate (103,613 results). The presence of residues in water sources cannot by itself constitute evidence of their transfer to plant commodities. To investigate the possible transfer from environmental water sources to plants, EFSA built a conservative scenario to estimate the residue concentration in water per substance (screening Cw), below which the quantitative transfer of residues to plant commodities when this water was used to irrigate plants is unlikely. The scenario assumes (among others) that the water used to irrigate the crop of interest contains residue concentrations equal to those measured in the water sample and that the volume of water used to irrigate the plants is 6,030,000 L/ha per year (highest irrigation volume for Tier 1 groundwater scenarios in FOCUS i.e. the Forum for the co-ordination of pesticide fate models and their use).

For 16 active substances and four plant metabolites, more than 99% of water samples analysed had residues at concentrations below the estimated screening Cw. Therefore, the transfer of residues from EU water sources used for irrigation to plant commodities is unlikely for fosetyl, cypermethrin, imidacloprid, tebuconazole, folpet and phthalimide, pirimiphos-methyl, lambda-cyhalothrin, acetamiprid, chlormequat and chlormequat-chloride, pendimethalin, spirotetramat-enol, spirotetramat-ketohydroxy, cyprodinil, chloridazon and chloridazon-desphenyl, pyriproxyfen, fludioxonil, difenoconazole and deltamethrin.

For five active substances, more than 1% of water samples analysed had residues at concentrations above their respective screening Cw. Therefore, the transfer of residues from EU water sources used for irrigation to plant commodities could not be excluded for glyphosate, boscalid, azoxystrobin, fluopyram and spirotetramat. Based on the above considerations, when residues of azoxystrobin, boscalid, fluopyram, glyphosate and spirotetramat are quantified in organic commodities, analysis of the water source used to irrigate the plants is recommended.

Few data from the literature examine the potential transfer of residues from industrial activity to environmental sources in their vicinity (air, water and soil) but no study was retrieved assessing the potential transfer from industrial emissions to plants. For active substances with more than 1% of water samples exceeding the estimated Cw, the potential impact of industrial activity in the surrounding areas was investigated. A mapping of the locations of these samples on IPCHEM with georeferenced data from the EEA's Industrial Emissions Portal did not show associations between environmental occurrence and industrial activity in the surrounding areas.

Drift from conventional crops treated close to organic crops cannot be excluded for most active substances. For pirimiphos-methyl, which is approved for indoor use only, and for chloridazon, which is no longer approved in the EU and the grace period for the withdrawal of authorisations expired, transfer of residues from conventional to organic agriculture due to drift is unlikely. For imidacloprid, which is no longer approved for plant protection in the EU, the transfer of residues from conventional to organic crops due to drift cannot be excluded in areas where emergency authorisations have taken place. For pendimethalin and glyphosate, where the worst-case drift was estimated to be lower than 3% of the applicable concentration in treated crops found at a 1 m distance from organic agriculture, the transfer of residues to organic plants via drift is less likely to explain residues in crops where the substance has not been actively used.

Based on data from the literature, medium to long-range aerial transport of residues to plants (i.e. the transfer of residues at distances 1 to 1,000 km and more than 1,000 km, respectively) cannot be excluded for tebuconazole and pendimethalin. There are indications for medium-range aerial transport of residues for fosetyl-Al, glyphosate, cypermethrin, boscalid, folpet,

azoxystrobin, fluopyram, acetamiprid, spirotetramat, cyprodinil, fludioxonil and difenoconazole so this cannot be excluded as an exposure route. Even for imidacloprid, which is no longer approved for plant protection purposes in the EU, the risk from the release of residues in the air due to its use in biocidal products or in the context of emergency authorisations cannot be excluded. For deltamethrin, the available evidence did not give indications for aerial transport of residues in the medium range from the treated areas, but neither can it be excluded. No information was retrieved regarding the long-range aerial transport of residues of chlormequat and pyriproxyfen. Medium- to long-range aerial transfer of residues of lambda-cyhalothrin is unlikely. Aerial transport of residues of pirimiphos-methyl, which is approved for indoor use only is unlikely. Following the end of the grace period for the withdrawal of authorisations for chloridazon, medium to long-range aerial transport of residues of chloridazon to plants is unlikely.

Among the active substances assessed, some are registered under REACH, used as biocides or veterinary medicines. These uses may also release residues in the environment that may be transferred from the environment to plants and to food/feed commodities. Conservative estimates on the possible transfer of residues from water used for irrigation to plant commodities combined with information on plant uptake of residues from soil indicate that the transfer of residues to plant commodities due to biocidal, veterinary or other non-plant protection use are minor contributors to the overall uptake of residues by plants.

A potential source of the unintentional presence of residues of pirimiphos-methyl is the cross-contamination from treated storage facilities. This, however, would not be expected to occur in products from organic agriculture where the legal provisions in place to avoid such incidents are adhered to.

Some residues such as those of phosphonic acid and phthalimide may have several origins. When residues of phosphonic acid are measured in randomly collected samples of organic agriculture, these may relate to the unauthorised use of fosetyl-Al or phosphonates. They may also relate to the use of diammonium phosphate as an oenological adjuvant, salts of phosphonic acid as fertilisers (unauthorised uses), plant strengtheners (unauthorised uses), or to the naturally occurring salts and esters of phosphonic acid and organic phosphonates. The presence of phthalimide in commodities of plant origin for which there is no authorisation for use of folpet requires investigation considering that phthalimide is a transformation product of the active substances phosmet and ditalimfos.

Glyphosate can be transferred to the environment and from the environment to plants due to applications of the active substance for weed control on railway tracks, urban areas, road and infrastructure management and use by private gardeners.

For all active substances, residues in the environment may arise from water contamination pathways, including the lateral movement of fluids in soil, leaching from soil and sediment particles, drainage systems, and bank infiltration from rivers, as well as point sources such as spillage, tank washing, application machinery cleaning and waste disposal of contaminated items. Additionally, contamination from rainwater (causing wet deposition of spray aerosol air residues, the available monitored levels of which have been reported for each of the substances), particularly after long dry periods, may contribute to water and soil contamination. Another water source might be the washing of the commodity post-harvest with water that contains residues. Some transfer of residues to plants and their products from these sources cannot be excluded.

Findings of not authorised substances in organic products

Despite accredited laboratories taking measures to avoid potential cross-contamination of the samples analysed, cross-contamination in the laboratory cannot be completely ruled out.

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1. Introduction

1.1 Background and terms of reference as detailed in the Service Level Agreement with the European Commission (SLA)¹

BACKGROUND

On 14 December 2023, the European Commission (EC) concluded a Service Level Agreement (SLA)¹ with EFSA tasking EFSA with the preparation of a technical report assessing the available scientific data on the substances listed in Annex A to the SLA¹.

In the SLA¹ between the EC and EFSA, in Part II Special Conditions, Point 1 of Section II.1 Provisions of the Agreement, the background is detailed as follows:

“Regulation (EU) 2018/848² of the European Parliament and of the Council on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 was adopted on 30 May 2018 applied from 1 January 2021.

According to the first recital of Regulation (EU) 2018/848², “[o]rganic production is an overall system of farm management and food production that combines best environmental and climate action practices, a high level of biodiversity, the preservation of natural resources and the application of high animal welfare standards and high production standards in line with the demand of a growing number of consumers for products produced using natural substances and processes”.

Therefore, organic production is highly restrictive in terms of the products and substances that can be used. However, these strict legal provisions notwithstanding, contaminations of food and feed products certified as organic with products and substances not authorised for use in organic production are sometimes detected.

As reflected in paragraph 5 of Article 29 (“Measures to be taken in the event of the presence of non-authorised products or substances”) of Regulation (EU) 2018/848², a number of Member States have in place rules providing for products that contain more than a certain level of products or substances not authorised for use in organic production not to be marketed as organic products.

According to paragraph 4 of Article 29 of Regulation (EU) 2018/848², “[b]y 31 December 2025, the Commission shall present a report to the European Parliament and the Council on the implementation of this Article, on the presence of products and substances not authorised pursuant to the first subparagraph of Article 9(3) for use in organic production and on the assessment of the national rules referred to in paragraph 5 of this Article. That report may be accompanied, where appropriate, by a legislative proposal for further harmonisation.”

TERMS OF REFERENCE

Against said background, EFSA agreed to provide input to enable the European Commission to produce the aforementioned report to the European Parliament and to the Council, in accordance

¹ Service Level agreement between DG SANTE, DG AGRI and EFSA: <https://open.efsa.europa.eu/questions/EFSA-Q-2024-00614>.

² Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 *OJ L 150, 14.6.2018, p. 1–92*

with Article 29(4) of Regulation (EU) 2018/848², by providing detailed scientific and technical information on the substances listed in Annex A to the SLA¹, which currently are not authorised for EU organic production and had been detected more frequently in food and feed products certified as organic in the years 2021 and 2022 according to notifications of suspicions of non-compliance with the organic legislation in the EU Organic Farming Information System (OFIS). This shortlist has been agreed mutually between the European Commission and EFSA.

In particular, EFSA should assess the available data on the substances listed in Annex A to the SLA¹ that are: fosetyl-aluminium (or fosetyl-Al), glyphosate, cypermethrin, imidacloprid, boscalid, tebuconazole, folpet, pirimiphos-methyl, azoxystrobin, fluopyram, lambda-cyhalothrin, acetamiprid, chlormequat, pendimethalin, spirotetramat, cyprodinil, chloridazon, pyriproxyfen, fludioxonil, difenoconazole and deltamethrin.

For this purpose, as indicated in the Objectives (point 2 of Section II.1 Provisions of the Agreement, under Part II Special Conditions) EFSA should:

- Screen previous EFSA Scientific Outputs including Scientific Opinions related to the substances under assessment;
- Liaise and collaborate with other EU Agencies and EU bodies to retrieve information not available in EFSA and seek technical support, as needed; in this respect, EFSA will
 - Engage with decentralised agencies namely the European Chemicals Agency (ECHA) and the European Environment Agency (EEA) and with the Joint Research Centre (JRC) of the European Commission for collecting data and their input according to their respective competencies, particularly on the substances listed in Annex A.
 - On a case-by-case basis, and based on the identified needs, involve Member States national competent authorities, in accordance with the rules applicable to EFSA or experts and to other stakeholders as appropriate to obtain all necessary data to fill the identified data gaps to aim to answer all questions and to validate findings/tasks.
- Perform bibliography searches;
- Address the following questions for each substance, highlighting any limitations and data gaps that could not be addressed:

Method(s)

- What is/are the residues to be monitored per substance currently not authorised for EU organic farming according to the residue definition (RD) for monitoring set in Regulation (EC) No 396/2005³? Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

Authorisation status and use

- Is the substance currently not authorised for EU organic farming currently authorised for non-organic farming or can it be legally used (authorised or not) for purposes other than plant

³ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

protection in the EU? If not, has that substance ever been authorised for non-organic farming or for other than PPP use in the EU? If so until when?

- What is/was the actual use of the substance currently not authorised for EU organic farming? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

Sources of residues in plants

- Natural occurrence:

Is there evidence that the substance currently not authorised for EU organic farming occurs naturally in situations relevant to primary production storage and transport? What is known about the natural origin of this substance?

- Active use (all legitimate uses of the substance):

When used as intended in conventional farming, what levels of the substance currently not authorised for EU organic farming per food/feed product would be consistent with active use of the substance based on the highest residues quantified in the residue trials performed according to the critical good agricultural practices (GAP)⁴?

Could the presence of the substance and/or its residues be due to biocide use?

- Behaviour in food and feed products:

What key physico-chemical properties of the substance currently not authorised for EU organic farming are expected to have an influence on its presence in plant produce? Indicate for each substance considered where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

- Drift:

What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

- Accumulated/historical residue levels in soil:

What is the persistence of an active substance and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

What is the current level of accumulated/historical levels in the soil with the substance currently not authorised for EU organic farming: which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical

⁴ Based on Reg. (EC) No 396/2005, 'good agricultural practice' (GAP) means the nationally recommended, authorised or registered safe use of plant protection products under actual conditions at any stage of production, storage, transport, distribution and processing of food and feed. It also implies the application, in conformity with Directive 91/414/EEC, of the principles of integrated pest control in a given climate zone, as well as using the minimum quantity of pesticides and setting MRLs/temporary MRLs at the lowest level which allows the desired effect to be obtained' and 'critical GAP' means the GAP, where there is more than one GAP for an active substance/product combination, which gives rise to the highest acceptable level of pesticide residue in a treated crop and is the basis for establishing the MRL'.

areas what evidence is there of an association with particular cropping systems or other relevant anthropogenic activity?

- Other sources such as industrial emissions, contaminated water, etc.

When is there evidence that residues from other sources such as industrial emissions, contaminated water might be important and need consideration?

- Prepare a technical report summarising the work performed.

1.2 Additional information

The screening and shortlisting of the substances to be considered in this technical report was based on an analysis of the notifications of suspicions of non-compliance with the organic legislation in the OFIS for the years 2021 and 2022. The report, however, considers data generated within a wider timeframe, from a broad spectrum of data sources that are presented in the next section. The assessment focuses on data from the EU Member States, Iceland and Norway. When relevant and available, information from other European countries was also used.

The report considers inputs from a Technical Support Group composed of experts from ECHA, EEA and the European Commission JRC to facilitate the exchange of data and to check the plausibility of the data within their remit.

With few exceptions, all findings of not authorised substances in organic products reported in the OFIS were on food and feed products of plant origin, honey and other apiculture commodities. Therefore, this report focuses on products of food and feed of plant origin, honey and other apiculture commodities. Products of animal origin other than honey were not assessed.

To ensure clarity, sub-questions were formulated for some of the SLA questions per substance. Instead of the terms 'non-organic farming'/'non-organic agriculture', terms 'conventional farming'/'conventional agriculture' were used throughout the document. Since there is no definition of 'contaminated water' as such, this term was not used in the report. Instead, the term 'environmental water samples with quantified residues on IPCHEM' was used instead.

2. Data and methodologies

2.1 Data sources used in the assessment

This technical report was prepared based on the following data sources and indicated timeframes for the substances under assessment:

- a) EFSA Peer Review Conclusions, EFSA MRL Reasoned Opinions and the respective Member State draft assessment (DAR), renewal assessment (RAR) and evaluation reports (ER) on pesticide active substances and their residues (all available sources were considered and no time limit applied);
- b) Data from the EU pesticides database⁵ (all available sources and no time limit applied);

⁵ https://food.ec.europa.eu/plants/pesticides/eu-pesticides-database_en

- c) Data from monitoring control programmes extracted from the EU OFIS in 2021 and 2022;
- d) Data from the ECHA website⁶ on biocidal products as authorised under the Biocidal Products Regulation (BPR)⁷, biocidal active substances and substances registered under Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH registrations)^{8,9} (all available sources and no time limit applied);
- e) Data on the occurrence of pesticides in food and feed of plant origin as well as honey and other apiculture products from the more recent years 2020 to 2022¹⁰.

These data were submitted to EFSA in the context of the EU pesticide monitoring activities and relate to measurements of samples collected and analysed by EU Member State¹¹, Iceland and Norway under the EU multiannual control programme (EU MACP) or the national control programmes (MANCP).

Sampling aiming for positive findings (non-random sampling) is out of the scope of this report and was not considered.

- f) Data on the occurrence of veterinary medicinal product residues (VMPR) in honey and feed products from 2020 to 2022¹⁰.

These data were submitted to EFSA in the context of the VMPR control activities and relate to EU samples collected and analysed by EU Member States¹¹, Iceland and Norway.

As above, sampling aiming for positive findings (non-random sampling) is out of the scope of this report and was not considered.

- g) Data on the occurrence of pesticides in soil and water samples from databases available on the EC's Information Platform for Chemical Monitoring (IPCHEM)¹²:

Results from the monitoring of pesticides in EU agricultural soil were retrieved from the 2018 Land Use and Cover Area Frame Survey (LUCAS) for pesticides (LUCAS Pesticides 2018) for 12 out of the 21 substances considered in this report¹³ (the database has been recently updated). The database integrates results on the occurrence of pesticides in agricultural soil collected from 3,473 georeferenced locations in the EU and UK based on a common sampling procedure and common methods of analysis, as described by Vieira et al. (2023). This makes LUCAS pesticides 2018 one of the largest standardised datasets of soil properties in the EU (Orgiazzi et al., 2018). Since occurrence data in soil from the next

⁶ <https://echa.europa.eu/>

⁷ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. *OJ L 167*, 27.6.2012, p. 1–123

⁸ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. *OJ L 396*, 30.12.2006, p. 1–849

⁹ <https://chem.echa.europa.eu/>

¹⁰ Although only the more recent data were considered, reports on the monitoring of pesticide residues in food and feed are available since 1999 in the EU and reports on the monitoring of VMPR in food and feed are available since 1997 in the EU.

¹¹ In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Windsor Framework in conjunction with Annex 2 to that Framework, for the purposes of this technical report, references to Member States include the United Kingdom in respect of Northern Ireland. For more information, please consult the EFSA European Union reports on pesticide residues in food (EFSA, 2022a, 2023a and 2024a) and the EFSA European Union reports on veterinary medicinal product residues in live animals and animal products (EFSA, 2022b, 2023b and 2024b).

¹² <https://ipchem.jrc.ec.europa.eu/>

¹³ Azoxystrobin, boscalid, chloridazon, cyprodinil, difenoconazole, fludioxonil, fluopyram, glyphosate, imidacloprid, pendimethalin, phthalimide (a metabolite of folpet) and tebuconazole.



survey round in 2022 are under assessment and not published yet, this report was based on data collected in 2018, acknowledging the lack of time frame correspondence of this data set in relation to residue monitoring of pesticide data (Franco et al., 2024). Generally, it is expected that patterns of pesticide use have not dramatically changed between the two periods. If there is a significant change on the authorisation status of a substance (especially if the substance is persistent in soil), this will be commented on for the particular case. Other limitations of the database relate to the non-provision of information on whether organic or conventional agriculture is applicable at the sites where the soil was sampled as well as the lack of data on the use of the substance/product of interest in the sampling area. These limitations were taken into account in the interpretation of the data.

Regarding occurrence of active substances in environmental water samples, only results from databases available on IPCHEM were considered and the dates of the data extraction were recorded. EFSA did not consult the individual databases. Among the water occurrence databases on IPCHEM only those displaying results for the years 2020 to 2022 were used in the assessment: EEA-WATERQUALITY¹⁴, EMPODAT¹⁵ and NAIADES¹⁶. In cases where environmental monitoring data were not available for the three consecutive years 2020 to 2022 for some substances, data from previous years (but not earlier than year 2017) available in these databases were considered.

Differences between datasets in the source databases (EEA-WATERQUALITY¹⁴, EMPODAT¹⁵ and NAIADES¹⁶) and datasets in these databases on IPCHEM may occur mainly due to updates in the source that are not simultaneously implemented on IPCHEM.

EEA-WATERQUALITY¹⁴ is an open access database that contains georeferenced data generated from samples collected and analysed in 36 European countries, both on a mandatory (priority substances) and voluntary (other substances) basis. Except for cypermethrin, the substances under assessment are monitored on a voluntary basis. The sampling strategy varies from one data source to another, and, consequently, the resulting data do not provide a comprehensive overview of the occurrence of pesticide residues in the EU waters (EEA, 2024 under Documentation as provided to EFSA). The types of water sources sampled and considered in this report are surface, groundwater, transitional and coastal water sources.

EMPODAT¹⁵ is an open access database of the NORMAN Database System that systemically collects data on georeferenced environmental monitoring in Europe, predominantly in surface water, sediment and biota (Dulio et al., 2018). It relies on data generated from samples collected and analysed in 27 European countries¹⁷ on a voluntary basis. Some regions benefit from more extensive monitoring activities, others from less (NORMAN, 2024 under Documentation as provided to EFSA). The types of water sources sampled and considered in this report are surface water and groundwater sources.

NAIADES¹⁶ is an open access database managed by the French public service and collects georeferenced data on the quality of continental water at the national level. The data are generated by water boards and the competent national agencies on water and biodiversity

¹⁴ European Environment Agency (EEA), Waterbase – Water Quality database. Available at: <https://www.eea.europa.eu/en/datahub/>

¹⁵ NORMAN EMPODAT Database – Chemical Occurrence Data. <https://www.norman-network.com/nds/empodat/>. Available online: <https://www.norman-network.com/nds/>

¹⁶ Naiades (Office Français de la Biodiversité). Available online: <https://naiades.eaufrance.fr/>

¹⁷ Austria, Belgium, Bulgaria, Switzerland, Czechia, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece, Croatia, Hungary, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Sweden and Ukraine



and have different purposes and origins such as to implement the Water Framework Directive¹⁸, study specific chemicals of interest or chemicals historically present in water, investigate the water quality, carry out monitoring activities for research purposes, etc. Information submitted to NAIADES is published as such; therefore, the format of the data is not standardised. The responsibility for the quality of the submitted information relies on the data provider (NAIADES, 2024 under Documentation as provided to EFSA). The types of water sources sampled and considered in this report are surface water sources.

Note was taken that EEA-WATERQUALITY, EMPODAT and NAIADES do not provide information regarding the practice of organic or conventional agriculture close to the area of sampling nor on whether the substance/product of interest was used in the area. EEA-WATERQUALITY, EMPODAT and NAIADES are not responsible for organising monitoring programmes. These are developed and implemented by the different bodies that collect and analyse environmental water samples for different purposes (e.g. random sampling vs targeted sampling) that do not always reflect the situation of residues in waters per geographic area.

Limitations on the specific datasets used in the assessment were also identified. One relates to the identification of outliers, i.e. samples with quantified values below the limit of quantification (LOQ) (e.g. 871 samples of glyphosate reporting concentrations below the LOQ) and samples with quantified values at high LOQs (≥ 1 $\mu\text{g/L}$) (e.g. 667 water samples reporting glyphosate concentrations equal to an LOQ of 20 $\mu\text{g/L}$). Although the identified outliers were disregarded, there may be some results with quantitative values at $\text{LOQ} \geq 1$ $\mu\text{g/L}$ that are not outliers. This may result in an underestimation of the total samples. Quantified results for which LOQs are not reported were considered in the assessment, assuming that the applicable analytical methods had LOQs lower than the quantified values. This inclusion may overestimate the total number of samples. Another limitation relates to the inclusion of results of transitional and coastal waters from the EEA-WATERQUALITY database that are out of the scope of this report. Samples of transitional and coastal water account for 12% of samples analysed for azoxystrobin in EEA-WATERQUALITY, 4.5% of samples analysed for boscalid, 2% of samples analysed for imidacloprid and 0.2% of samples analysed for glyphosate. These results are reported as 'other water' in the database, together with surface and groundwater samples. The inclusion of these samples overestimates the total number of samples. These limitations were taken into account in the interpretation of the data.

- h) Data on the occurrence of pesticides in environmental samples (soil, water and air samples) generated in the framework of the EU Sustainable Plant Protection Transition project (EU SPRINT project)¹⁹ and published in the scientific literature.
- i) Georeferenced data on the above-mentioned databases on IPCHEM for samples collected between 2020 and 2022.
- j) Georeferenced data from the European Industrial Emissions Portal²⁰. This source includes data on over 60,000 industrial sites spanning 65 economic activities across Europe²¹. For

¹⁸ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. OJ L 327, 22.12.2000, p. 1–73.

¹⁹ <https://sprint-h2020.eu/>

²⁰ <https://industry.eea.europa.eu/explore/explore-data-map/map>

²¹ EU Member States, Iceland, Liechtenstein, Norway, Serbia, Switzerland and the United Kingdom

the purposes of this report, the year 2021 was selected as the representative year, with a focus on chemical industry sites due to their potential link to pesticide occurrence. This selection resulted in nearly 3,000 relevant sites (i.e. location and administrative data) across Europe.

- k) When it was not possible to address the Terms of Reference based on the above information, other data sources were consulted (e.g. natural product databases²²) and/or a bibliography search was carried out, on a case-by-case basis. When a literature search was carried out, its purpose was not to exhaustively cover the identified data gap through a systematic literature review but rather to report on other uses (e.g. raw material in industrial processes) or effects (e.g. phytotoxicity) that are widely acknowledged but are not covered by the above-mentioned data sources.

2.2 Method(s)

- What is/are the residues to be monitored per substance currently not authorised for EU organic farming according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

Since all substances considered in this report are pesticide active substances, and the questions to address relate to findings in food and feed of plant origin and apiculture products, only methods of analysis of residues of pesticides in food and feed of plant origin and apiculture products were considered in this section.

The residues to be monitored per active substance are reflected in the residue definition for monitoring set in Regulation (EC) No 396/2005³ for the years 2020 to 2022. If the residue definition for monitoring was amended and more than one residue definition was applicable between 2020 and 2022 (case of spirotetramat), then both residue definitions were considered in the report; the final conclusions, however, refer to the most recent residue definition.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

The capacity of the available methods of analysis to quantify residues based on the applicable residue definitions for monitoring for the years 2020, 2021 and 2022 was assessed. Only routine methods of analysis for the monitoring of residues in food, feed of plant origin, honey and apiculture products were considered. Methods quantifying residues in animal products other than honey and apiculture products are out of the scope of this report.

The report provides information on the validity and sensitivity of the available methodologies as well as information on whether they are based on single or multi-residue methodologies. Note was taken that the Quick, Easy, Cheap, Effective, Rugged, and Safe method of analysis (QuEChERS) as well as method DFG S19 are multi-residue methods (CEN, 2008 and 2013).

Data sources for the development of the section on methods of analysis were the EFSA Peer Review Conclusions, the EFSA Reasoned Opinions on the review and setting of MRLs as well as the respective DARs, RARs and/or ERs developed by the National Authorities at Member State level. When information on the type of methodology was unavailable (single vs multi-residue),

²² Search was done using the substance's name and CAS number in the following natural product databases: COCONUT (<https://coconut.naturalproducts.net/>), NPASS (<https://bidd.group/NPASS/>), LOTUS (<https://lotus.naturalproducts.net/>) and SuperNatural (https://bioinf-applied.charite.de/supernatural_3/subpages/compounds.php) additional search was performed on PUBMED and Web of Science using as terms: substance name AND "natural occurrence" OR natural.

the competent Rapporteur/Evaluation Member States (RMS/EMS) were consulted. For substances where only information on single residue methods became available from these sources, a further literature search was carried out to investigate whether multi-residue methods were also developed in the more recent years in the EU. Also here, the purpose of the literature search was not to perform a systematic literature review but rather to investigate the lack of multi-residue methods for some substances.

For data gaps related to methods of analysis in honey and other apiculture products, EFSA reached out to both Member States and the EU Reference Laboratories for pesticide residues and received relevant information.

2.3 Authorisation status and use

Only authorisations and uses in the EU were considered for the substances under assessment.

Authorisation

- Is the substance currently not authorised for EU organic farming currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has that substance ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

The status of approval and authorisations for plant protection purposes in the EU was taken from the Commission EU Pesticides database⁵. The status of approval and authorisations for biocidal uses in the EU were taken from the ECHA website⁶. As such only biocidal products as authorised under the BPR⁷ have been taken into consideration. The countries authorising plant protection product(s) and/or biocidal product(s) that contain these substances have been listed per substance.

Substances that were registered under REACH⁸ were also considered. In this context, information from the REACH registrations of each substance was sought. REACH registration is not an approval/authorisation system and hence registrations have indefinite validity (they may be revoked/invalidated under specific situations, such as incorrect declaration of company size or the registrant is no longer established in the EU Member States¹¹, Iceland, Liechtenstein and Norway or is not legally registered anymore).

Some of the substances considered in this report are authorised for use as veterinary medicines^{23, 24}. Although products of animal origin are out of the scope of the present assessment, transfer of residues from manure to plants was considered relevant and is therefore discussed in the report.

Uses of the substance

- What is/was the actual use of the substance currently not authorised for EU organic farming? On what crops? For what purposes?

Information on the function (e.g. insecticide, fungicide, etc.) and mode of action of the active substance used in plant protection is given in this section. The EU area (Southern/Northern EU),

²³ Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. *OJ L 15, 20/01/2010, p. 1–72.*

²⁴ <https://medicines.health.europa.eu/veterinary/en/search-medicines>

types of crops on which the substance is used, types of applications (e.g. foliar, soil applications) and range of application rates (minimum–maximum) for the most critical GAPs⁴ assessed by EFSA are also reported. This information is available in the EFSA Peer Review Conclusions, MRL Reasoned Opinions and the Member State DARs, RARs and ERs.

- Are there uses other than PPPs in the EU? For what purposes?

For biocidal uses and uses falling within the remit of ECHA, information was retrieved from the ECHA website⁶. For biocidal products, the product assessment reports were considered.

For other uses which appear in registration dossiers submitted under REACH⁹, such information, as reported by the registrants, was considered, where available. In this section, the term 'active registration' means that the substance is manufactured or imported into the EU Member States, Iceland, Liechtenstein and Norway in quantities equal to or above 1 tonne per year. The opposite applies to inactive registrations.

Searches of peer-reviewed scientific literature were carried out on a case-by-case basis to acknowledge widely known uses of some substances that were not registered under REACH or were registered but data were unavailable due to confidentiality considerations.

The veterinary medicinal use of some substances is discussed in this report considering that residues in manure may be transferred to organic fertilisers and eventually to plants.

2.4 Sources of residues in plants

2.4.1 Natural occurrence

- Is there evidence that the substance currently not authorised for EU organic farming occurs naturally in situations relevant to primary production storage and transport? What is known about the natural origin of this substance?

Information available in the EFSA Peer Review Conclusions, EFSA MRL Reasoned Opinions as well as the Member State Assessment/Evaluation Reports was considered. When it was not possible to address the question of whether the substance of interest and/or its residues occur naturally based on the above sources, natural product databases²² were consulted.

2.4.2 Residue levels resulting from active use of the substance for plant protection

- When used as intended in conventional farming, what levels of the substance currently not authorised for EU organic farming per food/feed product would be consistent with active use of the substance based on the highest residues quantified in the residue trials carried out according to the critical GAP⁴?

To identify the **levels resulting from active use** of an active substance and its residues per crop, the following information was used:

Data from residue trials, submitted to support the use of the substance **in conventional (non-organic) crops and to derive MRLs** are available in the EFSA Peer Review Conclusions, EFSA MRL Reasoned Opinions as well as the Member State DARs, RARs and ERs: These trials, carried out according to the most critical GAP⁴ authorised per crop, are expected to generate the highest levels of residues. In its scientific assessments, EFSA does not have information on the

residue situation after product applications based on all the less critical GAPs that might be authorised in each Member State.

The following information was used in the assessment:

- **The range of quantified residues (minimum–maximum) and median residue concentrations** per crop based on the most critical GAP⁴ are indicators of the range of concentrations expected to result from active use. Since this range relates to the most critical GAP per crop, lower levels do not make it possible to exclude active use (especially from less critical GAPs) also considering that farmers adhering to GAP (also non-critical ones), will often use a product at the time a disease threshold is reached or a pest is present in a crop, which means in practice pre-harvest intervals are very often longer than that defined as the legal minimum on a particular product label.
- **Levels of residues in control (untreated) samples** (if applicable) were considered in conjunction with levels resulting from active use to see if they could support, or not, conclusions on active use. Their relevance in assessing the unintentional presence of residues due to 'Natural occurrence', 'Drift', 'Uptake from contaminated soil', 'Other sources such as industrial emissions, contaminated water, etc.' was also considered.

Residue concentrations were quantified based on the residue definition for enforcement. Considering, however, that some residue definitions were amended in the course of the years (e.g. fosetyl-Al), the residue concentrations derived from residue trials analysed for different residue definitions were amended to align with the residue definition applicable between years 2020 and 2022 in Regulation (EC) No 396/2005³.

Data from food and feed pesticide monitoring control programmes as extracted from the EFSA Scientific Data Warehouse for the relevant active substances submitted by EU Member States¹¹, Iceland and Norway. For some substances, data available in honey and feed products from the VMPPR EU control activities were also considered. Results from both raw primary commodities and processed commodities²⁵ are presented.

The following information was used in the assessment:

- The concentration ranges, median values and number of quantified results per commodity group for residues quantified in **unprocessed commodities not labelled as 'organic'** provide insight into the levels of residues resulting from active use under more realistic conditions than those covered by the residue trials (see above). This information incorporates the following uncertainties:
- It assumes that findings in products not labelled as organic result from active use which is not necessarily true (when a product is randomly taken from the market and analysed there is no way to know if a substance of interest was used or not in the product even if this comes from conventional agriculture). Because of this, this information should be handled with caution and considered in conjunction with the results from the residue trials (see previous bullet).

²⁵ According to Regulations (EC) 853/2004 and 848/2018, "processed products" are foodstuffs resulting from the processing of unprocessed products and these products may contain ingredients that are necessary for their manufacture or to give them specific characteristics irrespective of packaging or labelling operations. Term "processing" means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes, but does not include packaging or labelling operations.

- Exclusion of non-quantified results (i.e. results below the analytical LOQ²⁶) from the median calculations, assumes that none of the samples with measurements below the analytical LOQ underwent pesticide treatment. This would result in an overestimation of the medians.
- The concentration ranges, median values and number of quantified results per commodity group for residues quantified in **unprocessed commodities labelled as 'organic'**: Although these median values may represent the levels that are currently observed in organic crops, the origin of these residues (i.e. as result of active use and/or accidental) cannot be established based solely on this information.
- Information on the occurrence of the active substance and/or its **residues in processed products²⁵ labelled and not labelled as 'organic'**: Food processes that increase the concentration of residues in the processed commodity (e.g. dehydration), may uncover the presence of residues of the active substance in the raw commodity in which residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.
- According to the Compendium of Representative Processing Techniques Investigated in Regulatory Studies for Pesticides 'processing' means any action that substantially alters the initial product (Scholz et al., 2018; Zincke et al., 2022). The following processes are considered relevant in food processing: cooking in water, steaming, canning of fruits and vegetables (including jam/jelly/marmalade production as well as purée and paste production), dehydration/drying of fruits, vegetables, herbs and spices, frying and deep-frying, baking and roasting, microwaving, production of fruit and vegetable juices, wine manufacturing, fermentation and pickling, oil production including essential oils, soya drink and tofu production, beer brewing, milling processes, starch production, cocoa powder production and sugar production.
- The number, types of the samples analysed per commodity and in total (organic and conventional, unprocessed and processed) as well as the percentages of results below the LOQ, between the LOQ and the MRL and above the MRL per food/feed commodity group give insight into the occurrence of the substance of interest and/or its residues per type of commodities. The total number of samples per active substance covered by this report is given in Appendix A – Table A.1 for conventional production and Table A.2 for organic production.

The results from pesticide monitoring in food and feed were based on the applicable residue definition(s) for enforcement and applicable Maximum Residue Levels (MRLs) at the time of the collection of the samples. They have been summarised in tables that report the following information per type of commodity: min. analytical LOQ, concentration ranges from samples with quantified residues, total number of quantified results and median value of the quantified residues. Information on the sensitivity of the methods of analysis used is available. Only median values calculated based on five or more samples with quantified results in conventional and/or organic production were considered. For fewer than five quantitative findings per commodity the median estimates were not considered statistically robust and were not used (David and Nagaraja, 2003; Meeker et al., 2017).

Data from monitoring control programmes extracted from the EU OFIS are also presented for reasons of completeness (see Appendix A – Table A.3). They have not been used to drive conclusions in this report though, considering the rich data from random sampling available to EFSA (see above) and that the OFIS data do not result from random sampling processes.

²⁶ For the VMPPR data collection results may also be reported as below the limit of detection (LOD).

Although samples of food or feed products certified as organic are sometimes taken randomly under OFIS, they are most often taken on a risk basis, i.e. when there is a suspicion of a higher likelihood of non-compliance with the organic legislation (DG AGRI, 2024 under Documentation provided to EFSA).

Considering the significant number of products in Annex I of Regulation (EC) No 396/2005³ for which MRLs have been set, this technical report assesses data on plant commodities, honey and other apiculture products per active substance and its residues taking into account the broader categorisation code in Annex I for these plant commodities, honey and other apiculture products (i.e. X00 000) unless notable differences in results from residue trials and/or data from monitoring suggest using a more refined crop category (e.g. XX0 000, XXX 000, etc.) MRLs for the relevant food commodities and residue definitions extracted from the EU Pesticides Database⁵ were organised in a data format that can be used for the assessment.

2.4.3 Residue contribution from biocidal use

Investigation of the presence of the substance and/or its residues due to biocidal use is only applicable to substances that are also used as biocides. In this case, information from the ECHA website⁶ on biocidal products and the relevant product assessment reports are considered.

2.4.4 Behaviour in food and feed products

- What key physico-chemical properties of the substance currently not authorised for EU organic farming are expected to have an influence on its presence in plant produce? Indicate for each substance considered where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

This section is about the physico-chemical properties of each active substance of interest and its residue components (according to the residue definition for monitoring) which may affect its presence, transfer or transformation from farm to fork.

The following physico-chemical and environmental properties were considered relevant: hydrolytic degradation (>10%) of the active substance and plant metabolites included in the residue definition for monitoring, melting point, boiling point and temperature of decomposition, solubility in water, octanol/water partition coefficient (log Pow), acid dissociation constant (PKa), sorption to soil (K_{Foc}), disappearance time of the substance in soil (DT₅₀ and DT₉₀), vapour pressure, Henry's law constant, atmospheric half-life, octanol/air partition coefficient (log Poa). Whilst not strictly a physico-chemical property of a substance, predicted environmental concentrations in water (PEC_w) related to representative uses assessed at EU level have been reported and considered.

Most of these properties are available in the EFSA peer review conclusions for each active substance. When no recent reliable values were available to EFSA, they were retrieved from peer-reviewed scientific literature or technical data sheets from chemical manufacturing companies identified after a search carried out on the internet.

Data on the fate of residues under processing are also relevant and available in the EFSA MRL Opinions.

2.4.5 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

This section considers the potential transfer of residues during the treatment of a conventional crop that is in the vicinity of an organic crop. Spray drift values, assuming application via standard hydraulic nozzles that were used, were those provided by Rautmann et al. (2001). They quantify the 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. These spray drift values provide the proportion of the application rate that can be deposited over a neighbouring downwind field also considering typical distances between a treated and untreated downwind field. These values are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially whether the crop height requires downward or sideways spray orientation).

In addition to spray treatments, this report considers the transfer of residues due to methods of application that generate dust particles that can also contribute to the deposition of residues in neighbouring fields with organic crops. Seed always contains some dust that consequently gets active substance loaded on whilst it is being treated. Dust drift therefore occurs during sowing operations. Best practice is that seed should be as dust free as possible before it is treated.

For this exercise, the worst possible cases have been considered, disregarding any potential mitigation that could be applied by the farmer or recommended by Member State national authorities. The conclusions in this section are based only on qualitative considerations noting that the effect of drift depends also on the nature of the potential adjacent crops and their possible growth stage.

2.4.6 Accumulated/historical residue levels in soil

- What is the persistence of an active substance and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

The section investigates the potential plant uptake of an active substance and/or its residues due to their presence in soil based on information on the persistence of the active substance and its residues, data from studies on the nature and magnitude of residues in crops grown in rotation as well as monitoring data on the occurrence of pesticides in soil.

Information on the persistence and potential accumulation in soil is available from laboratory degradation and field soil dissipation studies and can be found in the EFSA Peer Review conclusions of the active substance of interest. When the disappearance time of 90% of the substance (DT₉₀) is estimated to be more than 365 days, a potential for accumulation in soil and possible presence of residues long after the use of the substance cannot be excluded (EFSA, 2023c). It should be noted that the available data on persistence in soil are generally very variable and that the realistic worst-case, among laboratory and field data, is selected by the fate and behaviour assessors to estimate the potential for accumulation of an active substance or its transformation products.

Studies on the metabolism and magnitude of residues in crops growing in rotation give a more realistic perspective on whether uptake of residues from soil takes place and to what extent.

Such studies are assessed in the EFSA Peer Review conclusions and/or the EFSA MRL Reasoned Opinions. These studies also give insight into the fate of residues once taken up by plants.

- What is the current level of accumulated/historical levels in soil with the substance currently not authorised for EU organic farming: which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Data on the levels of residues of active substances in soil and information on the geographical areas that are (mostly) affected by such accumulated/historical residues are provided in the LUCAS pesticides 2018 database that is available on IPCHEM (Vieira et al., 2023).

For some substances, results on the occurrence of residues in soil samples were also retrieved from the EU SPRINT project¹⁹ on the environmental and human health impact of Plant Protection Products and presented in this report.

- Other sources such as industrial emissions, water that contains residues, etc. When is there evidence that residues from other sources might be important and need consideration?

Other sources that were considered are discussed below (Sections 2.4.7 to 2.4.9).

2.4.7 Transfer of residues from water used to irrigate plants

In this section, data on the occurrence of pesticides in water samples from EEA-WATERQUALITY¹⁴, EMPODAT¹⁵ and NAIADES¹⁶ were filtered to shortlist the water samples for which transfer of residues to plant commodities cannot be excluded when used to irrigate plants.

To do so, an estimation of the water residue concentration (screening Cw in µg/L) that would have the potential to result in residues in plant commodities at the LOQ (mg/kg) was carried out for each substance based on the following equations and a number of worst-case assumptions (see below).

The results of these calculations are reported in Table 1.

$$\text{Screening Cw} = \frac{\text{Rw}}{\text{Vw}} \times 10^6 \quad \& \quad \text{Rw} = \frac{\text{LOQ} \times \text{Appl.R}_{\text{trials}}}{\text{HR}}$$

Where:

- Rw: the substance application rate by irrigation, i.e. the amount of the active substance applied by using irrigation water (Rw in g/ha) (estimated based on equations from the Forum for the Co-ordination of pesticide fate models and their Use (FOCUS) (EC, 2014a));
- Vw: the highest irrigation volume reported in FOCUS Tier 1 groundwater scenarios (6,030,000 L/ha per year);
- Appl.R_{trials}: the application rate leading to the HR (g/ha) according to the GAP⁴;
- HR: the highest residue reported in the GAP-compliant residue trials submitted to EFSA (mg/kg);
- LOQ: the limit of quantification in the GAP-compliant residue trial that derived the highest residue; when the LOQ of the analytical method used in the residue trials was not

available, the lowest LOQ from the trials carried out for the same commodity group was considered.

In these estimations the following conservative assumptions were considered:

- The water used to irrigate the crop of interest contains residue concentrations equal to those measured in the water sample;
- The substance application rate by irrigation (R_w in g/ha) is equivalent to the application rate of a PPP formulation (R_{PPP} in g/ha);
- There is a continuous uptake from the irrigation water and the residue builds up in the crop (e.g. from seed to fruit);
- The transfer of the active substance to the commodity is assumed to be equal to the transfer observed in the residue trial giving rise to the HR. This is a worst-case assumption as in several other residue trial samples (even for the same crop and the same application rate) the residue measured in the commodity is lower than HR. In addition, we establish the lower limit assuming there is a linear relationship between application rate and residue observed in the commodity.
- The availability of the active substance found in the water is the same as in the PPP formulation;
- The same rate of application always generates the same amount of residues in the plant commodity irrespective of the fresh commodity considered; nevertheless results of dried commodities are not considered to establish the screening C_w as it would not be at all appropriate to extrapolate residues observed in dried commodities (concentrated) to fresh commodities.
- Crops are irrigated with a water volume of 6,030,000 L/ha (highest value defined in FOCUS Tier 1 groundwater scenarios) (EC, 2014a).

Note was taken that C_w values were estimated for screening purposes only (screening C_w) considering that they are not based on experimental data but are the result of mathematic calculations that incorporate worst-case assumptions.

Table 1: Water samples for which transfer of residues to plant commodities cannot be excluded.

Active substance	Appl.R _{trials} (g a.s./ha)	HR (mg/kg)	LOQ (mg/kg)	R _w (g/ha)	Screening C _w (µg/L)	Total water samples	No of water samples ≥screening C _w	% water samples ≥screening C _w
Fosetyl	3,400	7.5	0.05	23	3.76	30,829	27	0.1%
Glyphosate	2,160	21.4	0.05	5.05	0.84	103,108	1,212	1.2%
Cypermethrin	118	2.1	0.01	0.56	0.09	60,441	79	0.1%
Imidacloprid	150	1.4	0.01	1.07	0.18	116,890	265	0.2%
Boscalid	400	29	0.05	0.69	0.11	2,842	854	30%
Tebuconazole	190	1.33	0.01	1.43	0.24	75,204	371	0.5%
Folpet	1610	6.3	0.02	5.11	0.85	42,700	0	0%
Phthalimide	5,000	2.45	0.05	102	16.9	2,150	1	0.05%
Azoxystrobin	500	6.2	0.01	0.81	0.13	75,085	1,393	1.9%
Fluopyram	400	10	0.01	0.40	0.07	6,788	3,878	57%
Lambda-cyhalothrin	24.9	0.63	0.01	0.40	0.07	49,167	7	0.01%
Acetamiprid	100	1.9	0.01	0.53	0.09	44,218	122	0.3%
Chlormequat (expressed as chlormequat chloride)	1638	7.4	0.05	11.07	1.84	219	0	0%
Pendimethalin	1590	0.76	0.02	41.84	6.94	66,095	0	0%
Spirotetramat	45	5.5	0.05	0.41	0.07	1,019	91	8.9%
Cyprodinil	800.05	8.9	0.01	0.90	0.15	55,874	178	0.3%
Chloridazon	2,580	0.47	0.05	274	45.52	123,074	0	0%
Chloridazon- desphenyl	2,580	0.93	0.05	138.7	23.0	16,637	7	0.04%
Pyriproxyfen	223	0.47	0.01	4.74	0.79	777	0	0%
Fludioxonil	518.9	11.42	0.01	0.45	0.08	52,827	146	0.3%
Difenoconazole	259.1	6.6	0.01	0.39	0.07	53,155	121	0.2%
Deltamethrin	37.5	1.38	0.01	0.27	0.05	52,790	478	0.9%
Pirimiphos-methyl	NA	NA	NA	NA	NA	NA	NA	NA

NA - not applicable

Water sources in the EU with residue concentrations below the screening C_w, would not be expected to transfer residues to plant commodities if these water sources are used to irrigate plants.

For water sources in the EU with residue concentrations at or above the screening C_w, transfer of residues from water to plant commodities via irrigation cannot be excluded.

In this report, when for an active substance >99% of residue concentrations were found below the screening C_w, then transfer of residues to plant commodities from water used to irrigate the plants was considered unlikely. When for an active substance ≥1% of residue concentrations were found equal to or above the screening C_w, then transfer of residues to plant commodities from water used to irrigate the plants could not be excluded.

Results on the occurrence of residues in water samples were also retrieved from the EU SPRINT project¹⁹¹⁹ on the environmental and human health impact of plant protection products and presented in this report.

2.4.8 Residues from industrial emissions

The section investigates the potential presence of residues in plants and their products as a result of their transfer from industrial emissions in the surrounding area (air, water and soil).

Provisions for the monitoring of emissions of plant protection products and biocides from industrial activities are set in Directive 2010/75/EU²⁷. These provisions are implemented at Member State level through regular monitoring.

²⁷ Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control). OJ L 334, 17.12.2010, p. 17–119.

For the substances assessed in this report, a literature search was carried out to cover the potential transfer of residues from industrial emissions to plants via air, water and soil. A search in the Scopus database was conducted between October 2024 and March 2025 using the keywords: 'compound name', industry/industrial, water OR soil/sediment OR air/atmosphere. The search was done within 'Article, abstract, keywords' including results from the EU from all available years between 1979 and 2025 and all types of documents (i.e. article, review, conference paper, conference review, note, book chapter, editorial).

To further investigate the potential transfer of pesticide residues from industrial sources, a mapping exercise was conducted for substances for which transfer of residues to plant commodities cannot be excluded. The selected substances – glyphosate, boscalid, azoxystrobin, spirotetramat, and fluopyram – were analysed by overlaying georeferenced water sampling data from IPCHEM (2020–2022) with georeferenced data on chemical industry facilities from the European Industrial Emissions Portal (2021)²⁰. The spatial overlap was assessed using a two-tier proximity criterion: (i) the number of relevant water samples (exceeding the screening concentrations C_w detailed in Table 1) within a 1 km radius of an individual chemical facility, and (ii) the number of such cases within a 5 km radius. This analysis was intended as an illustrative exercise to identify potential spatial trends and correlations, such as clusters of elevated water concentrations near specific industrial sites. However, a robust assessment of the link between monitoring locations and potential pollution sources (e.g. chemical industries) would require a more advanced modelling approach. This would need to incorporate factors such as industry-specific effluent routes, local and seasonal flow regimes corresponding to sampling times, contaminant behaviour (e.g. sorption, degradation), irrigation schemes, and temporally overlapping climate data, all of which were beyond the scope of this study.

2.4.9 Other sources

The section investigates the potential presence of residues in plants and their products as a result of their transfer from sources that are not covered by the ones above.

Results on the occurrence of residues in air samples were retrieved from the EU SPRINT project¹⁹ on the environmental and human health impact of plant protection products.

The aerial transport of residues over medium to long ranges that cannot be explained by drift, is also considered on a case-by-case basis depending on the properties of the active substance and data availability.

Information on the potential partition and transport of substances through the atmosphere (e.g. by volatilisation or by aerosol formation during hydraulic spraying) was collected from peer-reviewed dossiers submitted to EFSA on the authorisation or renewal of an active substance and the peer-reviewed scientific literature.

Runoff reaching roads or paths that can then drain to adjacent fields has also been reported as a source of transfer of residues in agricultural areas.

Another potential source of residues in organic agriculture is the transfer of residues to plants from organic fertilisers such as manure. This is relevant for substances that are used to treat crops used as animal fodder and particularly relevant for those used as veterinary drugs^{23, 24} among which are some of the substances considered in this report: cypermethrin, imidacloprid, cyhalothrin (that may release residues of lambda-cyhalothrin), pyriproxyfen and deltamethrin.

Other sources of residues such as e.g. accidents, emergency authorisations of substances that are no longer authorised in some areas, potential cross-contamination in the laboratory or under

storage may also result in residues in products of plant origin and are briefly considered in this report.

3 Assessment

3.1 Fosetyl-aluminium (or fosetyl-Al)

3.1.1 Method(s)

- **What is/are the residues to be monitored for the active substance fosetyl according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?**

For the active substance fosetyl aluminium (or fosetyl-Al), the residue definition for monitoring in food and feed of plant origin according to Regulation (EC) No 396/2005³ and its amendments for the years 2020 to 2022 was set as 'fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)'^{28, 29}. This residue definition is applicable to primary crops, rotational crops and processed products. The same residue definition is implemented in Reg. (EC) No 396/2005³ for honey and other apiculture products.

The active substance fosetyl-Al dissociates into fosetyl and Al^{2+} after application, fosetyl degrades further into phosphonic acid. Residues of phosphonic acid are not specific to fosetyl-Al but can result from other uses (see Section 3.1.2). In the more recent EFSA joint MRL review for fosetyl, disodium phosphonate and potassium phosphonates, it was proposed to change the residue definition for enforcement in commodities of plant origin from the sum of fosetyl, phosphonic acid and their salts (expressed as fosetyl) to phosphonic acid only and MRLs were derived considering not only results from trials carried out with fosetyl-Al, disodium phosphonate and potassium phosphonates but also based on monitoring data, in order to cover the residues of phosphonic acid resulting from all uses (EFSA, 2021a). This has now been implemented with Commission Reg. (EU) No 2024/2619³⁰.

Considering, however, that this report deals with results from 2020 to 2022, the applicable residue definition between 2020 and 2022 will be considered for foods of plant origin, honey and other apiculture products (i.e. the sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl).

- **Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?**

Analysis of fosetyl, phosphonic acid and their salts

In the context of the EFSA MRL review on fosetyl-Al, a single residue HPLC-MS/MS method was validated for the determination of fosetyl, phosphonic acid and their salts with an LOQ of 0.01 mg/kg for fosetyl and 0.1 mg/kg for phosphonic acid in high water, high acid, high oil content, and dry commodities (EFSA, 2012a; France, 2024 under 'Documentation as provided to EFSA').

²⁸ Commission Regulation (EU) 2022/1324 of 28 July 2022 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzovindiflupyr, boscalid, fenazaquin, fluazifop-P, flupyradifurone, fluxapyroxad, fosetyl-Al, isofetamid, metaflumizone, pyraclostrobin, spirotetramat, thiabendazole and tolclofos-methyl in or on certain products. *OJ L* 200, 29.7.2022, p. 68–108.

²⁹ Results are expressed as fosetyl and not as fosetyl-Al.

³⁰ Commission Regulation (EU) 2024/2619 of 8 October 2024 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fosetyl, potassium phosphonates and disodium phosphonate in or on certain products. *OJ L*, 2024/2619, 9.10.2024.

The EURLs report a similar HPLC-MS/MS method that is single residue (Anastassiades et al., 2023).

An analytical method based on GC-FPD and confirmed by GC-NPD, was validated for determining fosetyl, phosphonic acid and their salts in plant matrices with an LOQ of 0.5 mg/kg for both fosetyl and phosphonic acid in high water content and acidic commodities, and an LOQ of 2 mg/kg for fosetyl and 20 mg/kg for phosphonic acid in hops (EFSA, 2012a,b,c). It is noted that the method cannot differentiate fosetyl or phosphonic acid from their respective salts. The same method was considered suitable for herbal infusions and spices with the same LOQ as for hops.

Multi-residue HPLC-MS/MS methods are available to monitor fosetyl-Al and phosphonic acid residues at an LOQ of 0.01 mg/kg in high water and high acid content plant commodities, utilising modified QuPpe (Savini et al., 2019; Shinde and Banerjee, 2022).

According to the EURL for Residues of Pesticides (EURL, 2024, under 'Documentation as provided to EFSA'), a single residue LC-MS/MS QuPpe method is validated to monitor fosetyl residues at an LOQ of 0.02 mg/kg and phosphonic acid residues at an LOQ of 0.05 mg/kg in honey samples, with the sum LOQ of 0.09 mg/kg to cover the monitoring residue definition. Jesús et al. (2024) report a multi-residue LC-MS/MS method validated for monitoring of fosetyl-Al and phosphonic acid in honey samples and in honeybee-collected pollen at an LOQ of 0.005 mg/kg.

Analysis of fosetyl and its salts

A single residue quick polar pesticide QuPpe method based on LC-MS/MS was considered suitable for determining fosetyl and its salts in all plant commodity groups, with an LOQ of 0.01 mg/kg. However, an independent laboratory validation (ILV) was missing (EFSA, 2018a). According to Nortes-Méndez et al. (2016), fosetyl-Al can also be monitored by a multi-residue HPLC-MS/MS method in high oil content plant commodities, with an LOQ of 0.01 mg/kg.

In the EFSA MRL review on fosetyl-Al, a multi-residue QuEChERS method in combination with HPLC-MS/MS was reported for analysis of fosetyl only but without providing information on the sensitivity of the method and for which matrices it can be used (EFSA, 2012a).

Analysis of phosphonic acid and its salts

Phosphonic acid (and its salts) can be analysed utilising the single residue QuPpe method based on LC-MS/MS with an 0.1 mg/kg LOQ in high water content, acidic and dry commodities, and 0.5 mg/kg in high oil content commodities (EFSA, 2018a).

Summary of methods of analysis of fosetyl-Al (RD)

Overall, there are multi-residue methods available for monitoring residues of fosetyl, phosphonic acid and their salts in high water and high acid content plant commodities, as well as in honey and other apiculture products, covering the residue definition for enforcement that was in place during the analysis of the monitoring data from 2020 to 2022. Individually, fosetyl-Al can be monitored with multi-residue methods in high oil content plant commodities.

LOQs of the methods of analysis intended for enforcement purposes in food of plant origin range from 0.01 to 2 mg/kg for fosetyl and from 0.1 to 20 mg/kg for phosphonic acid and its salts.

According to the EURL for Residues of Pesticides (2024, under 'Documentation as provided to EFSA'), residues of fosetyl can be quantified in honey with an LOQ of a 0.02 mg/kg. Phosphonic acid residues can be monitored in honey with an LOQ of 0.05 mg/kg. The sum LOQ of 0.09

mg/kg is validated for analysis of fosetyl intended for enforcement purposes in honey and other apiculture products.

3.1.2 Authorisation status and use

- Is fosetyl-AI currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has fosetyl ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

a) Authorisations for plant protection use in conventional agriculture

Fosetyl-AI has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of approval of the active substance is 31 October 2026, as indicated by the EU Pesticides Database⁵ (accessed 14 March 2025). The application for the renewal of the approval of fosetyl-AI is under assessment.

According to the Pesticides database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, France, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, and Slovakia.

Phosphonic acid is a plant metabolite of fosetyl-AI but its presence in plants may also be due to agricultural applications of other approved active substances, i.e. disodium phosphonate and potassium phosphonates.

Disodium phosphonate has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of approval of the active substance is 31 January 2026, as indicated by the EU Pesticides Database⁵ (accessed 14 March 2025).

According to the EU Pesticides database⁵, at national level the substance has been authorised for use in Austria, Bulgaria, Czechia, Germany, Spain, France, Italy, Luxembourg, Portugal, Romania, Slovenia and Slovakia.

Potassium phosphonates have been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of approval of the active substance is 31 January 2026, as indicated by the EU Pesticides Database⁵ (accessed 14 March 2025).

According to the EU Pesticides database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, France, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, the Netherlands, Norway, Poland, Portugal, Romania, Slovenia and Slovakia.

³¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives. OJ L 309, 24.11.2009, p. 1–50

b) Authorisations for purposes other than plant protection

Biocidal use

Fosetyl-Al, phosphonic acid, disodium phosphonate and potassium phosphonates have not been approved for use in biocidal products in the EU Member States, Iceland, Liechtenstein and Norway as indicated by the ECHA website⁶ (accessed 6 June 2024).

Other uses

According to the search carried out on the ECHA website⁹ (accessed 6 June 2024), no products containing fosetyl are currently registered under REACH.

There are currently several registration dossiers for phosphonic acid, disodium phosphonate and dipotassium phosphonate as well as calcium phosphonate, calcium hydrogen phosphonate and diammonium phosphonate under REACH, which were active during the period 2020–2022. Collectively, these substances may have several uses the details of which are limited; however, the professional and consumer use of certain phosphonates as fertilisers is indicated in certain registration dossiers.

- What is/was the actual use of fosetyl? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of fosetyl-Al

Fosetyl-Al is an organophosphorous fungicide that inhibits the germination of spores or impedes the development of mycelium and sporulation. Fosetyl-Al has systemic properties and is rapidly absorbed through the plant leaves or roots with translocation both acropetally and basipetally. It is used across a diverse range of crops to control diseases caused by various pathogens, including *Phytophthora*, *Pythium*, *Plasmopara*, and *Bremia* spp. (EFSA, 2012a).

Conditions of use and applicable crops

Fosetyl-Al

The uses reported in the EFSA MRL review for fosetyl-Al included applications in northern and southern Europe belonging to the following crop groups: citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, stem vegetables, pulses (dried), herbal infusions from flowers, hops (dried), seed spices (dried), fruits spices (dried), sugar plants (EFSA, 2021a). Note was taken that the uses for tree nuts and pulses (dried) were supported by data (see Section 3.1.3.2 'Active use (all legitimate uses of the substance)').

Fosetyl-Al treatment included foliar applications (indoor and outdoor), soil treatments (indoor and outdoor), seed treatment (outdoor), dipping (indoor) and post-harvest treatments (indoor) (EFSA, 2021a).

Outdoor applications:

- Foliar treatments were reported for commodities belonging to the following crop groups: citrus fruits, tree nuts (chestnuts), pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, leaf

vegetables, herbs and edible flowers, stem vegetables, herbal infusions from flowers, hops (dried), seed spices (dried), fruit spices (dried) and sugar plants. Application rates ranged from 0.47 kg a.s./ha to 120 kg a.s./ha (EFSA, 2021a).

- Soil treatments were reported for commodities belonging to the following crop groups: berries and small fruits, brassica vegetables (excluding brassica roots and brassica baby leaf crops) and fruiting vegetables. Application rates ranged from 0.93 kg a.s./ha to 6 kg a.s./ha (EFSA, 2021a).
- Seed treatment applications were reported for pulses (dried peas) at a rate of 0.32 kg a.s./100 kg (EFSA, 2021a).

Indoor applications:

- Foliar treatments were reported for commodities belonging to the following crop groups: berries and small fruits, root and tuber vegetables, fruiting vegetables and leaf vegetables, herbs and edible flowers. Application rates ranged from 0.78 kg a.s./ha to 4 kg a.s./ha (EFSA, 2021a).
- Soil treatments were reported for root and tuber vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers and stem vegetables. Application rates ranged from 9.3 kg a.s./ha to 80 kg a.s./ha (EFSA, 2021a).
- Indoor post-harvest treatments by drenching were reported for citrus fruits at a rate of 0.32 kg a.s./hL (EFSA, 2021a).
- Local treatments by dipping were reported for witloof at a rate of 12.4 g a.s./hL (EFSA, 2021a).

Potassium phosphonates

The uses reported in the EFSA MRL review for potassium phosphonates included applications in northern and southern Europe belonging to the following crop groups: citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, olives for oil production, cereals and herbal infusion from leaves and herbs (EFSA, 2021a).

After the MRL review, applications were submitted to EFSA to modify the existing MRLs for stone fruits, bulb vegetables, leaf vegetables, herbs and edible flowers (chards/beet leaves), stem vegetables, and honey (EFSA, 2022c,d, 2023d).

Potassium phosphonates treatment includes foliar applications (indoor and outdoor), drip irrigation (outdoor) and post-harvest treatment drenching (indoor) (EFSA, 2018b, 2021a, 2022c,d, 2023d).

Outdoor applications

- Foliar treatments were reported for commodities belonging to the following crop groups: citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, stem vegetables, olives for oil production and cereals. Application rates range from 0.37kg a.s./ha to 6.91 kg a.s./ha (EFSA, 2021a, 2022c,d, 2023d).
- Drip irrigation was reported for stone fruits at an application rate of 7.26 kg a.s./ha (EFSA, 2018b).

Indoor applications

- Foliar treatments were reported for commodities belonging to the following crop groups: berries and small fruits, fruiting vegetables, leaf vegetables, herbs and edible flowers and herbal infusions from leaves and herbs. Application rates range from 1.28 kg a.s./ha to 3.02 kg a.s./ha (EFSA, 2021a).
- Post-harvest treatment drenching was reported for citrus fruits and pome fruits with an application rate of 0.25 kg a.s./hL (EFSA, 2021a).

Disodium phosphonate

The uses reported in the EFSA MRL review for disodium phosphonate included outdoor foliar applications in northern and southern Europe for berries and small fruits (wine and table grapes) and root and tuber vegetables (horseradishes). Application rates range from 1.0 kg a.s./ha to 1.5 kg a.s./ha (EFSA, 2021a).

b) Uses for purposes other than plant protection

Biocidal use

Fosetyl-Al, phosphonic acid, disodium phosphonate or potassium phosphonates are not approved for biocidal use, therefore, use of the substances in biocidal products is not expected (see also 'authorisations for purposes other than plant protection/biocidal use').

Other uses

According to the ECHA website⁹, fosetyl is not registered under REACH. However, phosphonic acid, disodium phosphonate and dipotassium phosphonate as well as calcium phosphonate, calcium hydrogen phosphonate and diammonium phosphonate are registered under REACH; among their uses, notable is that in professional use and consumer use fertilisers.

Salts of phosphonic acid are used in fertilisers, plant strengtheners, manure, and for soil amendments but EFSA does not have information on their conditions of use. Treatment of plants with such products could lead to the presence of phosphonic acid in the respective agricultural commodities (EFSA, 2021a).

A search in the literature showed that phosphonic (phosphorous) acid, as a substance included in the residue definition for enforcement, is known to be among the synthetic precursors of several organophosphorus pesticides (Savignac and Iorga, 2003).

The use of diammonium phosphate as an oenological adjuvant could potentially contribute to the presence of phosphonic acid in the processing of agricultural commodities (Trinchera et al., 2024).

3.1.3 Sources of residues in plants

3.1.3.1 Natural occurrence

- Is there evidence that fosetyl and/or its residues occur naturally? What is known about the natural origin of this substance?

Fosetyl-Al is a synthetic fungicide (Lewis et al., 2016). No information on the potential natural presence of fosetyl-Al was found in the literature²².

Phosphonates and several of its esters are naturally occurring compounds. Phosphonates have been identified in naturally occurring terrestrial rocks (serpentinites) (Pasek et al., 2022).

Several organic phosphonates and phosphonate esters occur naturally within living organisms (see for example: Horsman and Zechel, 2017). These organic phosphonates may generate phosphonic acid in the environment. Low levels of organic phosphonates have been found in manure (used as fertiliser in organic production). However, uptake and build-up to quantifiable levels of these natural occurring phosphonates in crops have only been demonstrated for fruits, due to the accumulation of the phosphonates in the wood of the trees (Trinchera, et al. 2020).

Other organic phosphonates are industrial products that upon degradation into the environment may produce phosphonates. EFSA has no information on the natural occurrence of ethyl phosphonate (fosetyl).

3.1.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of fosetyl per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of fosetyl-Al in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.1.3.2-1 to 3.1.3.2-5. Findings relating to residues in control (untreated) samples are also discussed in this section.

In all matrices and for both residue trials and results from monitoring, fosetyl-Al residue concentrations refer to the applicable residue definition for enforcement between 2020 and 2022 (i.e. the sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl).

Occurrence of fosetyl-Al (RD) from residue trials carried out for the critical GAP per crop

Following product applications based on the critical GAPs⁴ reported to EFSA, residues of fosetyl-Al (RD) were quantified in all commodity groups for which residue trials were available except for fosetyl residues for root and tuber vegetables. Specifically, residues of i) fosetyl, ii) phosphonic acid and iii) sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl were quantified in citrus fruits, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, stem vegetables, herbal infusions from flowers, hops (dried), seed spices (dried), fruits spices (dried), sugar plants (Belgium, 2020a; EFSA, 2009a, 2012a,c, 2015a, 2018b, 2021a; France, 2012a, 2018a; Germany, 2020a; Greece, 2020a; Italy, 2020a,b; Portugal, 2012; Spain, 2020a). For root and tuber vegetables, only phosphonic acid residues were quantified.

Although EU GAPs were reported for all uses indicated under 3.1.2 'Conditions of use and applicable crops', data on residue trials for tree nuts and pulses (dried) were not submitted and evaluated in the EFSA MRL review (EFSA, 2021a).

The results from residue trials carried out for the critical GAP per crop for fosetyl-Al in commodities for which uses were submitted to EFSA are summarised in Table 3.1.3.2-1 'Occurrence of fosetyl-Al (RD) from residue trials carried out for the critical GAP per crop'.

Note was taken that residues of fosetyl were not significant when compared to the measured levels of phosphonic acid. This is due to fosetyl's degradation to ethanol and phosphonic acid.

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Table 3.1.3.2.-1: Occurrence of fosetyl-Al (RD) from residue trials carried out for the critical GAP per crop

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fosetyl-Al (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop					
			Fosetyl		Phosphonic acid		Sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl	
			Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)
Food								
0110000	Citrus fruits	75–150	0.03–2.3	0.22	0.8–23	6.6	5.7–11.8	8.9
0120000	Tree nuts ^{c)}	500–1500	NR	-	NR	-	NR	-
0130000	Pome fruits	150	<LOQ (0.2)–0.5	0.3	1.5–27	5.15	2.21–39	6.9
0140000	Stone fruits	2*–50	<LOQ (0.01)–1.2	0.2	1.2–32	6.7	1.8–43	9.2
0150000	Berries and small fruits	2*–300	<LOQ (0.2)–7.5	0.6	1.9–50	14.5	3.5–68	17.9
0160000	Miscellaneous fruits	2*–200	<LOQ (0.5)–2.4	0.5	2.9–60	11.6	4.4–81	16.1
0210000	Root and tuber vegetables	2*–200	<LOQ (0.01) – <LOQ (0.2)	<LOQ (0.05)	<LOQ (0.15)–23.1	7.3	<LOQ (0.2)–31	10.0
0220000	Bulb vegetables	2*–50	<LOQ (0.2) – <LOQ (0.5) ^{d)}	<LOQ (0.5)	1.3–22	8.3	2.2–30	11.6
0230000	Fruiting vegetables	2*–130	<LOQ (0.01)–3.4	0.5	<LOQ (0.2)–53	12.0	3.9–76	19.2
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	10–70	<LOQ (0.01)–2.5	0.2	<LOQ (0.2)–3.7	0.3	<LOQ (0.3)–7.5	0.5
0250000	Leaf vegetables, herbs and edible flowers	2*–400	<LOQ (0.01) – <LOQ (2.0) ^{e)}	0.2	<LOQ (0.2)–92	8.5	<LOQ (0.47)–124	12
0270000	Stem vegetables	2*–50	<LOQ (0.01)–0.3	0.2	<LOQ (0.2)–53	12	<LOQ (0.2)–71 ^{f)}	16.3
0300000	Pulses (dried) ^{c)}	2*	NR	-	NR	-	NR	-
0631000	Herbal infusions from flowers	500	NR	-	96	96	NR	-
0700000	Hops (dried)	2000	1.9–10.0	5.4	236–368	312	328–504	428
0810000	Seed spices (dried)	400	<LOQ (0.01)–0.018	0.01	30–131	74	40–176	99
0820000	Fruit spices (dried)	400	<LOQ (0.01)–0.018	0.01	30–131	74	40–176	99
0900000	Sugar plants	2*–75	<LOQ (0.2)–1.0	0.3	4.7–42	14.5	6.6–57	19.7

* Limit of quantification in Reg. (EC) No 396/2005; NR: no residue trials are available; '-': not estimated due to lack of data.

a) Maximum Residue Level in Reg. (EU) No 2022/1324 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA, 2009a, 2012a,c, 2015a, 2018b, 2021a; c) For uses not supported by data, the MRLs were lowered to the LOQ except for tree nuts; d) Quantified residues of fosetyl between the two analytical LOQs of 0.2 and 0.5 mg/kg were also measured in the residue trials; e) Quantified residues of fosetyl between the two analytical LOQs of 0.01 and 2 mg/kg were also measured in the residue trials; f) Residues quantified above the MRLs come from the joint EFSA MRL review for fosetyl, disodium phosphonate and potassium phosphonates (EFSA, 2021a) that has not been considered by risk managers yet.

Occurrence of fosetyl-Al under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to fosetyl-Al are given by Regulation (EU) 2019/552³² for the year 2020, Regulations (EU) 2019/552³² and 2021/1807³³ for the year 2021 and Regulations (EU) 2022/93³⁴ and 2022/1324²⁸ for the year 2022. Results were reported by the national authorities for the sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl, therefore, it is not possible to know whether these residues are due to the uses of fosetyl, potassium or disodium phosphonates, or other agricultural products containing salts of phosphonic acid.

Regarding commodities not labelled as organic, 18,187 samples were collected and analysed for fosetyl-Al in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 17,088 (93.96%) were unprocessed and 1099 (6.04%) processed commodities. No residues were quantified in 15,005 samples out of the 18,187 samples (82.5%). In 3,148 samples out of the 18,187 samples (17.31%) fosetyl-Al was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-1.1. MRLs were exceeded in 34 samples out of the 18,187 samples (0.19%). The highest concentrations for samples exceeding the MRLs were 140 mg/kg in berries and small fruits (strawberries) and 185 mg/kg in leaf vegetables, herbs and edible flowers (lettuces and salad plants – roman rocket/rucola).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of fosetyl-Al are summarised in Table 3.1.3.2-2a for unprocessed, and in Table 3.1.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on fosetyl-Al in feed not labelled as organic were submitted to EFSA.

³² Commission regulation (EU) 2019/552 of 4 April 2019 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, bicyclopyrone, chlormequat, cyprodinil, difenoconazole, fenpropimorph, fenpyroximate, fluopyram, fosetyl, isoprothiolane, isopyrazam, oxamyl, prothioconazole, spinetoram, trifloxystrobin and triflumezopyrim in or on certain products. OJ L 96, 5.4.2019, p. 6–49

³³ Commission Regulation (EU) 2021/1807 of 13 October 2021 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, aqueous extract from the germinated seeds of sweet Lupinus albus, azoxystrobin, clopyralid, cyflufenamid, fludioxonil, fluopyram, fosetyl, metazachlor, oxathiapiprolin, tebufenozide and thiabendazole in or on certain products. OJ L 365, 14.10.2021, p. 1–37

³⁴ Commission Regulation (EU) 2022/93 of 20 January 2022 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acrinathrin, fluvalinate, folpet, fosetyl, isofetamid, 'Pepino Mosaic Virus, EU strain, mild isolate Abp1', 'Pepino Mosaic Virus, CH2 strain, mild isolate Abp2', spinetoram and spirotetramat in or on certain products. OJ L 16, 23.1.2022, p. 1–32

Table 3.1.3.2-2a: Occurrence of fosetyl-AI (RD) from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fosetyl-AI (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0110000	Citrus fruits	75–150	0.004	0.017–26.5	352	1.605
0120000	Tree nuts	500–1500	0.01	0.013–1.3	10	0.395
0130000	Pome fruits	150	0.001	0.024–64.5	545	2.2
0140000	Stone fruits	2*–50	0.008	0.011–8.5	153	0.27
0150000	Berries and small fruits	2*–300	0.001	0.013–140	706	1.95
0160000	Miscellaneous fruits	2*–200	0.008	0.027–8.526	72	0.46
0210000	Root and tuber vegetables	2*–200	0.001	0.027–24	86	1.69
0220000	Bulb vegetables	2*–50	0.01	0.019–20.19	53	2.5
0230000	Fruiting vegetables	2*–130	0.001	0.015–46.6	296	0.49
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	10–70	0.001	0.007–38.004	78	0.395
0250000	Leaf vegetables, herbs and edible flowers	2*–400	0.001	0.008–185	291	2.07
0270000	Stem vegetables	2*–50	0.01	0.015–34.8	45	0.93
0300000	Pulses (dried)	2*	0.01	0.041–3.2	12	0.755
0631000	Herbal infusions from flowers ^{d)}	500	ND	ND	ND	ND
0700000	Hops (dried)	2000	0.34	0.97–84.6	3	58.6
0810000	Seed spices (dried) ^{d)}	400	ND	ND	ND	ND
0820000	Fruit spices (dried) ^{d)}	400	ND	ND	ND	ND
0900000	Sugar plants	2*–75	0.01	<LOQ	0	<LOQ
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of fosetyl-AI is not expected)						
0260000	Legume vegetables	2*	0.01	0.008–185	6	0.021
0280000	Fungi, mosses and lichens	2*	0.004	0.012–1.080	76	0.043
0290000	Algae and prokaryotes organisms	2*	0.01	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	2*–100	0.01	0.24–10	6	0.625
0500000	Cereals	2*–150	0.004	0.016–7.1	74	0.14
0600000	Teas, coffee, herbal infusions, cocoa and carobs ^{d)}	5*–2000	0.1	2.4–3.3	2	2.85
0800000	Spices (dried) ^{d)}	400	ND	ND	ND	ND
1040000	Honey and other apiculture products	0.5*	0.02	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2022/1324 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Herbal infusions from flowers and Spices (dried) appear in both higher and lower parts of the table to indicate the use of the substance for commodities 06310000, 0810000 and 0820000 and non-use of the substance for all other commodities '06N0000' and '08N0000' that are reported under the

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'broader' category 0600000 and 0800000 on the table. This creates an inconsistency where the results indicating non-uses are overestimated.

In addition to the pesticide monitoring data collection, analysis of residues of fosetyl-Al in honey and other apiculture products was carried out in the framework of the VMPP national control activities (not reported in Table 3.1.3.2-2a). For unprocessed products of conventional agriculture two out of the six samples collected had quantified residues at 0.19 and 0.55 mg/kg (LOQ at 0.1 mg/kg).

Table 3.1.3.2-2b: Occurrence of fosetyl-Al from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fosetyl-Al (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0110000	Citrus fruits	75–150	0.01	0.15–13.1	58	2.1
0120000	Tree nuts	500–1500	0.3	0.42	1	0.42
0130000	Pome fruits	150	0.01	0.22–12.4	4	0.51
0140000	Stone fruits	2*–50	0.004	0.034	1	0.034
0150000	Berries and small fruits	2*–300	0.001	0.031–63	225	4.5
0160000	Miscellaneous fruits	2*–200	ND	ND	ND	ND
0210000	Root and tuber vegetables	2*–200	0.01	<LOQ	0	<LOQ
0220000	Bulb vegetables	2*–50	ND	ND	ND	ND
0230000	Fruiting vegetables	2*–130	0.067	0.23–10.1	7	1.6
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	10–70	ND	ND	ND	ND
0250000	Leaf vegetables, herbs and edible flowers	2*–400	0.01	2.7	1	2.7
0270000	Stem vegetables	2*–50	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	2*	0.01	0.394	1	0.394
0631000	Herbal infusions from flowers ^{d)}	500	ND	ND	ND	ND
0700000	Hops (dried)	2000	0.13	9.3–128	5	29.4
0810000	Seed spices (dried) ^{d)}	400	ND	ND	ND	ND
0820000	Fruit spices (dried) ^{d)}	400	ND	ND	ND	ND
0900000	Sugar plants	2*–75	ND	ND	ND	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of fosetyl-Al is not expected)						
0260000	Legume vegetables	2*	ND	ND	ND	ND
0280000	Fungi, mosses and lichens	2*	0.34	43.6	1	43.6
0290000	Algae and prokaryotes organisms	2*	ND	ND	ND	ND
0400000	Oilseeds and oil fruits	2*–100	0.005	<LOQ	0	<LOQ
0500000	Cereals	2*–150	0.001	0.03–1.2	12	0.26
0600000	Teas, coffee, herbal infusions, cocoa and carobs ^{d)}	5*–2000	ND	ND	ND	ND
0800000	Spices (dried) ^{d)}	400	ND	ND	ND	ND
1040000	Processed apiculture products	0.5*	ND	ND	ND	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2022/1324 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Herbal infusions from flowers and Spices (dried) appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0631000, 0810000 and 0820000 and non-use of the substance for all other commodities '06N0000' and '08N0000' that are reported under the 'broader' category 0600000 and 0800000 on the table. This creates an inconsistency where the results indicating non-uses are overestimated.

Occurrence of fosetyl-AI in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 2,378 samples were collected and analysed for fosetyl-AI from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 2,042 (85.87%) were unprocessed and 336 (14.13%) processed commodities. No residues were quantified in 2,284 samples out of the 2,378 samples (96.05%). In 94 samples out of the 2,378 samples (3.95%) fosetyl-AI was found at or above the analytical LOQ but below or at the MRL. No samples labelled as organic were above MRLs. These findings are summarised in Appendix B, Table B-1.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.1.3.2-3a for unprocessed and in Table 3.1.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on fosetyl-AI in feed labelled as organic were submitted to EFSA.

Table 3.1.3.2-3a: Occurrence of fosetyl-AI from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fosetyl-AI (RD) occurrence results from the unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	75–150	0.01	0.120–0.324	4	0.224
0120000	Tree nuts	500–1500	0.05	<LOQ	0	<LOQ
0130000	Pome fruits	150	0.01	0.018–0.044	3	0.031
0140000	Stone fruits	2*–50	0.01	0.032–0.13	3	0.059
0150000	Berries and small fruits	2*–300	0.005	0.057–1	6	0.28
0160000	Miscellaneous fruits	2*–200	0.01	0.058–0.954	5	0.093
0210000	Root and tuber vegetables	2*–200	0.01	0.03–1.5	2	0.765
0220000	Bulb vegetables	2*–50	0.01	0.031	1	0.031
0230000	Fruiting vegetables	2*–130	0.01	0.038–0.37	8	0.062
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	10–70	0.005	0.016	1	0.016
0250000	Leaf vegetables, herbs and edible flowers	2*–400	0.009	0.033–1.2	4	0.585
0260000	Legume vegetables	2*	0.01	0.053	1	0.053

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fosetyl-AI (RD) occurrence results from the unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0270000	Stem vegetables	2*-50	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	2*	0.01	0.043-1.3	7	0.082
0290000	Algae and prokaryotes organisms	2*	ND	ND	ND	ND
0300000	Pulses (dried)	2*	0.01	0.46	1	0.46
0400000	Oilseeds and oil fruits	2*-100	0.01	<LOQ	0	<LOQ
0500000	Cereals	2*-150	0.004	0.02-0.306	14	0.057
0600000	Teas, coffee, herbal infusions, cocoa and carobs	5*-2000	ND	ND	ND	ND
0700000	Hops (dried)	2000	ND	ND	ND	ND
0800000	Spices (dried)	400	0.34	<LOQ	0	<LOQ
0900000	Sugar plants	2*-75	ND	ND	ND	ND
1040000	Honey and other apiculture products	0.5*	0.01	<LOQ	0	<LOQ

*Limit of quantification in Reg. (EC) No 396/2005; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2022/1324 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.1.3.2-3b: Occurrence of fosetyl-AI from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fosetyl-AI (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	75-150	0.01	0.23	1	0.23
0120000	Tree nuts	500-1500	0.01	0.7	1	0.7
0130000	Pome fruits	150	0.01	0.16	1	0.16
0140000	Stone fruits	2*-50	ND	ND	ND	ND
0150000	Berries and small fruits	2*-300	0.01	0.069-3.7	30	0.565
0160000	Miscellaneous fruits	2*-200	0.01	0.5	1	0.5
0210000	Root and tuber vegetables	2*-200	0.01	<LOQ	0	<LOQ
0220000	Bulb vegetables	2*-50	ND	ND	ND	ND
0230000	Fruiting vegetables	2*-130	0.34	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	10-70	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	2*-400	0.34	<LOQ	0	<LOQ

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fosetyl-Al (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0260000	Legume vegetables	2*	ND	ND	ND	ND
0270000	Stem vegetables	2*–50	ND	ND	ND	ND
0280000	Fungi, mosses and lichens	2*	0.34	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	2*	ND	ND	ND	ND
0300000	Pulses (dried)	2*	0.13	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	2*–100	0.005	<LOQ	0	<LOQ
0500000	Cereals	2*–150	0.01	0.15–0.25	2	0.2
0600000	Teas, coffee, herbal infusions, cocoa and carobs	5*–2000	ND	ND	ND	ND
0700000	Hops (dried)	2000	ND	ND	ND	ND
0800000	Spices (dried)	400	0.34	<LOQ	0	<LOQ
0900000	Sugar plants	2*–75	ND	ND	ND	ND
1040000	Processed apiculture products	0.5*	ND	ND	ND	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2022/1324 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of fosetyl-Al in the EU Organic Farming Information System

The EU OFIS reported 149 findings for fosetyl-Al, one sample for phosphonic acid and two samples only for fosetyl in 2021 and 2022. Forty-seven (47) of the products sampled and analysed had EU origin and 105 were of non-EU origin. Residues were found in nine samples of citrus fruits (two grapefruits, five lemons, one lime and one mandarin), eight samples of tree nuts (seven almonds and one cashew nut), seven samples of pome fruits (five apples and two pears), one sample of stone fruits (cherries – sweet), 18 samples of berries and small fruits (one table grape, one wine grape, 11 strawberries, one blackberry, two blueberries and two currants), 27 samples from miscellaneous fruits (one kiwi fruit, 19 avocados, two bananas and five mangoes), two samples of root and tuber vegetables (all potatoes), three samples of bulb vegetables (two garlands and one onions), one sample of tomatoes (goji berry), 10 samples of legume vegetables (one beans, three peans and six lentils), two samples of fungi, five samples of oilseeds (three samples of pumpkin seeds and two samples of chia seeds), five samples of cereals (four buckwheat and one wheat), six samples of tea, coffee, herbal infusions, cocoa and carobs (one tea, one coffee beans and four cocoa beans) and 46 samples of spices (1 seed spices and 45 root and rhizome spices). Phosphonic acid was detected in one sample of root and tuber vegetables (potatoes). Fosetyl was detected in two samples (one sample of tree nuts – almonds and one sample of root and rhizome spices – ginger). The concentrations of fosetyl-al residues were above LOQ but below MRL in 146 samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005³. MRLs exceeded in three samples, all from non-EU countries. The highest concentration was reported for a sample of mushroom

powder from non-EU origin, with a quantified level of 54.8 mg/kg. These findings are summarised in Table 3.1.3.2-4.

Table 3.1.3.2-4: Occurrence of fosetyl, phosphonic acid and fosetyl-Al from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
Fosetyl				
0120010	Almonds	1500	<0.01 – Almonds	ND
Phosphonic acid without fosetyl				
0211000	Potatoes	200	1.2 – Potatoes	ND
Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)				
0110010	Grapefruits	75	0.025 – Grapefruits	ND
0110030	Lemons	150	0.44; 0.47 – Lemons	ND
0110050	Mandarins	150	0.59 – Clementines	ND
0120010	Almonds	1500	2.2; 0.76; 0.128; 0.4; 0.96 – Almonds	ND
0130010	Apples	150	ND	0.17; 0.71; 0.17; 0.71 – Apple (juice)
0140020	Cherries (sweet)	2*	ND	0.27 – Cherries (purée)
0151020	Wine grapes	200	ND	0.43 – Wine grapes (red wine)
0152000	Strawberries	100	0.13 – Strawberries	0.12 – Strawberries (juice); 0.043; 0.043 – Strawberries (purée)
0153010	Blackberries	300	0.029 – Blackberries	ND
0154010	Blueberries	200	1.2 – Blueberries	ND
0154030	Currants (black, red and white)	200	4.1; 5 – Currants (dried)	ND
0162010	Kiwi fruits (green, red, yellow)	200	5 – Kiwi	ND
0163010	Avocados	70	0.94; 0.2; 0.59; 2.1; 2.4; 0.17; 0.24; 21 – Avocados	ND
0163030	Mangoes	2*	0.044; 0.028 – Mangoes	ND
0211000	Potatoes	200	1.2 – Potatoes	0.028 – Potatoes flakes
0260040	Peas (without pods)	2*	0.82; 0.98; 0.7 – Chickpeas	ND
0260050	Lentils	2*	0.22; 0.46; 0.63 – Lentils	ND
0280020	Wild fungi	2*	ND	0.113 – Oyster mushroom (substrate)
0500020	Buckwheat and other pseudocereals	2*	0.21 – Buckwheat	0.21 – Buckwheat (peeled)
Samples of non-EU origin				
Fosetyl				
0840020	Ginger ^{c)}	200	<0.01 – Ginger (fresh)	ND
Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)				
0110010	Grapefruits	75	<0.01 – Grapefruits	ND
0110030	Lemons	150	0.03; 0.91; 0.3 – Lemons	ND
0110040	Limes	150	0.078 – Limes	ND
0120010	Almonds	1500	7.9; 4.3 – Almonds	ND
0120030	Cashew nuts	500	0.23 – Cashew nuts	ND
0130010	Apples	150	ND	1 – Apples (juice concentrate)
0130020	Pears	150	0.023; 0.158 – Pears	ND
0151010	Table grapes	100	0.98 – Sultanas	ND
0152000	Strawberries	100	0.63; <0.01; 0.505, 0.3; 14.7; 0.156 – Strawberries	4.6 – Strawberries juice (concentrate)
0154010	Blueberries	200	0.67 – Blueberries	ND
0163010	Avocados	70	0.067; 0.083; 0.47; 0.021; 0.021; 0.19; 0.5; 7.9, 0.42, 37.7; 0.36 – Avocados	ND
0163020	Bananas	2*	0.032; 0.074 – Bananas	ND

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
0163030	Mangoes	2*	0.067; 0.276; 0.574 – Mangoes	ND
0220010	Garlic	30	2.3 – Garlic	ND
0220020	Onions	50	1.6 – Onions	ND
0231010	Tomatoes	100	0.14 – Goji berries	ND
0260020	Beans (without pods)	2*	0.56 – White beans	ND
0260050	Lentils	2*	0.17; 0.39; 1.3 – Lentils (red and brown)	ND
0280000	Fungi, mosses and lichens	2*	ND	54.8 – Mushroom (powder)
0401100	Pumpkin seeds	2*	2.3; 0.21; 0.25 – Pumpkin seeds	ND
0401990	Others	2*	0.62; 0.62 – Chia seeds	ND
0500020	Buckwheat and other pseudocereals	2*	0.22 – Buckwheat; 3.6 – Quinoa	ND
0500090	Wheat	150	0.3 – Wheat	ND
0610000	Teas	5*	0.025 – Tea (green)	ND
0620000	Coffee beans	5*	0.4 – Coffee beans	ND
0640000	Cocoa beans	2*	0.411; 0.035; 0.067; 0.924 – Cocoa beans	ND
0810070	Fennel	400	0.53 – Fennel	ND
0840020	Ginger ^{c)}	200	0.035; 0.24; 0.41; 0.3; 0.12; 0.076; 0.021; 0.092; 0.12; 1.2; 2.1; 0.24; 3; 0.036; 0.055; 0.52; 1.6; 0.52; 2.9; 0.048; 0.061; 0.036; 0.037; 0.088; 0.056; 0.065; 0.096; 0.038; 1.3; 0.13; 0.25; 8; 0.028; 0.74; 5; 0.11; 0.013; 0.02; 0.27; 0.029; 0.63; 0.37; 2.1 – Ginger	ND
0840030	Turmeric/curcuma	400	0.04 – Turmeric/curcuma	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2022/1324 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) As from 1 January 2020, the applicable maximum residue level for ginger (*Zingiber officinale*) in the spice group (code 0840020) is the one set for ginger roots (*Zingiber officinale*) in the Part B of the Annex 1 (code 0213040-006, equal to the one of horseradish (*Armoracia rusticana*) code 0213040), taking into account changes in the levels by processing (drying), according to Art. 20 (1) of Regulation (EC) No 396/2005.

Occurrence of fosetyl and phosphonic acid in untreated samples (control samples) from residue trials

Quantified findings in control (untreated) samples were observed for fosetyl and phosphonic acid in several European residue trials. These trials were carried out in mandarins from Italy, Spain, and Greece, oranges from Italy and Spain, peaches from Spain and Portugal, tangerines from Spain and apricots from Italy and Greece (France 2017a, 2018a; Greece, 2020a,b,c,d; Italy, 2020a,b; Spain, 2020a,b,c). According to the applicant, the quantified findings in mandarin and orange control samples from Spain and peach control samples from Portugal were likely due to the use of phosphonic acid fertiliser (Greece, 2020b; Spain, 2020c). Additionally, residues in peach control samples from a trial in Spain could be due to potassium phosphonate (used as a fertiliser) or fosetyl-Al applications, the latter applied multiple times 1–3 years before the trial began (France, 2017a).

Residues were also found in almond control samples from Spain and southern France and pistachio control samples from Greece and Italy (Greece, 2019). Also, control samples from trials

carried out in strawberries from Italy, Spain and Germany, and blueberries, blackcurrants, raspberries and blackberries from Germany contained quantified residues (Greece, 2020d; Finland, 2020; France, 2012a, Germany, 2015a, 2020a,b; Portugal, 2020; Spain, 2020b).

Additionally, residues were found in control potato samples from residue trials carried out in Greece, Portugal, Italy, Spain and southern France and one tomato trial from Spain (Greece 2020d; Italy, 2020a,b; Spain 2020a). Several trials on avocados and pineapples from Spain, and melons from Spain and southern France also showed residues (Greece, 2020d,e; Italy, 2020a,b; Spain, 2020a). Residues were also quantified in one residue trial on cucumbers from the Netherlands, one trial on kohlrabi from Germany, and several trials on lettuces from Germany, Greece, Italy and southern France (Germany, 2019a, 2020b,c, 2023a; Italy, 2020a; the Netherlands, 2021a). According to the study director, the quantified residues in lettuce control samples from southern France and Greece were likely due to the use of phosphonic acid fertiliser, however, no information was provided to substantiate this (Netherlands, 2021a).

Further residues were found in several leek control samples from residue trials carried out in Belgium, Germany, Italy, the Netherlands, northern and southern France, Spain and the United Kingdom³⁵ (Netherlands, 2023). According to the applicant, the residues were due to the use of phosphonic acid fertiliser (Netherlands, 2023). Moreover, residues occurred in the control samples of parsley from a residue trial carried out in Germany (Germany, 2019b, 2020b).

Furthermore, residues occurred in various grape control samples from residue trials carried out in Hungary, Germany, northern and southern France, Italy and Spain (France, 2016a, 2018a,b; Germany, 2020d; Greece, 2020d, Italy, 2020c,d). Residue trials carried out in apples from northern France, Spain, and Italy, and pear samples from trials carried out in Belgium, Spain, southern France, and Italy also showed residues in the control samples (France, 2017b, 2018a; Italy, 2020e). The two highest residues in pears were likely due to an inversion between untreated and treated specimens. Additionally, some high levels of phosphonic acid residues in grapes were likely due to the previous or additional application of a product containing potassium phosphonates (see details from Table 3.1.3.2-5) (France, 2018a,b). Residues were also found in untreated pollen samples from a residue trial in Germany (Netherlands, 2021b).

No other evidence-based explanations on the causes for these occurrences in control (untreated) samples were provided in the above Member State ERs and RARs.

The summary of the quantified findings of residues of fosetyl and phosphonic acid in control (untreated) samples from residue trials carried out for the critical GAP⁴ per crop is given below in Table 3.1.3.2-5.

Table 3.1.3.2-5: Summary of the quantified findings for fosetyl and phosphonic acid in control (untreated) samples from residue trials carried out for the critical GAP per crop.

Commodity	Country/ Area	Fosetyl concentration (mg/kg)	Phosphonic acid concentration (mg/kg)
Almond (whole nuts, nutmeat, hulls)	Southern France	ND	<0.05–2.3
	Spain	ND	11–39
Apple (fruit)	Italy	ND	0.55; 2.2; 4.1
	Northern France	0.2 ^{a)}	0.3; 0.3; 0.33; 0.34; 3.8; 0.4; 4.9

³⁵ The data from the United Kingdom refer to a period during which the UK was still a Member State of the European Union.

Findings of not authorised substances in organic products

	Spain	ND	0.23; 0.24; 2.92; 3.21; 3.96; 4.12; 5.23; 5.80
Apricot (fruit)	Greece	ND	1.6; 1.8
	Italy	ND	0.15; 0.47
Avocado	Spain	ND	0.594; 0.70 (pulp); 0.701; 0.83 (peel); 1.11; 1.53; 2.14; 2.66; 5.34; 8.37; 8.58
Blackberry (fruit)	Germany	ND	0.23; 1.3 ^{b)} ; 1.4 ^{b)} ; 1.6 ^{b)} ; 2.0 ^{b)} ; 4.2 ^{b)} ; 5.7 ^{b)}
Blackcurrant (fruit)	Germany	ND	0.38; 0.42; 1.9
Blueberry (fruit)	Germany	ND	0.25
Cucumber (fruit)	Netherlands	ND	0.21; 0.28; 0.28; 0.35
	Germany	0.29 ^{a)} ; 0.32 ^{a)} ; 0.39 ^{a)} ; 0.43 ^{a)} ; 0.48 ^{a)}	0.35; 0.36; 0.4; 0.65; 0.75; 0.89; 0.9; 0.93; 1.18; 1.19; 1.2; 1.8; 5.6; 7.4; 7.5; 9.2; 10; 11; 11.19; 12; 12; 12.05
	Hungary	ND	Up to 2.33
	Italy	ND	0.27; 0.37; 0.38; 0.39; 0.40; 0.40; 0.66; 5.5
	Northern France	0.57 ^{a)}	0.21; 0.4; 0.41–0.74; 0.44; 0.61; 0.70; 0.7; 0.79; 0.8; 0.91; 0.94; 0.99; 1.0; 1.1; 1.26; 1.47; 1.7; 2.0; 2.3; 2.5; 2.6; 5.0; 5.56; 5.6
	Southern France	0.01 ^{a)}	0.52; 0.75; 0.83; 0.83; 0.86; 1.0; 1.1; 1.1; 1.2; 1.3; 1.3; 1.8; 1.8; 2.26; 2.5; 2.58; 2.60; 5.1; 5.3; 5.8; 6.1; 6.44 ^{c)} ; 6.8; 7.63 ^{c)} ; 10.0 ^{c)}
	Spain	ND	0.58; 0.6–0.9; 0.63; 0.7; 0.83; 0.85; 0.88; 0.94; 1.7
Kohlrabi (corm)	Germany	0.015	0.81
Leek (whole plant without roots) ^{d)}	Belgium	ND	0.15; 0.31
	Germany	ND	0.20; 0.23; 0.25; 0.25; 0.29; 0.37; 1.2
Leek (whole plant without roots) ^{d)}	Italy	ND	0.21; 0.24; 0.27; 0.29
	Netherlands	ND	0.10; 0.12; 0.12; 0.12; 0.17; 0.28; 0.50; 0.54
	Northern France	ND	0.14; 0.15; 0.29; 0.30; 0.39; 0.48; 0.51; 1.5
	Southern France	ND	0.29; 0.31; 0.36; 0.42; 0.46; 0.50; 0.51; 0.51
	Spain	ND	0.21; 0.40; 0.43; 0.43
	United Kingdom ³⁵	ND	0.12; 0.14; 0.25; 0.39
	Germany	ND	0.15; 0.30
Lettuce (head)	Greece ^{e)}	ND	0.11; 0.13; 0.23; 0.25; 7.9; 9.5; 10; 11
	Italy	ND	0.69; 1.1; 1.4
	Southern France ^{e)}	ND	0.71; 1.9
Mandarin	Greece	0.031 (fruit)	2.3 (fruit); 6.1 (fruit)
	Italy	ND	1.9 (fruit); 2.2 (fruit); 2.3 (fruit); 2.4 (fruit)
	Spain	ND	0.283 (fruit); 0.33 (fruit); 0.33 (fruit); 0.34 (fruit); 0.35 (fruit); 0.37 (fruit); 0.38 (fruit); 0.38 (fruit); 0.45 (fruit); 1.0 (fruit) ^{e)} ; 1.4 (fruit) ^{e)} ; 3.6 (fruit) ^{e)} ; 4.37 (fruit); 0.468 (fruit); 5.7 (fruit) ^{e)} ; 7.93 (pulp)
Melon	Southern France	ND	0.21 (fruit); 0.21 (fruit)
	Spain	ND	0.22 (fruit); 0.65 (fruit); 0.79 (peel); 0.93 (fruit)
Orange (fruit)	Italy	ND	0.20
	Spain	ND	0.22 ^{e)} ; 1.0 (whole fruit); 1.1 (whole fruit); 1.6 (flesh); 1.7 ^{e)} ; 4 ^{e)}
Parsley (whole plant without roots)	Germany	ND	0.40; 1.2
Peach	Portugal ^{e)}	ND	7.78; 12.7
	Spain ^{e)}	ND	1.12; 1.21; 1.29; 1.30; 1.54
Pear (fruit)	Belgium	ND	0.88; 1.1
	Italy	ND	1.4; 1.8; 1.9; 2.4; 2.4; 2.4; 2.6
	Southern France	ND	0.23; 0.29; 0.34; 12 ^{f)} ; 17 ^{f)}
	Spain	ND	0.26; 0.51; 0.72
Pineapple	Spain	ND	0.11; 0.12; 1.24; 2.36
Pistachio (whole nuts, nut meat)	Greece	ND	1.9–7.5
	Italy	ND	0.75–1.4

Pollen	Germany	ND	0.11; 0.11
	Greece	ND	0.645
	Italy	ND	1.7
Potato (tuber)	Portugal	ND	22; 24
	Southern France	ND	1.37
	Spain	ND	0.61; 0.79
Raspberry	Germany	ND	0.41; 0.53; 0.56
Strawberry (fruit)	Germany	ND	0.31; 1.0; 1.0; 1.7; 4.8
	Italy	ND	0.33; 0.65; 0.83
	Spain	ND	0.26; 3.3; 4.0; 4.3; 9.6; 13.0
Tangerine	Spain	ND	1.2 (peel); 1.5 (flesh); 5.2 (peel); 5.3 (flesh); 5.7 (fruit)
Tomato (fruit)	Spain	ND	0.48; 0.59

ND – no data available

a) Calculated as fosetyl-Al; b) Calculated as fosetyl; c) The farmer applied a product containing potassium phosphonates two times before the trial started; d) Residues in the control samples could result from potassium phosphonate (used as a fertiliser) or fosetyl-Al applications. Fosetyl-Al was applied multiple times 1–3 years before the trial began; e) The study director/applicant reported that the use of phosphonic acid fertiliser in the field likely caused positive findings in the control samples, but no supporting information was provided; f) Probable inversion between untreated and treated specimen.

Could the presence of fosetyl and/or its residues be due to biocide use?

Fosetyl-Al, phosphonic acid, disodium phosphonate and potassium phosphonates are not authorised for use as biocides, therefore, residues due to biocidal use are not expected for fosetyl.

3.1.3.3 Behaviour in food and feed products

- What key physico-chemical properties of fosetyl are expected to have an influence on its presence in plant products? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of **fosetyl-Al** are reported in Table 3.1.3.3a.

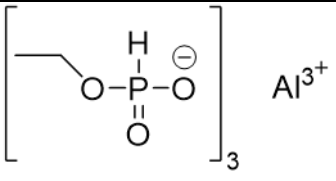
Fosetyl-Al is a water-soluble compound and exhibits very low persistence in soil (see also Section 3.1.3.5). The low K_F , OC reported in Table 3.1.3.3a indicate that fosetyl-Al has very high mobility in soil (EFSA, 2018a).

The maximum calculated PEC_w for fosetyl-Al for the representative uses was 143.2 µg/L (application to pome fruits; $1 \times 3,600$ g a.s./ha) (EFSA, 2018a).

Fosetyl-Al was demonstrated to be hydrolytically stable under standard conditions of pasteurisation, baking, brewing, boiling and sterilisation (EFSA, 2021a). Considering that fosetyl is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Fosetyl-Al and other salts of fosetyl may be considered non-volatile compounds (vapour pressure $<10^{-7}$ Pa) (EFSA, 2018a).

Table 3.1.3.3a: Physico-chemical properties of fosetyl-Al (EFSA, 2018a)

Structural formula	
Appearance (state purity)	White powder (99.1%)
Melting point (state purity)	215°C (99.1%)
Boiling point	not available
Temperature of decomposition	277–279°C (99.1%)
Vapour pressure (state temperature, state purity)	< 10 ⁻⁷ Pa (25°C)
Henry's law constant (state temperature)	< 3.2 × 10 ⁻¹⁰ Pa m ³ mol ⁻¹ (20°C)
Solubility in water (state temperature, state purity and pH)	pH 3.1: 111.4 g/L at 20°C (99.1%) pH 6.0: 111.3 g/L at 20°C (99.1%) pH 8.6: 109.8 g/L at 20°C (99.1%)
Partition coefficient (state temperature, pH and purity)	log Pow = -2.1 at 21–23°C [Purity (99.1%)] As water solubility is not pH dependent, log Pow is considered not pH dependent.
Partition coefficient (octanol/air)	NA
Atmospheric half-life	DT ₅₀ of 2.22 hours derived by the Atkinson model (AOPWIN version 1.92a). OH (12h) radical concentration in air assumed in the model = 1.5 × 10 ⁶ cm ⁻³
Dissociation constant (state purity)	pK _a = 4.7 at 20–25°C (99.1%)
Soil adsorption (geometric mean)	K _{Foc} = 0.1 mL/g
Hydrolytic degradation (>10%)	Stable at pH range 5–9 at 20°C up to 70°C

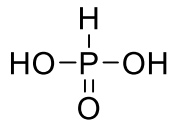
DT₅₀ – Disappearance time of 50% of the substance in field studies; NA – not applicable; pH – Potential of Hydrogen; Pow – Octanol/water Partition Coefficient

The physico-chemical properties of **phosphonic acid** are reported in Table 3.1.3.3b.

Phosphonic acid exhibited moderate to high persistence in soil (EFSA, 2018a). The K_{F, oc} reported in Table 3.1.3.3b indicates that phosphonic acid has low mobility in soil (EFSA, 2018a).

Phosphonic acid is hydrolytically stable under conditions representative of pasteurisation, baking, brewing, boiling and sterilisation (EFSA, 2018a). Considering that phosphonic acid is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Table 3.1.3.3b: Physico-chemical properties of phosphonic acid (EFSA, 2018a)

Structural formula	
Appearance (state purity)	white solid
Melting point (state purity)	62.5°C
Boiling point	decomposes before boiling
Temperature of decomposition	decomposes above 200°C
Vapour pressure (state temperature, state purity)	10 ⁻³ Pa at 20°C

Henry's law constant (state temperature)	NA
Solubility in water (state temperature, state purity and pH)	>1kg/L at 20°C (soluble)
Partition coefficient (state temperature, pH and purity)	NA (insoluble in octanol)
Partition coefficient (octanol/air)	NA
Atmospheric half-life	NA
Dissociation constant (state purity)	pK1 = 2.0, pK2 = 6.59 at 20°C
Soil adsorption (geometric mean)	K _{Foc} = 827 mL/g
Hydrolytic degradation (>10%)	Stable at pH range 5–9 at 20°C up to 70°C

NA – not applicable, pH – Potential of Hydrogen.

The physico-chemical properties of **disodium and dipotassium phosphonate** are reported in Table 3.1.3.3c.

No hydrolysis studies are available or required on disodium and dipotassium phosphonates. Phosphonate salts are expected to degrade via oxidation microbial-mediated processes. Hydrolysis conditions simulating food processing would only alter their conversion rate to phosphonic acid (EFSA, 2021a).

Table 3.1.3.3c: Physico-chemical properties of disodium and dipotassium phosphonate (EFSA, 2012b)

Structural formula	$\begin{array}{c} \ominus \quad \text{H} \quad \ominus \\ \quad \quad \\ \text{O} - \text{P} - \text{O} \\ \\ \text{O} \end{array} \quad 2 \text{Na}^+ / \text{K}^+$
Appearance (state purity)	colourless liquid (aqueous TK solution)
Melting point (state purity)	Not relevant (aqueous TK solution)
Boiling point	Not relevant (aqueous TK solution)
Temperature of decomposition	Not relevant (aqueous TK solution)
Vapour pressure (state temperature, state purity)	negligible
Henry's law constant (state temperature)	Not relevant (aqueous TK solution)
Solubility in water (state temperature, state purity and pH)	soluble in water
Partition coefficient (state temperature, pH and purity)	No data, not required
Partition coefficient (octanol/air)	NA
Atmospheric half-life	No data provided, data not required
Dissociation constant (state purity)	phosphonic acid: pK1 = 2.0, pK2 = 6.59
Hydrolytic degradation (>10%)	No reliable data provided. Not applicable to an inorganic salt that is dissociated not hydrolysed

NA – not applicable, pH – Potential of Hydrogen.

3.1.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. These values are not dependent on

the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from the soil surface at which it is applied). The highest drift of fosetyl-Al to neighbouring fields may occur during its applications to fruit crops (up to 29.2%), hops (19.33%), vineyards and vegetables (up to 8.02%) and field crops (up to 2.77%). Drift values should be considered the rate received by neighbouring fields, expressed as percentages of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. buffer zones or spray drift-reducing nozzles).

If organic crops are present adjacent to the conventional crops treated, measurable residues of fosetyl-Al in the untreated crop cannot be excluded. However, since the nature of the potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

Fosetyl is used as a seed treatment, which necessitates consideration of potential dust drift. Deposition percentile values were considered for neighbouring fields, up to 17% for different crops and techniques (EFSA, 2012b). According to Adriaanse et al. (2022), the use of techniques (deflectors), size of the dust particles and average wind speed were the most important factors determining the amount of dust drift.

3.1.3.5 Accumulated/historical residue levels in soil

- What is the persistence of fosetyl and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

According to available data (EFSA, 2018a), the DT₅₀ and DT₉₀ of fosetyl-Al in soil (carried out in seven laboratory dark aerobic experiments) have a worst-case laboratory value of 0.06 and 0.2 days, respectively, exhibiting very low persistence in soil.

Phosphonic acid, the main degradation product of fosetyl-Al in soil showed high persistence with a DT₉₀ of > 1000 days, indicating a potential for accumulation in soil and a continued presence after discontinued use of the precursor substances (EFSA, 2018a).

In order to investigate the potential uptake of residues of phosphonic acid by plants, confined rotational crops metabolism studies were carried out with radish, lettuce and barley with bare soil applications of phosphonic acid at 4.9 mg/kg soil. This concentration corresponds to an application of 15 kg fosetyl-Al/ha that is lower than the application rates reported for some critical GAPs⁴. Residues of phosphonic acid were found in radish tops (0.35 mg eq/kg) and roots (0.8 mg eq/kg), lettuce leaves (0.76 mg eq/kg), and barley grain (0.14 mg eq/kg) and straw (0.42 mg eq/kg) at 30-day plant-back interval (PBI). In another study with radish tops and roots planted 6 months after soil treatment residues of phosphonic acid were below 0.1 mg/kg (EFSA, 2018a). Field rotational crop studies carried out in carrots, lettuce and winter wheat or winter barley in the context of the peer review for fosetyl did not generate residues of phosphonic acid above the LOQ of 0.5 mg/kg in straw and above the LOQ of 0.1 mg/kg for all other commodities, except for one trial where phosphonic acid was quantified in one grain sample at concentrations 0.21 mg/kg. Also here, the field trials were underdosed (0.775 kg a.s./ha) when compared with the application rates of the critical GAPs (EFSA, 2018a).

Based on the above, transfer of fosetyl in plants planted or sown in soil previously treated with fosetyl-Al is not expected. Transfer of residues of phosphonic acid to plants planted or sown in

soil previously treated with fosetyl-Al cannot be excluded in organic crops, even if they are planted 2 years after the last chemical treatment, as required by the regulatory provisions for organic agriculture.²

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Fosetyl-Al is not expected to accumulate in soil.

Results from field and laboratory studies with phosphonic acid showed plateau concentrations for phosphonic acid in soil ranging from 9.875 mg/kg to 17.810 mg/kg (EFSA, 2018a). This suggests that accumulation of phosphonic acid in soil is expected, in addition plant uptake of phosphonic acid from soil that contain residues is plausible based on the previous section. Therefore, if phosphonic acid is quantified in organic commodities, analysis of the soil in which the plants were grown is recommended.

3.1.3.6 Residues from water used for irrigation

- Is there evidence that residues of fosetyl present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for fosetyl-Al in water samples were considered:

- The EMPODAT database (data retrieved on 25 March 2024) reports 100 analytical results from surface water samples collected in the Netherlands between 2017 and 2019;
- The NAIADES database (data retrieved on 2 April 2024) reports 31,525 analytical results from surface water samples collected in France from 2020 to 2022.

Among the 31,625 analytical results for fosetyl, 777 were disregarded as found to report quantitative values below the analytical LOQ and 19 were disregarded as found to report quantified residues equal to LOQs as high as 1 µg/L and above. Therefore, the number of water samples considered is 30,829.

Based on the screening process described in section 'Data and methodologies', for 99.9% of surface water samples analysed and reported in EMPODAT and NAIADES (30,802 samples), the residue concentrations were below the screening Cw of 3.76 µg/L.

For 0.1% of samples (27 out of 30,829 samples), the residue concentrations were found to be at or above the screening Cw of 3.76 µg/L and the potential transfer of residues to plant commodities if water containing residues at these levels is used for irrigation cannot be excluded.

Overall, considering that for 99.9% of water samples analysed and reported in EMPODAT and NAIADES (30,829 samples), the residue concentrations were below the screening Cw of 3.76 µg/L, it can be concluded that transfer of fosetyl-Al residues from water sources to plant commodities when this water is used to irrigate the plant is unlikely.

Information on the occurrence of phosphonic acid in water was not available from IPCHEM.

3.1.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *fosetyl-al*, *industry/industrial*, and *air/atmosphere*) identified only one European study, which was considered irrelevant for this section.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water. A literature review was carried out to gather relevant information. Based on conservative estimations of the possible transfer of residues from water used for irrigation to plant commodities, transfer of residues of fosetyl from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

A search in the Scopus database (conducted on March 4, 2025, using the keywords *fosetyl-Al*, *industry/industrial*, and *water*) did not identify any articles with potentially relevant information.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Based on information on the possible plant uptake of fosetyl from soil, transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely. This conclusion does not apply for phosphonic acid that is a persistent substance and uptake from soil cannot be excluded.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on March 5, 2025, using the keywords *fosetyl-Al*, *industry/industrial*, and *soil/sediment*) did not identify any articles with potentially relevant information.

3.1.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Medium and long-range aerial transport of residues

In a study by Mazzi et al. (2024) the authors assessed the contamination caused by plant protection products in size-segregated (coarse, fine, ultrafine) urban aerosol in the city of Mestre (Venice, Italy) during the summer and autumn 2023. The sampling location was highlighted as interesting due to its proximity to the industrial area of Porto Marghera, several public parks, and busy roads. The sampling location further allowed investigation of aerosol coming from short and long-range transport distances, with the latter potentially serving as a significant source of plant protection products from surrounding rural areas. Fosetyl-Al was mostly detected in the coarse/fine fractions (10^{-1} μm), with maximum concentrations of 0.03 ng m^{-3} in the total suspended particulate (TSP) and 0.02 ng m^{-3} in the PM_{10} aerosol filters. The authors conclude that the main phenomenon that influences fosetyl-Al concentration into the atmosphere is likely

the drift during orchard treatments, which might explain the low concentrations but also the presence in a finer aerosol fraction in this urban area.

These results suggest that medium-range aerial transport of residues of fosetyl-Al cannot be excluded.

Uptake from organic fertilisers

Phosphonic acid and its salts have been found in various types of manure, such as poultry manure at a concentration of 1.8 mg/kg (Trinchera et al., 2020) and ruminant manure at 0.2 mg/kg (Nader et al., 2020), likely originating from bacterial fermentation in animal intestines or compost. These findings suggest that using manure as fertiliser may contribute to residues of phosphonic acid in food and feed of plant origin.

3.1.4 Conclusions on fosetyl-Al

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use. Some of the residues quantified in the residue trials are higher than the current MRLs for the respective commodities. This is because these trials were evaluated in the more recent MRL review that has not been considered yet by the risk managers (see Section 3.1.3.2).
- Residue trials carried out to support the critical GAP⁴ for fosetyl-Al, gave residue concentrations of up to 176 mg/kg in seed and fruit spices and up to 504 mg/kg in hops (dried) for the sum of fosetyl, phosphonic acid and their salts (expressed as fosetyl). For fosetyl only, residue concentrations were up to 7.5 mg/kg in berries and small fruits and up to 10 mg/kg in hops (dried). Concentrations in the ranges reported in Table 3.1.3.2-1 might be associated with active use of fosetyl-Al according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.
- Concentrations of phosphonic acid after applications of fosetyl-Al according to the critical GAP per crop, ranged up to 131 mg/kg in seed and fruit spices and up to 368 mg/kg in hops.
- Presence of residues of phosphonic acid in randomly collected samples is not necessarily linked to active use of fosetyl-Al since phosphonic acid and its salts can be quantified after applications of two other approved active substances: disodium phosphonate and potassium phosphonates. However, the presence of phosphonic acid may still indicate active use of fosetyl-Al. In addition, salts of phosphonic acid are frequently used as fertilisers, plant strengtheners, manure or for soil amendments. Some technological additives for the oenological industry such as diammonium phosphate could contribute to these residues.
- The possible occurrence of residues of phosphonic acid and its salts in non-actively treated crops is supported by results from residue trials in several European countries where phosphonic acid was quantified in several untreated (control) samples. The highest concentration observed for phosphonic acid was in several control samples of almond from Spain (11–39 mg/kg).

- Fosetyl was also quantified in some untreated (control) samples taken in the context of residue trials. The highest concentration measured (calculated as fosetyl-Al) was in one control sample of grapes from Northern France (0.57 mg/kg).
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for the sum of fosetyl, phosphonic acid and their salts (expressed as fosetyl) in unprocessed commodities with authorised uses of fosetyl-Al, ranged from 0.27 mg/kg in stone fruits up to 2.5 mg/kg in bulb vegetables.
- In organic commodities that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings, the median concentrations for the sum of fosetyl, phosphonic acid and their salts (expressed as fosetyl) in unprocessed commodities ranged between 0.057 mg/kg in cereals up to 0.28 mg/kg in berries and small fruits. Without additional information on the individual samples' history and context, it cannot be discerned whether such occurrence may relate to active use or to any other factors.
- In organic processed commodities, residues of fosetyl-Al (RD) with five or more quantified findings, were quantified only in berries and small fruits at a median concentration of 0.57 mg/kg. In samples from processed products not labelled as organic with five or more quantified findings, residues ranged from 1.6 mg/kg in fruiting vegetables to 29.4 mg/kg in hops (dried). Considering that fosetyl is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.
- Overall, in commodities labelled as organic, the sum of fosetyl, phosphonic acid and their salts (expressed as fosetyl-Al) were quantified in 3.95% of samples (94 out of 2,378 samples). This percentage is >4 times lower than the percentage reflecting the number of findings in samples not labelled as organic (17.5%) (see Appendix B, Tables B-1.1 and B-1.2). These results suggest that significantly fewer commodities from organic agriculture are expected to contain quantified concentrations of fosetyl, phosphonic acid or their salts when compared with conventional crops.
- Fosetyl-Al and its salts do not occur naturally and do not have other known uses, therefore, the unintentional presence of residues in plants is generally not expected.
- Potential sources of fosetyl-Al residues are drift from conventional crops treated in the vicinity of organic crops and long-range medium-range aerial transport of residues.
- Fosetyl-Al is not persistent in soil. Plant uptake of residues of fosetyl-Al from soil containing residues of fosetyl is unlikely. On the other hand, phosphonic acid is persistent in soil. Studies assessed by EFSA on crops growing in rotation showed that plant uptake of residues of phosphonic acid from soil containing residues of phosphonic acid cannot be excluded. The occurrence of phosphonic acid in agricultural soil may relate to the use of salts of phosphonic acid used as fertilisers, plant strengtheners, manure, and for soil amendments. If phosphonic acid is quantified in organic commodities, analysis of the soil the plant was grown in is recommended.

Findings of not authorised substances in organic products

- Transfer of fosetyl to plants from EU water sources used for irrigation and containing residues of fosetyl is unlikely.
- Overall, based on conservative estimations of the possible transfer of residues of fosetyl from water used for irrigation to plant commodities and information on the possible plant uptake of fosetyl from EU soil, the transfer of residues from industrial emissions to the environment and from the environment to plants and plant commodities is less likely. This conclusion is applicable to fosetyl only and does not cover phosphonic acid.

The pathways of residues of fosetyl-Al and phosphonic acid to plants and plant commodities are summarised in Figures 1.1 and 1.2.



Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded

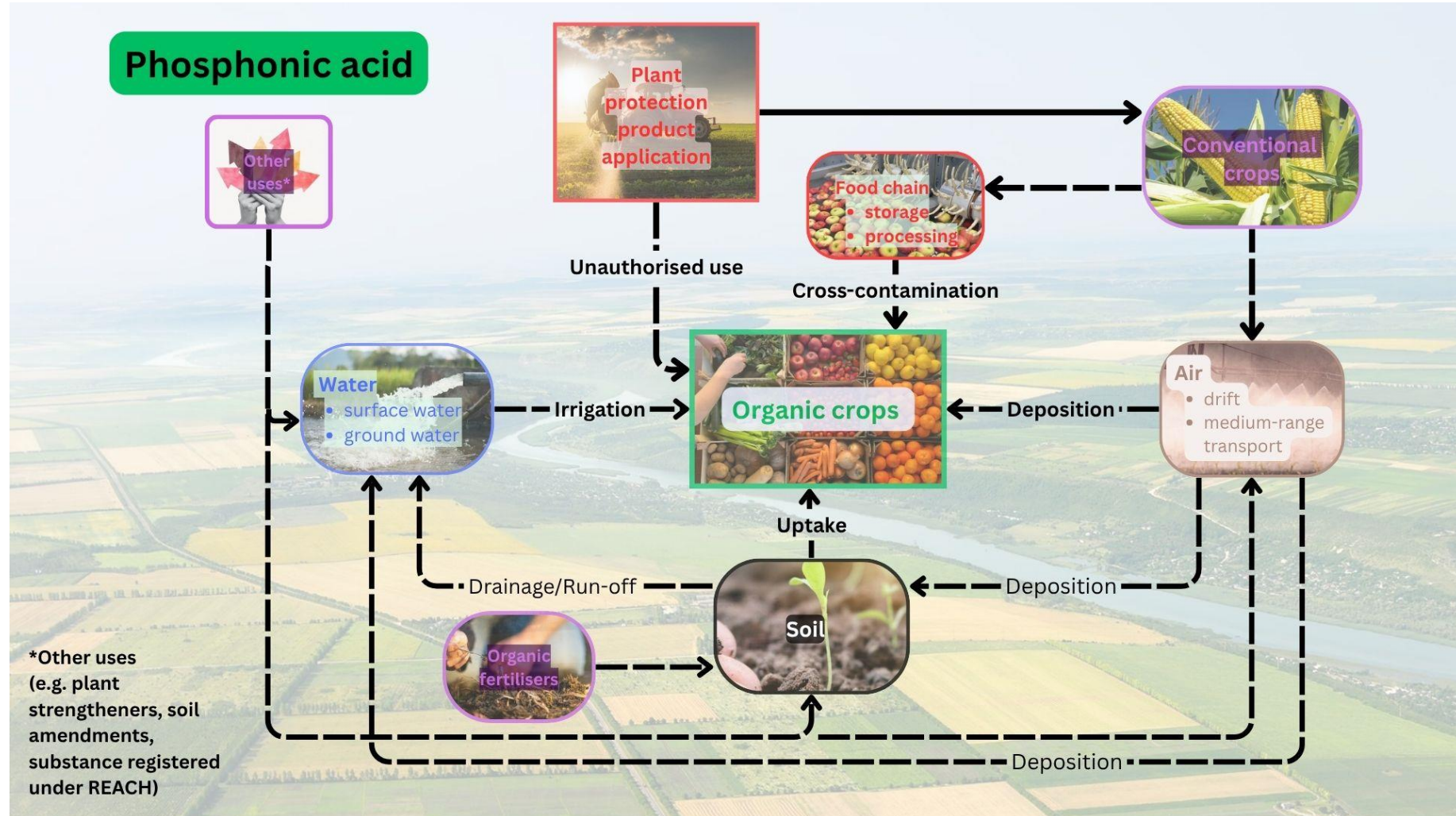


Figure 1.2: Pathways of residues of phosphonic acid to plants and plant commodities

Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded

3.2 Glyphosate

3.2.1 Method(s)

- What is/are the residues to be monitored for glyphosate according to the residue definition for monitoring set in Regulation (EC) No 396/2005?

In Regulation (EC) No 396/2005³⁶, the residue definition for enforcement in food and feed of plant origin has been set as glyphosate³⁶ and is applicable to primary, rotational crops, processed products, honey and other apiculture products. This residue definition is aligned with EFSA's MRL and peer review 'main' residue definition proposal (Option 2) for conventional (non-genetically modified) crops (EFSA, 2019a and 2023e). Note was taken that the different residue definitions proposed by EFSA in the framework of the MRL review and under the more recent peer review were not yet implemented in Regulation (EC) No 396/2005³.

Based on the above only residues of glyphosate are to be monitored in foods of plant origin, honey and other apiculture products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

Multi-residue LC-MS/MS methods are available for the monitoring of glyphosate residues in food and feed of plant origin with LOQs as low as 0.025 mg/kg in high water content, high acid, high oil and dry commodities of plant origin.

Sensitivities as low as 0.02 mg/kg were reported by the EURLs for the monitoring of residues of glyphosate in high water, high acid, and dry commodities. Lower sensitivities were reported in high oil content matrices (LOQ of 0.1 mg/kg) (EFSA, 2019a).

No fully validated analytical methods are available for the analysis of glyphosate residues in complex matrices such as hops, spices, tea, coffee, herbal infusions and carobs (EFSA, 2019a).

For the monitoring of glyphosate residues in honey and other apiculture products, a multi-residue LC-MS/MS method is available with an LOQ of 0.025 mg/kg (EFSA, 2023e; AGG, 2024 under 'Documentation as provided to EFSA'). The EURL for Residues of Pesticides developed a single residue QuPpe method for honey analysis (LOQ: 0.02 mg/kg), based on LC-MS/MS (EURL, 2024, under 'Documentation as provided to EFSA').

Overall, there are multi-residue methods available for monitoring glyphosate residues in high water, high acid, high oil content and dry plant commodities, as well as in honey and other apiculture products. LOQs for methods of analysis of glyphosate residues range from 0.02 to 0.1 mg/kg, covering the residue definition for enforcement in place from 2020 to 2022.

³⁶ Commission Regulation (EU) No 293/2013 of 20 March 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for emamectin benzoate, etofenprox, etoxazole, flutriafol, glyphosate, phosmet, pyraclostrobin, spinosad and spirotetramat in or on certain products. OJ L 96, 5.4.2013, p. 1–30.

3.2.2 Authorisation status and use

- Is glyphosate currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has glyphosate ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

a) Authorisations for plant protection use in conventional agriculture

Glyphosate has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of approval of the active substance is 15 December 2033, as indicated in the EU Pesticides Database⁵ (accessed 10 January 2024).

According to the EU Pesticides database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, France, Croatia, Hungary, Ireland, Italy, Lithuania, Latvia, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, and Slovakia.

b) Authorisations for purposes other than plant protection

Biocidal use

According to the ECHA website⁶, glyphosate has not been approved for use in biocidal products in the EU Member States, Iceland, Liechtenstein and Norway (accessed on 6 June 2024).

Other uses

A search carried out on the ECHA website⁹ on 6 June 2024 indicates that glyphosate is not currently registered under REACH.

- What is/was the actual use of glyphosate? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of glyphosate

Glyphosate is a broad-spectrum herbicide absorbed through plant leaves, rapidly moving throughout the plant, and inhibiting the shikimate pathway essential for producing vital amino acids. It controls annual and perennial grasses and broad-leaf weeds across various sectors, including agriculture, horticulture, viticulture, forestry, orchards, plantation crops, recreational areas, home gardens, and greenhouses. Additionally, it is used for weed control in aquatic environments, industrial zones, railway tracks, roadsides, and non-cultivated areas. Whilst glyphosate is systemic within plants, its high potency limits translocation within crops before they wither, as uptake occurs exclusively through treated foliage (EFSA, 2009b, 2012d, 2019a).

The phytotoxic effects of glyphosate were investigated³⁷. The available studies indicate that applying glyphosate below and certainly above the recommended rates affects the growth and development of various types of crops (Blackshaw and Harker, 2016; Primo et al., 2020; Mohseni-Moghadam et al., 2016; Cederlund, 2017) in addition to target weed species. This

³⁷ A literature search was performed on Web of Science using terms 'glyphosate AND phytotoxic*' for the timeframe 2010-2024.

information indicates that the use of glyphosate needs careful management to prevent phytotoxic effects on non-target plants including crop species that have not been genetically modified to be tolerant to it.

Conditions of use and applicable crops

The uses reported in the EFSA MRL review for glyphosate include weed control during the cultivation of crops producing food commodities belonging to the following crop groups: citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, cultivated and wild fungi³⁸, pulses (dried), oilseeds and oil fruits, cereals, teas, coffee beans, herbal infusions, carobs, hops (dried), spices (dried) and sugar plants (EFSA, 2019a). Regarding feed commodities, uses were reported for weed control in alfalfa, clover, grass and fodder beets (EFSA, 2019a). Note was taken that uses in cultivated fungi, teas, coffee beans, carobs, hops, spices, alfalfa forage, clover forage and grass were not supported by data (see Section 3.2.3.2 'Active use (all legitimate uses of the substance)').

Glyphosate treatment included outdoor and indoor downward spray weed treatments, outdoor foliar applications and outdoor local treatments by rubbing and dabbing (EFSA, 2019a).

Downward spray weed treatments were reported for weed control in crops producing citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, cultivated fungi, pulses (dried), oilseeds and oil fruits, teas, coffee beans, herbal infusions, carobs, hops, spices (dried) and sugar plants (EFSA, 2019a). Residues may also occur in wild fungi resulting from the use to control weeds in forestry. Regarding feed commodities, downward spray weed treatments were reported for alfalfa, clover, grass and fodder beets. Application rates range from 0.36 kg a.s./ha to 4.32 kg a.s./ha.

Foliar applications (desiccation uses) were reported for root and tuber vegetables, pulses (dried), oilseeds, cereals and grass (EFSA, 2019a). Application rates range from 0.70 kg a.s./ha to 2.52 kg a.s./ha.

Local treatments (by rubbing and dabbing) were reported for root and tuber vegetables, fruiting vegetables, legume vegetables, stem vegetables and fodder beet (EFSA, 2019a). Application rates range from 0.72 kg a.s./ha to 4.30 kg a.s./ha or up to 11.8 kg a.s./hL. Residues may also occur in wild fungi resulting from uses to control weeds in forestry.

b) Uses for purposes other than plant protection

Biocidal use

Glyphosate is not approved for biocidal use in the EU, therefore, use of the substance in biocidal products is not expected (see also 'authorisations for purposes other than plant protection/biocidal use').

³⁸ Uses in cultivated and wild fungi are related to forestry.

Other uses

According to the ECHA website⁹, glyphosate is not registered under REACH (see 'authorisations for purposes other than plant protection/other uses').

3.2.3 Sources of residues in plants

3.2.3.1 Natural occurrence

- Is there evidence that glyphosate occurs naturally? What is known about the natural origin of this substance?

Glyphosate is a synthetic chemical, produced industrially through chemical processes (Lewis et al., 2016). No information on the potential natural presence of glyphosate was found in the literature²².

3.2.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of glyphosate per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of glyphosate in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.2.3.2-1 to 3.2.3.2-4. Findings relating to residues in control (untreated) samples are also discussed in this section.

In all matrices and for both residue trials and results from monitoring, glyphosate residue concentrations refer to the residue definition for enforcement (i.e. glyphosate).

Occurrence of glyphosate from residue trials carried out for the critical GAP per crop

When applied at the critical GAPs⁴ reported to EFSA, residue levels of glyphosate were below the LOQ in citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, stem vegetables and sugar plants (EFSA, 2019a, 2023e).

Quantified residues of glyphosate were found in miscellaneous fruits (table olives picked from the ground), roots and tuber vegetables (potatoes), pulses (dried), oil seeds and oil fruits (olives for oil production picked from the ground), cereals and honey and other apiculture products (EFSA, 2019a, 2023e).

Regarding feed commodities, residues of glyphosate were below the LOQ in fodder beet roots, and they were quantified in cereal straw and grass forage (EFSA, 2019a, 2023e). No residue trials are available for cultivated fungi, teas, coffee beans, herbal infusions, carobs, hops, spices (dried), alfalfa forage and clover forage (EFSA, 2019a).

The results from residue trials carried out for the critical GAP per crop for glyphosate in commodities for which uses were submitted to EFSA are summarised in Table 3.2.3.2-1 'Occurrence of glyphosate from residue trials carried out for the critical GAP per crop'.

Table 3.2.3.2-1: Occurrence of glyphosate from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Glyphosate (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
Food				
0110000	Citrus fruits	0.1*-0.5	<LOQ (0.05)	<LOQ (0.05)
0120000	Tree nuts	0.1*	<LOQ (0.05)	<LOQ (0.05)
0130000	Pome fruits	0.1*	<LOQ (0.05)	<LOQ (0.05)
0140000	Stone fruits	0.1*	<LOQ (0.05)	<LOQ (0.05)
0150000	Berries and small fruits	0.1*-0.5	<LOQ (0.05)	<LOQ (0.05)
0160000	Miscellaneous fruits ^{c)}	0.1*-1	<LOQ (0.05)-0.93	0.05
0210000	Root and tuber vegetables ^{d)}	0.1*-0.5	<LOQ (0.05)-0.59 ^{e)}	0.05
0220000	Bulb vegetables	0.1*	<LOQ (0.05)	<LOQ (0.05)
0230000	Fruiting vegetables	0.1*-3	<LOQ (0.05)	<LOQ (0.05)
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.1*	<LOQ (0.05)	<LOQ (0.05)
0250000	Leaf vegetables, herbs and edible flowers	0.1*	<LOQ (0.05)	<LOQ (0.05)
0270000	Stem vegetables	0.1*	<LOQ (0.05)	<LOQ (0.05)
0280010	Cultivated fungi	0.1*	NR	-
0300000	Pulses (dried)	0.1*-10	<LOQ (0.05)-7.62	0.05
0400000	Oil seeds and oil fruits	0.1*-10	<LOQ (0.05)-16.4 ^{e)}	0.7
0500000	Cereals	0.1*-20	0.05-21.4 ^{e)}	2.4
0610000	Teas ^{f)}	2	NR	-
0620000	Coffee beans ^{f)}	0.1	NR	-
0630000	Herbal infusions ^{f)}	2*	NR	-
0650000	Carobs ^{f)}	0.1*	NR	-
0700000	Hops ^{f)}	0.1*	NR	-
0800000	Spices (dried) ^{f)}	0.1*	NR	-
0900000	Sugar plants	0.1*-15	<LOQ (0.05)	<LOQ (0.05)
1040000	Honey and other apiculture products	0.05*	0.87-6.9 ^{e)}	3.85
Feed				
1200000	Cereal straw	NA	1.4-175	31.8
	Alfalfa forage	NA	NR	-
	Clover forage	NA	NR	-
	Grass forage	NA	3.2-139	16
	Fodder beet roots	NA	<LOQ (0.05)	<LOQ (0.05)

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; NR – no residue trials are available; '-': not estimated due to lack of data

a) Maximum Residue Level in Reg. 293/2013 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA, 2019a, 2023e; c) Residues were quantified only in olives picked from the ground (EFSA, 2023e); d) Residues were quantified only in potatoes (EFSA, 2019a); e) Residues quantified above the MRLs come from the EFSA MRL Review and EFSA peer review for glyphosate (EFSA, 2019a, 2023e) that has not been considered by risk managers yet; f) In cultivated fungi, teas, coffee beans, herbal infusions, carobs, hops and spices, the reported uses are not supported by data (EFSA, 2019a).

Occurrence of glyphosate under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to glyphosate are given by Regulation (EU) 293/2013³⁶ for the years 2020–2022.

Regarding commodities not labelled as organic, 26,535 samples were collected and analysed for glyphosate in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 24,504 (92.35%) were unprocessed and 2031 (7.65%) processed commodities. No residues were

quantified in 26,105 samples out of the 26,535 samples (98.38%). In 321 samples out of the 26,535 samples (1.21%) glyphosate was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-2.1. MRLs were exceeded in 109 samples out of the 26,535 samples (0.41%). The highest concentration for samples exceeding the MRLs was 23.1 mg/kg in oilseeds and oil fruits (oilseeds – soyabeans).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of glyphosate are summarised in Table 3.2.3-2a for unprocessed and in Table 3.2.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on glyphosate in feed not labelled as organic were submitted to EFSA.

Table 3.2.3.2-2a: Occurrence of glyphosate monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Glyphosate (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0110000	Citrus fruits	0.1*-0.5	0.001	0.02-0.242	9	0.042
0120000	Tree nuts	0.1*	0.05	<LOQ	0	<LOQ
0130000	Pome fruits	0.1*	0.001	0.012-0.16	11	0.044
0140000	Stone fruits	0.1*	0.005	0.02-0.055	7	0.034
0150000	Berries and small fruits	0.1*-0.5	0.002	0.011-1.8	11	0.059
0160000	Miscellaneous fruits	0.1*-1	0.002	0.015-0.511	4	0.025
0210000	Root and tuber vegetables	0.1*-0.5	0.001	0.021-0.098	5	0.06
0220000	Bulb vegetables	0.1*	0.002	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.1*-3	0.002	0.014-0.21	7	0.059
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.1*	0.002	0.02-0.039	2	0.03
0250000	Leaf vegetables, herbs and edible flowers	0.1*	0.002	0.06	1	0.06
0270000	Stem vegetables	0.1*	0.01	0.027	1	0.027
0280010	Cultivated fungi ^{d)}	0.1*	0.002	0.012-0.018	3	0.018
0300000	Pulses (dried)	0.1*-10	0.001	0.016-2.9	34	0.27
0400000	Oil seeds and oil fruits	0.1*-10	0.01	0.012-23.1	34	0.11
0500000	Cereals	0.1*-20	0.002	0.011-4.9	234	0.18
0610000	Teas ^{d)}	2	0.01	0.031	1	0.031
0620000	Coffee beans ^{d)}	0.1	ND	ND	ND	ND
0630000	Herbal infusions ^{d)}	2*	0.01	0.014-0.41	7	0.11
0650000	Carobs ^{d)}	0.1*	ND	ND	ND	ND
0700000	Hops (dried)	0.1*	0.1	<LOQ	0	<LOQ
0800000	Spices (dried)	0.1*	ND	ND	ND	ND
0900000	Sugar plants	0.1*-15	0.05	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.01	0.013-1.5	16	0.047
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
	Alfalfa forage	NA	ND	ND	ND	ND

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Glyphosate (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
	Clover forage	NA	ND	ND	ND	ND
	Grass forage	NA	ND	ND	ND	ND
	Fodder beet roots	NA	ND	ND	ND	ND
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of glyphosate is not expected)						
0260000	Legume vegetables	0.1*	0.01	0.016–0.14	4	0.096
0280000	Fungi, mosses and lichens	0.1*–50	0.002	0.012–0.018	3	0.018
0290000	Algae and prokaryotes organisms	NA	0.03	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs ^{d)}	0.1–2*	0.01	0.014–0.41	8	0.11

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 293/2013 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Cultivated fungi, teas, coffee beans, herbal infusions and carobs appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0280010, 0610000, 0620000, 0630000 and 0650000 and non-use of the substance for all other commodities '028N000' and '06N0000' and that are reported under the 'broader' categories 0280000 and 0600000 on the table. This creates an inconsistency where the results indicating non-uses are overestimated.

In addition to the pesticide monitoring data collection, analysis of residues of glyphosate in honey and other apiculture products was carried out in the framework of the VMPP national control activities. For unprocessed products of conventional agriculture (101 samples) quantified residues were found for two samples. These results (0.024 and 0.062 mg/kg with an LOQ at 0.01 mg/kg), which are not reported in Table 3.2.3.2-2a, are consistent with the results from the pesticide data collection, i.e. the highest concentration reported in the VMPP data collection is below the highest concentration reported in the pesticide data collection.

Table 3.2.3.2-2b: Occurrence of glyphosate from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Glyphosate (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0110000	Citrus fruits	0.1*-0.5	0.02	0.062	1	0.062

Findings of not authorised substances in organic products

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Glyphosate (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0120000	Tree nuts	0.1*	0.05	<LOQ	0	<LOQ
0130000	Pome fruits	0.1*	0.02	<LOQ	0	<LOQ
0140000	Stone fruits	0.1*	0.002	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.1*-0.5	0.002	0.01-0.082	5	0.03
0160000	Miscellaneous fruits	0.1*-1	ND	ND	ND	ND
0210000	Root and tuber vegetables	0.1*-0.5	0.02	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.1*	ND	ND	ND	ND
0230000	Fruiting vegetables	0.1*-3	0.02	0.32-3.1	4	1.15
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.1*	ND	ND	ND	ND
0250000	Leaf vegetables, herbs and edible flowers	0.1*	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.1*	0.01	<LOQ	0	<LOQ
0280010	Cultivated fungi ^{d)}	0.1*	0.002	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.1*-10	0.01	<LOQ	0	<LOQ
0400000	Oil seeds and oil fruits	0.1*-10	0.002	<LOQ	0	<LOQ
0500000	Cereals	0.1*-20	0.001	0.013-0.98	26	0.073
0610000	Teas ^{d)}	2	ND	ND	ND	ND
0620000	Coffee beans ^{d)}	0.1	ND	ND	ND	ND
0630000	Herbal infusions ^{d)}	2*	0.03	<LOQ	0	<LOQ
0650000	Carobs ^{d)}	0.1*	ND	ND	ND	ND
0700000	Hops (dried)	0.1*	0.1	<LOQ	0	<LOQ
0800000	Spices (dried)	0.1*	ND	ND	ND	ND
0900000	Sugar plants	0.1*-15	ND	ND	ND	ND
1040000	Processed apiculture products	0.05*	0.025	0.037	1	0.037
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
	Alfalfa forage	NA	ND	ND	ND	ND
	Clover forage	NA	ND	ND	ND	ND
	Grass forage	NA	ND	ND	ND	ND
	Fodder beet roots	NA	ND	ND	ND	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of glyphosate is not expected)						
0260000	Legume vegetables	0.1*	0.01	0.026-0.17	2	0.098
0280000	Fungi, mosses and lichens	0.1*-50	0.1	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	NA	ND	ND	ND	ND
0600000 ^{d)}	Teas, coffee, herbal infusions, cocoa and carobs	0.1-2*	0.03	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 293/2013 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Cultivated fungi, teas, coffee beans, herbal infusions and carobs appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0280010, 0610000, 0620000, 0630000 and 0650000 and non-use of the substance for all other commodities '0280000' and '0600000' and that are reported under the 'broader' categories 0280000 and 0600000 on the table. This creates an inconsistency where the results indicating non-uses are overestimated.

Occurrence of glyphosate in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 3,249 samples were collected and analysed for glyphosate from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 2,699 (83.07%) were unprocessed and 550 (16.93%) processed commodities. No residues were quantified in 3,246 samples out of 3,249 samples (99.91%). In three samples out of 3,249 samples (0.09%) glyphosate was found at or above the analytical LOQ but below or at the MRL. No samples labelled as organic were above MRLs. These findings are summarised in Appendix B, Table B-2.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.2.3.2-3a for unprocessed and in Table 3.2.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on glyphosate in feed labelled as organic were submitted to EFSA.

Table 3.2.3.2-3a: Occurrence of glyphosate from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Glyphosate (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.1*–0.5	0.01	<LOQ	0	<LOQ
0120000	Tree nuts	0.1*	0.05	<LOQ	0	<LOQ
0130000	Pome fruits	0.1*	0.005	<LOQ	0	<LOQ
0140000	Stone fruits	0.1*	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.1*–0.5	0.005	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.1*–1	0.01	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.1*–0.5	0.002	0.021	1	0.021
0220000	Bulb vegetables	0.1*	0.002	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.1*–3	0.01	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.1*	0.005	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.1*	0.01	<LOQ	0	<LOQ
0260000	Legume vegetables	0.1*	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.1*	0.005	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.1*–50	0.01	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	NA	ND	ND	ND	ND
0300000	Pulses (dried)	0.1*–10	0.01	0.021	1	0.021
0400000	Oil seeds and oil fruits	0.1*–10	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.1*–20	0.002	0.01	1	0.01
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1–2*	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	0.1*	ND	ND	ND	ND
0800000	Spices (dried)	0.1*	0.1	<LOQ	0	<LOQ
0900000	Sugar plants	0.1*–15	ND	ND	ND	ND

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Glyphosate (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
1040000	Honey and other apiculture products	0.05*	0.01	<LOQ	0	<LOQ

*Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 293/2013 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

In addition to the pesticide monitoring data collection, an analysis of residues of glyphosate in honey and other apiculture products was carried out in the framework of the VMPP national control activities. For unprocessed products of organic agriculture, 2 out of the 13 samples collected had quantified residues at 0.011 and 0.019 mg/kg (LOQ at 0.01 mg/kg).

Table 3.2.3.2-3b: Occurrence of glyphosate from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Glyphosate (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.1*–0.5	0.02	<LOQ	0	<LOQ
0120000	Tree nuts	0.1*	0.01	<LOQ	0	<LOQ
1300000	Pome fruits	0.1*	0.005	<LOQ	0	<LOQ
1400000	Stone fruits	0.1*	ND	ND	ND	ND
0150000	Berries and small fruits	0.1*–0.5	0.005	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.1*–1	0.02	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.1*–0.5	0.03	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.1*	ND	ND	ND	ND
0230000	Fruiting vegetables	0.1*–3	0.1	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.1*	0.1	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.1*	0.05	<LOQ	0	<LOQ
0260000	Legume vegetables	0.1*	ND	ND	ND	ND
0270000	Stem vegetables	0.1*	ND	ND	ND	ND
0280000	Fungi, mosses and lichens	0.1*–50	0.1	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	NA	ND	ND	ND	ND
0300000	Pulses (dried)	0.1*–10	0.01	<LOQ	0	<LOQ
0400000	Oil seeds and oil fruits	0.1*–10	0.002	<LOQ	0	<LOQ

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Glyphosate (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0500000	Cereals	0.1*-20	0.001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1-2*	0.03	<LOQ	0	<LOQ
0700000	Hops (dried)	0.1*	ND	ND	ND	ND
0800000	Spices (dried)	0.1*	0.1	<LOQ	0	<LOQ
0900000	Sugar plants	0.1*-15	ND	ND	ND	ND
1040000	Processed apiculture products	0.05*	0.05	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 293/2013 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of glyphosate in the EU Organic Farming Information System

The EU OFIS reported 115 findings for glyphosate in 2021 and 2022; 38 of the products sampled and analysed had EU origin and 77 were of non-EU origin. Residues were found in two samples of citrus fruits (limes), two samples of tree nuts (almond flour and pine nut kernels (pine buds)), one sample of stone fruits (plums), two samples of berries and small fruits (elderberry juice), one sample of root and tuber vegetables (sweet potatoes), nine samples of leaf vegetables, herbs and edible flowers (thyme (oregano), basil and edible flowers (peppermint), tarragon (nettle leaves) and lemongrass), seven samples of legume vegetables (peas (without pods) and lentils (lentils)), 32 samples of linseeds, sesame seeds, sunflower seeds and kernels, rapeseeds/canola seeds (rapeseeds), soyabeans and pumpkin seeds, nine samples of cereals (buckwheat and other pseudocereals (chia seeds) and wheat), 39 samples of teas, coffee, herbal infusions, cocoa and carobs (teas, coffee beans, herbal infusions, rose, strawberry and cocoa beans), 5 samples of spices (bark spices – cinnamon) and six samples of honey and other apiculture products. The concentrations of glyphosate residues were above LOQ but below MRL in 102 samples and in 13 samples the residues were above MRL. The highest concentration was reported for a sample of peas without pods of EU origin, with quantified levels of 1.114 and 1.478 mg/kg. These findings are summarised in Table 3.2.3.2-4.

Table 3.2.3.2-4: Occurrence of glyphosate from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
0120010	Almonds	0.1*	ND	0.022 – Almond flour
0120090	Pine nut kernels	0.1*	0.162 – Pine buds/shoots/sprouts	ND
0154080	Elderberries	0.1*	ND	0.045; 0.035 – Elderberries (juice)
0211000	Potatoes	0.5	0.1 – Sweet potatoes	ND

Findings of not authorised substances in organic products

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
0256100	Tarragon	0.1*	0.068; 0.044; 0.12 – Nettle leaves	ND
0260040	Peas (without pods)	0.1*	1.478; 0.063; 0.041; 1.114 – Peas (without pods)	ND
0260050	Lentils	0.1*	0.048 – Lentils	0.069 – Lentils salad
0401010	Linseeds	10	0.035 – Linseed 0.058 – Flax	ND
0401040	Sesame seeds	0.1*	ND	0.35; 0.66 – Roasted sesame seeds
0401050	Sunflower seeds	20	0.139; 0.065; 0.069; 0.139; 0.065; 0.069 – Sunflower seeds 0.042; 0.065; 0.069 – Sunflower kernels	ND
0401060	Rapeseeds/canola seeds	10	0.021 – Rapeseeds	0.032; 0.032 – Rapeseeds (cake)
0401100	Pumpkin seeds	0.1*	0.02; 0.024; 0.037; 0.053 – Pumpkin seeds	ND
0500990	Cereals – others	0.1*	ND	0.017 – Bread (wholemeal multigrain)
0630000	Herbal infusions	2*	0.21 – Herbal infusions	ND
0632010	Strawberry	2*	ND	0.022 – Strawberries (juice concentrate) 0.022 – Strawberry (purée)
Samples of non-EU origin				
0110040	Limes	0.1*	0.12; 0.16 – Limes	ND
0140040	Plums	0.1*	ND	0.22 – Plums (dehydrated)
0256070	Thyme	0.1*	0.058; 0.071; 1.1 – Oregano	ND
0256080	Basil and edible flowers	0.1*	ND	0.13 – Peppermint (crushed)
0256100	Tarragon	0.1*	0.056 – Nettle; 0.032 – Lemongrass;	ND
0260050	Lentils	0.1*	0.011 – Lentils (green)	ND
0401010	Linseeds	10	0.012; 0.028 – Flax (seeds) 0.02 – Linseed	ND
0401040	Sesame seeds	0.1*	0.023 – Sesame	ND
0401050	Sunflower seeds	20	ND	0.077 – Sunflower lecithin 0.019 – Sunflower seed cake
0401070	Soyabeans	20	0.036; 0.016; 0.162; 0.014; 0.021 – Soyabeans	0.014 – Soybean meal
0500020	Buckwheat and other pseudocereals	0.1*	0.012; 0.019; 0.054; 0.13; 0.028 – Chia seed	ND
0500090	Wheat	10	0.016; 0.022 – Spelt 0.012 – Kamut (registered trademark of wheat cultivar Khorasan)	ND
0610000	Teas	2	0.044; 0.095; 0.057; 0.064 – Teas	0.12 – Green tea organic Granada ginger
0620000	Coffee beans	0.1	0.05; 0.041; 0.031; 0.041; 0.019; 0.011; 0.017; 0.059; 0.018; 0.044; 0.056; 0.067; 0.014; 0.023 – Coffee beans	0.014 – Decaffeinated coffee beans
0631030	Rose	2*	0.12; 0.23 – Elderflowers	ND
0632010	Strawberry	2*	0.073 – Aloe Vera; 0.237 – Blackberry leaves; 0.046 – Orange bitter leaves; 0.037; 0.14 – Organic lemon verbena leaves	0.016 – Strawberry juice (concentrate)
0640000	Cocoa beans	0.1*	0.011; 0.011; 0.029; 0.029; 0.035; 0.025; 0.013 – Cocoa beans	0.014 – Criollo cocoa powder
0830010	Cinnamon	0.1*	0.013; 0.014 – Broken cassia 0.037 – Cinnamon	ND

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
0840030	Turmeric/curcuma	0.1*	ND	0.29; 0.014 – Turmeric/Curcuma
1040000	Honey and other apiculture products	0.05*	0.017; 0.029; 0.049; 0.016; 0.038; 0.01 – Honey	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 293/2013 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of glyphosate in untreated samples (control samples) from residue trials

In the evaluation report of glyphosate, quantified findings in control (untreated) samples were observed in several residue trials of sugar beets from Germany (Germany, 2017). Additionally, residues were found in the control pasture samples from residue trials carried out in one trial in grass in the Netherlands and several trials carried out in France, Finland, and Germany (Germany, 2017).

Residues were also quantified in several residue trials on peas from different parts of the UK, six trials on barley from France including four trials on straw and two trials on grain. Residues of glyphosate were measured in three trials on straw and one trial on wheat grain from France and several trials on different oat plant portions from the UK (Germany, 2019c).

Furthermore, residues occurred in winter soft wheat control samples from residue trials carried out in France (Germany, 2013a).

No evidence-based explanations on the causes for these occurrences in control (untreated) samples were provided in the above Member State ERs and RAR.

The summary of the quantified findings of residues of glyphosate in control (untreated) samples from residue trials carried out for the critical GAP⁴ per crop is given below in Table 3.2.3.2-5.

Table 3.2.3.2-5: Summary of the quantified findings for glyphosate in control (untreated) samples from residue trials carried out for the critical GAP per crop.

Crop	Country/Area	Result (mg/kg)
Barley	France	Grain: 0.087
		Straw: 0.059, 0.096, 0.11, 0.16, 0.18
Oat	UK	Grain: 0.030, 0.033, 0.040
		Straw: 2×0.05, 2×0.06, 2×0.07, 3×0.08, 0.09, 0.18, 0.25, 0.26, 1.6
		Whole plant: 2×0.050, 0.080, 0.10, 0.17
Pasture	Finland	Silage: 6×1.1; 3×2.2
	France	Hay: 2×6.4, 6.7, 7.6
		Silage: 10
	Germany	Leaves: 0.06, 1.2
		Root body: 0.50
	Netherlands	Grass: 0.24

	UK	Hay: 14.9
		Grass: 2×0.070, 2×0.090, 0.10, 2×0.13, 2×0.20, 2×0.23
Peas	UK	Rest of the plant: 0.08, 3×0.10, 0.12, 0.17, 2×0.60, 4×0.70
Sugar beet	Germany	Leaves: 0.30, 0.50, 2×0.60, 0.70, 1.2, 2×2.3
		Shoot leaves: 0.80
		Bolter leaves: 0.60, 0.80, 2.7
		Plant: 0.40, 0.70, 3.3
		Root body: 0.060; 0.15; 0.40; 0.50; 0.54
Wheat	France	Grain: 0.033
		Straw: 0.081, 0.093, 0.18
Winter soft wheat	France	Grain: 0.15, 0.22
		Straw: 0.22

- Could the presence of glyphosate and/or its residues be due to biocide use?

Glyphosate is not authorised for use as a biocide, therefore, residues due to biocidal use are not expected for glyphosate.

3.2.3.3 Behaviour in food and feed products

- What key physico-chemical properties of glyphosate are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of **glyphosate** are reported in Table 3.2.3.3.

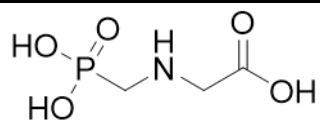
Glyphosate exhibited low to moderate persistence in soil (see also Section 3.2.3.5). Regarding sorption to soil, the geometric mean of K_{Foc} in Table 3.2.3.3 indicates that the substance has slight mobility in soil (EFSA, 2023e).

The maximum calculated PEC_w for glyphosate for the representative uses was 13.62 µg/L (spray drift application to winter oil seed rape; 1 × 2.16 kg a.s./ha) (EFSA, 2015b).

Glyphosate is hydrolytically stable under standard conditions of pasteurisation, baking, brewing, boiling and sterilisation (EFSA, 2023e). Considering that glyphosate is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Glyphosate is characterised by low volatility (vapour pressure = 10⁻⁵ Pa) and a short atmospheric half-life (1.6 hours). Field experiments showed that volatilisation of glyphosate from plants and soil surfaces was not detectable after 24 hours (EFSA, 2015b, 2023e).

Table 3.2.3.3: Physico-chemical properties of glyphosate (EFSA, 2023e)

Structural formula	
Appearance (state purity)	White solid (99.6 %)
Melting point (state purity)	189.5°C (99.9 %)
Boiling point	Not applicable because glyphosate decomposes during melting
Temperature of decomposition	200°C (99.6 %)
Vapour pressure (state temperature, state purity)	1.31×10^{-5} Pa at 25°C (98.6 %)
Henry's law constant (state temperature)	$< 2.21 \times 10^{-8}$ Pa m ³ mol ⁻¹ (25°C)
Solubility in water (state temperature, state purity and pH)	pH 1.9: 10.5 g/L at 20°C (99.5%) pH 5.0: >100 g/L at 20°C (99.9%) pH 7.0: >100 g/L at 20°C (99.9%) pH 9.0: 171 g/L at 20°C (99.9%)
Partition coefficient (octanol/water) (state temperature, pH and purity)	(99.9%) Log Pow = -5.39 at 25°C (at pH buffers at 5) Log Pow = -6.28 at 25°C (at pH buffers at 7) Log Pow = -5.83 at 25°C (at pH buffers at 9)
Partition coefficient (octanol/air)	NA
Atmospheric half-life	DT ₅₀ = 1.62 hours derived by the Atkinson model (AOPWINTM 1.92a). OH (12h) radical concentration assumed = 1.5×10^6 cm ⁻³
Dissociation constant (state purity)	pKa1 = 2.34 (99 %) pKa2 = 5.73 (99 %)
Soil adsorption (geometric mean)	K _{Foc} = 4348 mL/g
Hydrolytic degradation (>10%)	Stable at pH 4, 5, 7 and 9 at 50°C (also at lower temperatures)

DT₅₀ – Disappearance time of 50% of the substance in field studies; NA – not applicable; pH – Potential of Hydrogen; Pow – Octanol/water Partition Coefficient

3.2.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from the soil surface at which it is applied).

The highest drift of glyphosate to neighbouring fields may occur during its applications to control weeds using downward spraying at ground level in fruit crops, hops, vineyards, vegetables and field crops (all up to 2.77%). Drift values should be considered the rate received by neighbouring fields, expressed as percentages of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. Buffer zones or spray drift-reducing nozzles).

Considering the above, if organic crops are present adjacent to the conventional crops treated, measurable residues of glyphosate in the untreated crop are not expected. However, since the nature of the potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

3.2.3.5 Accumulated/historical residue levels in soil

- What is the persistence of glyphosate and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

According to available data (EFSA, 2023e), the DT₉₀ of glyphosate in soil (investigated in eight field dissipation studies) has a worst-case field value of 192 days indicating accumulation in soil is not expected.

However, the potential for residues to occur in succeeding crops was investigated as glyphosate residues can be present in soil when a succeeding crop is planted. Studies on the nature of residues in rotational crops were carried out with leafy vegetables, root and tuber vegetables, cereals and legume vegetables planted at different intervals after application rates up to 6500 g a.s./ha of the active substance in soil. According to the results from these studies, residues of glyphosate are not expected in rotational root and leafy crops following annual application of glyphosate, if the active substance is used according to the GAPs⁴. Residues of glyphosate above the LOQ of 0.05 mg/kg cannot be excluded in forage and chaff grown in rotation with crops treated with glyphosate.

Although these residues can be considered negligible compared to the residues expected according to the most critical GAP for desiccation authorised on cereals, Member States were recommended to implement proper mitigation measures when granting authorisation of plant protection products containing glyphosate, in order to avoid residues occurring in rotated cereals (EFSA, 2019a).

Considering, however the worst-case DT₉₀ of 192 days for glyphosate, transfer of residues of glyphosate to plants (including cereal forage and chaff) planted or sown in soil previously treated with glyphosate is not expected in organic crops planted 2 years after the last chemical treatment, as required by the regulatory provisions for organic agriculture³⁸.

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Monitoring data for glyphosate in soil are available from the LUCAS pesticides 2018 (JRC, 2023) on IPCHEM¹². According to Franco et al. (2024), glyphosate was detected in 16% of sites included in the LUCAS soil survey, ranking among the most frequently identified pesticide residues in European soil.

The data from LUCAS pesticides show background levels of the substance in soil samples from 23 EU countries: Austria (1 sample), Belgium (1 sample), Bulgaria (11 samples), Czechia (27 samples), Denmark (22 samples), Estonia (11 samples), Finland (48 samples), France (106 samples), Germany (20 samples), Greece (7 samples), Hungary (9 samples), Ireland (1 sample), Italy (22 samples), Latvia (13 samples), Lithuania (12 samples), Luxembourg (1

sample), the Netherlands (6 samples), Poland (48 samples), Portugal (12 samples), Romania (3 samples), Slovakia (5 samples), Spain (123 samples) and Sweden (25 samples). The reported residue levels ranged from 0.026 mg/kg to 2.4 mg/kg. In LUCAS soil, the lack of information on the agricultural use history of the sites where soil was sampled precluded knowing whether the reported quantified findings were related to recent active use or historical levels in soil for glyphosate.

Further evidence of glyphosate residues in soil is provided in a study by Silva et al. (2023) in a study carried out under the EU SPRINT project. This study assessed the presence of 209 pesticide residues in 100 soil samples from conventional agriculture and 63 soil samples from organic agriculture collected during the 2021 growing season across 10 study sites in Europe: Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark. Glyphosate was found in 41 soil samples from conventional agriculture (41%) at concentrations ranging from 0.02 to 8.6 mg/kg and three soil samples under organic production systems (5%) from the Czechia and Denmark at concentrations ranging from 0.02 to 0.04 mg/kg. In both cases, the highest concentrations were found in conventional soil from Portugal.

Considering the available evidence, plant uptake of glyphosate from soil under organic production systems containing glyphosate is less likely even for crops growing in soil that contain residues at the levels quantified in these studies.

3.2.3.6 Residues from water used for irrigation

- Is there evidence that residues of glyphosate present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for glyphosate in water samples were considered:

- The EEA-WATERQUALITY³⁹ database (data retrieved on 10 April 2024) reports 30,871⁴⁰ analytical results from water samples collected in Belgium (157), Croatia (19), Cyprus (56), Denmark (1071), Estonia (275), Finland (33), France (21,720), Ireland (967), Italy (6,112), Lithuania (33), the Netherlands (289), Slovakia (85), Slovenia (18) and Sweden (36) between 2019 and 2021;
- The EMPODAT database (data retrieved on 2 April 2024) reports 4,949 analytical results from surface water samples collected in the Netherlands between 2018 and 2020;
- The NAIADES database (data retrieved on 2 April 2024) reports 69,048 analytical results from surface water samples collected in France from 2019 to 2021.

Among the 104,868 analytical results for glyphosate, 871 were disregarded as found to report quantitative values below the analytical LOQ and 1335 were disregarded as found to report quantified residues equal to LOQs as high as 1 µg/L and above. Therefore, the number of water samples considered is 102,662.

Based on the screening process described in section 'Data and methodologies', for 98.8% of water samples analysed and reported in the above-mentioned databases (101,450 samples),

³⁹ The water samples considered from EEA-WATERQUALITY are indicated as 'other water' on IPCHEM. Therefore, they relate to all water sources (other than 'suspended particulate matter'), that do not only include surface water but also groundwater, transitional or coastal water. This is part of the uncertainty associated with the results from this database.

⁴⁰ The total number of results in the database is 30,871. The number reported does not include outliers.

the residue concentrations in these waters were below the screening Cw of 0.84 µg/L and, therefore, transfer of residues from water sources to plant commodities is unlikely.

For 1.2% of samples (1212 out of 102,662 samples), the residue concentrations were found to be at or above the screening Cw of 0.84 µg/L and the potential transfer of residues to plant commodities if water containing residues at these levels is used for irrigation cannot be excluded. Since Cw is a screening value derived from worst-case calculations it requires experimental evidence in order to confirm or rule out the potential transfer of residues from the specific water sources. Therefore, if glyphosate is quantified in organic commodities, analysis of the water source used to irrigate the plant is recommended.

Further evidence of glyphosate in water was provided by Silva et al. (2023) in a study carried out under the EU SPRINT project. The study assessed the presence of glyphosate in 58 water samples collected in 2021 across 10 study sites in Europe (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). Glyphosate was detected in 57 samples (98%) at concentrations up to 3.5 µg/L, with 28 samples found to contain residues above 0.1 µg/L. The highest concentration was found in a sample from Italy.

In a study by Suciu et al. (2023), the presence of glyphosate was assessed in groundwater samples from 26 wells used for drinking water and for irrigation in the Tidone Valley, Province of Piacenza (Northwest Italy). The study was carried out under the framework of the EU SPRINT project. Glyphosate was detected at values between <0.05 and 5.5 µg/L in 40% of groundwater samples, 41% of which were above the limit of 0.1 µg/L. According to the authors, the non-agricultural use of glyphosate for weed control in the farmyard, the point source contamination of wells and the possible transport with the subsurface lateral inflow of water from an up-hill vineyard are considered possible sources of glyphosate in the area (Suciu et al., 2023).

Overall, the available evidence suggests that the transfer of residues of glyphosate from EU water sources to plant commodities used to irrigate plants cannot be excluded.

3.2.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *glyphosate*, *industry/industrial*, and *air/atmosphere*) identified three European studies, none of which were considered relevant for this section.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water.

A mapping exercise was conducted by overlaying georeferenced water sampling data from IPCHEM (2020–2022) with georeferenced data on chemical industry facilities from the European Industrial Emissions Portal. Of the 1212 relevant water samples (exceeding the screening value and excluding outliers, as reported in Table 1), 535 were collected between 2020–2022. For the

conducted spatial analysis, it is important to note that these numbers reflect the total number of sampling events rather than distinct sampling locations, as some sites were monitored multiple times during the study period. Of these 535 samples, only five were located within a 1 km radius of a chemical facility, whilst 54 fell within a 5 km radius. No clear spatial association was identified.

A literature review was carried out to gather additional relevant information. A search in the Scopus database (conducted on February 7, 2025, using the keywords *glyphosate, industry/industrial, and water*) identified two articles with potentially relevant information.

In a study by Desmet et al. (2016), the presence of glyphosate and AMPA have been described in surface water samples from river Meuse (The Netherlands), an important source for drinking water production. Monitoring data on glyphosate concentrations were obtained from RIWA-Maas (international association of drinking water companies that use the river Meuse as a source) from monitoring for the period 1995–2011 (Volz, 2007, 2009, 2011). At the upstream boundary, the median glyphosate concentration was 0.08 µg/L and the 90th percentile value reached 0.27 µg/L, with about 45% of the glyphosate concentrations exceeded the drinking water standard of 0.1 µg/L. At the drinking water intake, the median glyphosate concentration was 0.07 µg/L and the 90th percentile value was 0.15 µg/L, with about 32% of the glyphosate concentrations exceeded the drinking water standard of 0.1 µg/L. The authors suggest that wastewater treatment plant (WWTP) effluents are important contributors to glyphosate in the river catchment, with the relative contribution being above 29% for glyphosate. Main sources of WWTPs located in the area include urban (households, including the use of detergent and cleaning product), industrial (chemical industries, cooling water conditioning industries) and agricultural activities. However, the authors noted that the agricultural use of glyphosate does not or hardly contributes to the total load of glyphosate to the river Meuse. Therefore, the industrial sector could be among the factors contributing to these residue concentrations.

In a study by Masiol et al. (2018), residues of glyphosate were analysed in surface water samples collected from 24 major rivers of Veneto (Italy). Eighty-six samples were collected in 2015 at multiple sampling points. The maximum concentration was 2.1 µg/L in a sampling point from the Lagoon of Venice, with the threshold of 0.1 µg/L exceeded in 26 samples. According to the authors, urban/industrial discharges were among the factors contributing to these residue concentrations. However, no evidence was provided in the paper to support this argument.

Overall, a mapping of the locations of water samples on IPCHEM that were analysed for glyphosate with georeferenced data from the EEA's Industrial Emissions Portal did not show associations between environmental occurrence and industrial activity in the surrounding areas. The one study from the literature showing a transfer of residues from industrial activity to environmental water sources does not give insight into the potential transfer of residues from water to plants.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Based on information on the possible plant uptake of glyphosate from EU soil, the transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 17, 2025, using the keywords *glyphosate, industry/industrial,*

and soil/sediment) identified one European study which was considered irrelevant for this section.

3.2.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Medium and long-range aerial transport of residues

In a study by Ravier et al. (2019) the authors investigated the presence of glyphosate in the ambient atmosphere at four sampling sites distributed throughout the Provence-Alpes-Côte-d'Azur (PACA), from January 2015 to December 2016. The three urban sampling sites (i.e. Avignon, Nice, and Port-de-Bouc) were located in the city centres, whereas the rural site of Cavaillon was located in an intensive arboriculture area. Glyphosate was detected with frequencies ranging from 0% (Nice) to 23% (Cavaillon), with the maximum concentration of 1.04 ng m⁻³ reached in Cavaillon. The authors indicate as a possible source an air mass passing over the orchards surrounding the sampling sites.

Zaller et al. (2022) employed passive air samplers across 15 regions in Austria with varying land uses over a period of up to 8 months (March to November 2020). The authors identified conventional agriculture as the likely source, as the compound is approved for conventional but not for organic farming. The samples were analysed for 566 substances, and relationships between the detected concentrations, land use types, substance properties, and meteorological conditions were examined. Glyphosate was quantified in all targeted samples, at mean concentrations of 116 ± 90 ng/sample.

Silva et al. (2023) investigated the presence of glyphosate in 20 outdoor air samples collected during the 2021 growing season across 10 study sites in Europe of organic and conventional agriculture (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). The study was carried out under the framework of the EU SPRINT project. Organic fields had not been treated for 5 consecutive years. Glyphosate was detected in all targeted samples at the maximum concentration of 451.4 ng m⁻³. Aerial concentrations of glyphosate in the organic field surrounding areas ranged from 10.3 ng m⁻³ to 120 ng m⁻³. These levels suggest that glyphosate aerial transport to untreated areas cannot be excluded.

In another study by Mazzi et al. (2024) the authors assessed the contamination caused by plant protection products in size-segregated (coarse, fine, ultrafine) urban aerosol in the city of Mestre (Venice, Italy) during the summer and autumn 2023. The sampling location was highlighted as interesting due to its proximity to the industrial area of Porto Marghera, several public parks, and busy roads. The sampling location further allowed investigation of aerosol coming from short- and long-range transport distances, with the latter potentially serving as a significant source of plant protection products from surrounding rural areas. Glyphosate was mostly detected in the coarse fractions (2.5–10 µm), with maximum concentrations of 0.08 ng m⁻³ in the total suspended particulate (TSP) and 0.05 ng m⁻³ in the PM₁₀ aerosol filters. The authors suggest that due to its presence in the coarse fractions, the source was likely very local, such as private gardens and public green areas.

Overall, medium and long-range aerial transport of residues of glyphosate outside the treated areas cannot be excluded.

Other sources (not mentioned above)

Other sources of residues of glyphosate in plants may relate to transfer from water contamination pathways following applications of the substance for weed control on railway tracks, urban areas, road and infrastructure management and use by private gardeners (Skark et al., 1998; Börjesson et al., 2000, Torstensson et al., 2005, Staub et al., 2024).

3.2.4 Conclusions on glyphosate

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use. Some of the residues quantified in the residue trials are higher than the current MRLs for the respective commodities. This is because these trials were evaluated in the more recent MRL and peer reviews that have not been considered yet by the risk managers (see Section 3.2.3.2).
- Residue trials carried out to support the critical GAPs⁴ for glyphosate, gave residue concentrations of up to 21.4 mg/kg in cereal grain and up to 175 mg/kg in cereal straw. Concentrations in the ranges reported in Table 3.2.3.2-1 might be associated with active use of glyphosate according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.
- Application at rates above the recommended GAP rates is unlikely as both these and below GAP application rates can cause phytotoxicity to the treated crops when care is not taken to prevent spray deposition on foliage or non-woody stems.
- Glyphosate was quantified in the context of residue trials in several European countries in untreated (control) samples with the highest concentrations observed in one sample of cereal grain from France (0.087 mg/kg), and one of pasture hay from the UK (14.9 mg/kg) and a sample of pasture silage from France (10 mg/kg).
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for glyphosate in unprocessed commodities with authorised uses ranged from 0.034 mg/kg in stone fruits to 0.27 mg/kg in dried pulses.
- In organic unprocessed commodities that were analysed under the pesticide residues monitoring programme between 2020 and 2022, residues of glyphosate were not quantified or were quantified in fewer than five samples per commodity.
- Without additional information on the individual samples' history and context, it is not possible to conclude if quantified results in organic commodities are associated with active use or unintentional presence of glyphosate.
- In organic processed commodities, residues of glyphosate were not quantified. In samples from processed products not labelled as organic with five or more quantified findings, residues of glyphosate were quantified only in berries and small fruits and cereals at median concentrations of 0.03 and 0.073 mg/kg, respectively. Considering that glyphosate is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of

some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

- Overall, in commodities labelled as organic, glyphosate was quantified in 0.09% of samples (three out of 3,249 samples). This percentage is 18 times lower than the percentage reflecting the number of findings in samples not labelled as organic (1.62%) (see Appendix B, Tables B-2.1 and B-2.2). These results suggest that the occurrence of residues of glyphosate in organic products is less likely when compared with conventional commodities.
- Potential sources of the unintentional presence of residues of glyphosate in commodities of plant origin are aerosol transport or use of glyphosate in urban areas (e.g. private gardens or public green areas). Transfer of residues of glyphosate from conventional to organic crops due to drift is unlikely.
- Results from LUCAS pesticides showed glyphosate occurrence in samples taken from agricultural soil throughout the EU but without knowing whether these findings are associated with organic or conventional agriculture. Glyphosate is persistent in soil, but not persistent enough to accumulate, however, not all substances present in soil are taken up by plants. Considering the available evidence, plant uptake of glyphosate from soil containing glyphosate is less likely.
- Transfer of residues from glyphosate-containing water to plant commodities via irrigation cannot be excluded. If glyphosate is quantified in organic commodities, analysis of the water source used to irrigate the plants is recommended.
- Transfer to plants may come from water contamination pathways following applications of the substance for weed control on railway tracks, urban areas, road and infrastructure management and use by private gardeners, weed control in the farmyard, point source contamination of wells and the transport with the subsurface lateral inflow of water from up-hill vineyards.
- A mapping of the locations of samples analysed for glyphosate on IPCHEM with georeferenced data from the EEA's Industrial Emissions Portal did not show associations between environmental occurrence and industrial activity in the surrounding areas. The one study from the literature showing a transfer of residues from industrial activity to environmental water sources does not give insight into the potential transfer of residues of glyphosate from water to plants.

The pathways of residues of glyphosate to plants and plant commodities are summarised in Figure 2.

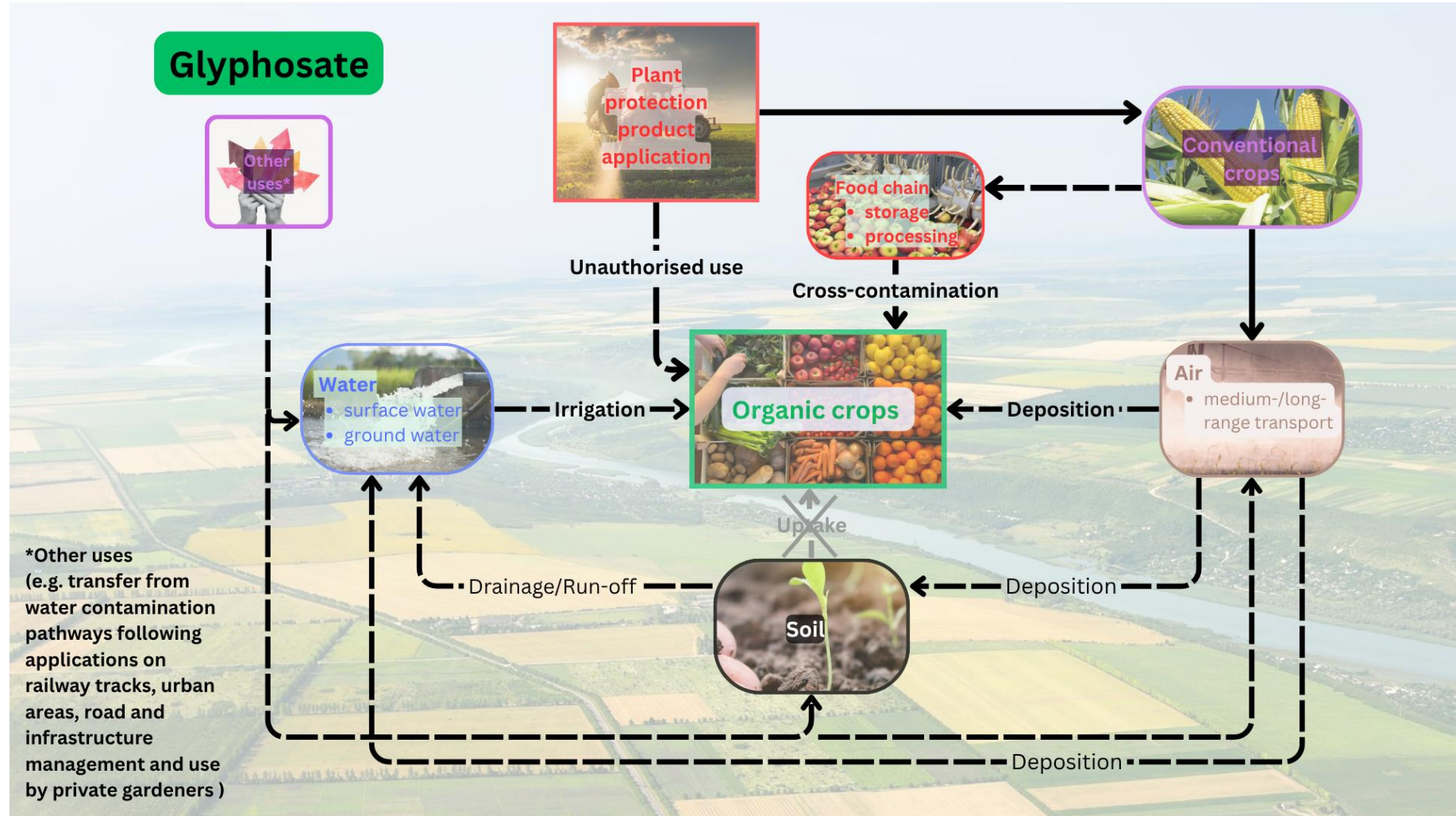


Figure 2: Pathways of residues of glyphosate to plants and plant commodities

Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded

3.3 Cypermethrin

3.3.1 Method(s)

- What is/are the residues to be monitored for cypermethrin according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

For the active substance cypermethrin, the residue definition for enforcement in food and feed of plant origin has been proposed as 'cypermethrin including other mixtures of constituent isomers (sum of isomers)⁴¹' in the EFSA peer review conclusion and MRL review (EFSA, 2018c, 2023f). This residue definition is applicable to primary, rotational crops, processed products, as well for honey (EFSA, 2018c). This residue definition for enforcement is implemented in Regulation (EC) No 396/2005³.

Based on the above only residues of cypermethrin (sum of isomers) are to be monitored in foods of plant origin, honey and other apiculture products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

Multi-residue DFG S19 and QuEChERS methods using GC-MS/MS are validated for the determination of cypermethrin residues (sum of isomers) with an LOQ of 0.01 mg/kg in high water, high acid, high oil content, dry matrices and honey, and an LOQ of 0.05 mg/kg in difficult matrices (EFSA, 2014a, 2023f).

A multi-residue method based on GC-MS has been validated for the determination of the individual cypermethrin diastereoisomers; *cis*-I, *cis*-II, *trans*-III, and *trans*-IV. The sum of all isomers corresponds to the total amount of cypermethrin residues. The reported LOQs for the sum of isomers are 0.01 mg/kg in high water, high acid, high-oil content, and dry matrices and 0.1 mg/kg in complex matrices, respectively (EFSA, 2018c, 2023f).

Another multi-residue method utilising GC-ECD (DFG S23) has been validated for the determination of the individual and the sum of cypermethrin residues with an LOQ of 0.05 mg/kg in high oil content matrices and an LOQ of 0.025 mg/kg in dry matrices (EFSA, 2011a).

Overall, multi-residue methods of analysis are available for the monitoring the sum of cypermethrin isomers in high water, high acid, high oil content, dry and complex matrices of plant origin as well as honey and other apiculture products. LOQs range from 0.01 to 0.1 mg/kg.

3.3.2 Authorisation status and use

- Is cypermethrin authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has cypermethrin ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

⁴¹ Cypermethrin is a mixture of four diastereomeric pairs of enantiomers.

a) Authorisations for plant protection use in conventional agriculture

Cypermethrin has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of approval of the active substance is on 31 January 2029, as indicated by the EU Pesticides Database⁵ (accessed 9 January 2024).

According to the Pesticides database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Estonia, Greece, Spain, Finland, France, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Poland, Portugal, Romania, Sweden, Slovenia, and Slovakia.

Based on information from the EU Pesticides database⁵, only the mixture of constituent isomers has been approved and authorised for use in the EU. The alpha-, beta-, and zeta- isomers of cypermethrin have not been approved for use in the EU and, therefore, are not considered.

b) Authorisations for purposes other than plant protection

Biocidal use:

Cypermethrin has been approved for biocidal use in the EU Member States, Iceland, Liechtenstein and Norway in accordance with Regulation (EU) No 528/2012⁷, since 1 June 2015. The expiry date of approval of the active substance is 30 November 2027 for use as a wood preservative, and 31 May 2030 for use as a broad-spectrum insecticide against crawling and flying insects. The application for the renewal of the approval of cypermethrin as a wood preservative is under assessment (see ECHA website⁶ accessed 12 May 2025).

According to the ECHA website⁶, at national level, cypermethrin has been authorised for use as a wood preservative in Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden and as an insecticide, acaricide and a product to control other arthropods in Belgium, Bulgaria, Croatia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Slovakia, Slovenia, Spain.

Other uses

According to the search carried out on the ECHA website⁹ on 6 June 2024, cypermethrin is not currently registered under REACH.

According to the EU Veterinary Medicines Database^{24, 24}, cypermethrin is authorised as a veterinary medicine for cats, dogs, horses, cattle, goats, sheep and Atlantic salmon.

- What is/was the actual use of cypermethrin? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of cypermethrin

Cypermethrin is an insecticide widely used in northern and southern Europe to control a broad spectrum of insects (EFSA, 2018c).

Cypermethrin affects primarily the nervous system mainly through prolonged opening of sodium channels in nerve cells, leading to hyper-excitation of the central nervous system. This causes an overstimulation of the nerves, resulting in neurotoxicity and motor deficits. Beyond its impact on sodium channels, cypermethrin also affects other ion channels, including chloride, voltage-gated calcium, and potassium channels. Additionally, it influences neurotransmitter systems by altering the activity of glutamate and acetylcholine receptors, and ATPases, which can lead to oxidative stress, DNA damage, and changes in neurotransmitter levels like gamma-aminobutyric acid (GABA) and dopamine (Singh et al., 2012).

Conditions of use and applicable crops

The uses reported in the EFSA MRL review for cypermethrin include applications from the northern and southern EU in food and feed commodities belonging to the following crop groups: pome fruits, stone fruits, berries and small fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds and oil fruits, cereals, herbal infusions from leaves and herbs, hops (dried), sugar plants, beans and peas for forage, fodder beets, alfalfa forage, trefoil and vetch forage and cereal forage (EFSA, 2023f).

Note was taken that uses in stone fruits, herbal infusions from leaves, herbs, and hops (dried) were not supported by data (see Section 3.3.3.2 'Active use (all legitimate uses of the substance)').

Cypermethrin treatment included outdoor and indoor foliar applications and outdoor soil treatments and indoor post-harvest treatments:

- Foliar applications were reported for food and feed commodities belonging to the following crop groups: pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds and oil fruits, cereals, herbal infusions from leaves and herbs, hops (dried), sugar plants, fodder beets, beans and peas for forage, alfalfa forage, trefoil and vetch forage and cereal forage (EFSA, 2023f). Application rates range from 7 g a.s./ha to 100 g a.s./ha for food and feed commodities (EFSA, 2023f).
- Soil treatments of cypermethrin were reported for root and tuber vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), oilseeds and cereals (also for forage). Application rates range from 96 g a.s./ha to 192 g a.s./ha (EFSA, 2023f).
- Post-harvest treatment was reported only for indoor cereal grains. Application rates range up to 1.68 g a.s./ton (EFSA, 2023f).

b) Uses for purposes other than plant protection

Biocidal use

Biocidal products containing cypermethrin are used as insecticides indoors and/or outdoors for preventive and remedial treatments of wood and for pest control around buildings (ECHA, 2017).

They can be applied by professional (all products) and non-professional users (wood preservative uses only by brush painting or spraying). Product application rates range for wood and timber applications from 150 g a.s./m³ to 1000 g a.s./m³ and for pest control applications from 25 mg a.s./m² to 50 mg a.s./m² (ECHA, 2017) (see also 'authorisations for purposes other than plant protection/biocidal use').

Other use

According to the ECHA website⁹, cypermethrin is not registered under REACH (see 'authorisations for purposes other than plant protection/other uses').

Cypermethrin is a veterinary medicine²³ used in cats, dogs, horses, cattle, goat, sheep and Atlantic salmon (see previous section).

3.3.3 Sources of residues in plants

3.3.3.1 Natural occurrence

- Is there evidence that cypermethrin occurs naturally? What is known about the natural origin of this substance?

Cypermethrin is a synthetic chemical, produced industrially through chemical processes (Lewis et al., 2016). No information on the potential natural presence of cypermethrin was found in the literature²².

3.3.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of the cypermethrin would be consistent with active use of the substance?

Results from analysis of residues of cypermethrin in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.3.3.2-1 to 3.3.3.2-4. Findings relating to residues in control (untreated) samples are also discussed in this section.

In all matrices and for both residue trials and results from monitoring, cypermethrin residue concentrations refer to the residue definition for enforcement (i.e. cypermethrin (sum of isomers)).

Occurrence of cypermethrin from residue trials carried out for the critical GAP per crop

Following product applications based on the critical GAPs⁴ reported to EFSA, residue levels of cypermethrin were below the LOQ in pulses (dried) (EFSA, 2023f).

Residues of cypermethrin were quantified in pome fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, oilseeds and oil fruits, cereals and sugar plants (EFSA, 2023f). No residue trials are available for stone fruits and herbal infusions from leaves and herbs (EFSA, 2023f).

Regarding feed commodities, residues of cypermethrin were below the LOQ in cereal (maize) forage (EFSA, 2023f). Residues were quantified in cereal straw, fodder beet roots, sugar beet,

Findings of not authorised substances in organic products

fodder beet and turnip tops, fodder bean and pea vines, alfalfa forage, trefoil and vetch forage (EFSA, 2023f).

The results from residue trials carried out for the critical GAP per crop for cypermethrin in commodities for which uses were submitted to EFSA are summarised in Table 3.3.3.2-1 'Occurrence of cypermethrin from residue trials carried out for the critical GAP per crop'.

Table 3.3.3.2-1: Occurrence of cypermethrin from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Cypermethrin (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
Food				
0130000	Pome fruits	1	<LOQ (0.01)–0.08	0.02
0140000	Stone fruits ^{d)}	2	NR	-
0150000	Berries and small fruits	0.05*–0.5	<LOQ (0.01)–0.27	0.03
0160000	Miscellaneous fruits	0.05*–2	0.09–0.21	0.11
0210000	Root and tuber vegetables	0.05*	<LOQ (0.01)–0.07 ^{c)}	0.01
0220000	Bulb vegetables	0.05*–0.1	<LOQ (0.01)–0.06	0.01
0230000	Fruiting vegetables	0.05*–0.5	<LOQ (0.01)–0.04	0.01
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.5–1	<LOQ (0.01)–0.19	0.01
0250000	Leaf vegetables, herbs and edible flowers	0.05*–2	0.03–2.1 ^{c)}	0.63
0260000	Legume vegetables	0.7	<LOQ (0.01)–0.11	0.02
0270000	Stem vegetables	0.05*–2	<LOQ (0.01)–0.29	0.06
0300000	Pulses (dried)	0.05*	<LOQ (0.02)	<LOQ (0.02)
0400000	Oilseeds and oil fruits	0.05*–0.2	<LOQ (0.01)–0.21 ^{c)}	0.02
0500000	Cereals	0.3–2	<LOQ (0.01)–2.38 ^{c)}	0.065
0632000	Herbal infusions from leaves and herbs ^{d)}	0.01*	NR	-
0700000	Hops (dried) ^{d)}	30	NR	-
0900000	Sugar plants	0.05*–1	<LOQ (0.01)–0.02	0.01
Feed				
1200000	Cereal straw	NA	<LOQ (0.1)–1.65	0.63
	Fodder beet roots	NA	<LOQ (0.01)–0.02	0.01
	Sugar beet tops	NA	0.01–0.32	0.23
	Fodder beet tops	NA	0.16–0.99	0.32
	Turnip tops	NA	0.16–0.99	0.32
	Fodder bean and pea vines	NA	1–2.53	1.49
	Alfalfa forage	NA	0.75–3	1.6
	Trefoil & vetch forage	NA	1.4–4.9	1.8
	Cereal forage	NA	<LOQ (0.01)	<LOQ (0.01)

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; NR- no residue trials are available; '-': not estimated due to lack of data.

a) Maximum Residue Level in Reg. (EU) No 2017/626 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA, 2023f; c) Residues quantified above the MRLs come from the EFSA MRL review for cypermethrin (EFSA, 2023f) that has not been considered by risk managers yet; d) For uses not supported by data, the MRLs were lowered to the LOQ except for stone fruits and hops (dried) where higher MRLs of 2 and 30 mg/kg, respectively were set (Codex MRL).

Occurrence of cypermethrin under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to cypermethrin are given by Regulation (EU) 2017/626⁴² for the years 2020–2022.

Regarding commodities not labelled as organic, 114,437 samples were collected and analysed for cypermethrin in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 105,548 (92.23%) were unprocessed and 8,889 (7.77%) processed commodities. No residues were quantified in 113,313 samples out of the 114,437 samples (99.02%). In 1067 samples out of the 114,437 samples (0.93%) cypermethrin was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-3.1. MRLs were exceeded in 57 samples out of the 114,437 samples (0.05%). The highest concentrations for samples exceeding the MRLs were 23.1 mg/kg in oilseeds and oil fruits (oilseeds – soyabeans). 14.901 mg/kg in leaf vegetables, herbs and edible flowers (spinaches and similar leaves – spinaches).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of cypermethrin are summarised in Table 3.3.3.2-2a for unprocessed and in Table 3.3.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on cypermethrin in feed not labelled as organic were submitted to EFSA.

Table 3.3.3.2-2a: Occurrence of cypermethrin monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Cypermethrin (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0130000	Pome fruits	1	0.002	0.002–0.75	40	0.042
0140000	Stone fruits	2	0.002	0.01–6.1	111	0.043
0150000	Berries and small fruits	0.05*–0.5	0.001	0.006–8.7	90	0.04
0160000	Miscellaneous fruits	0.05*–2	0.001	0.002–0.26	18	0.01
0210000	Root and tuber vegetables	0.05*	0.002	0.009–1.3	26	0.023
0220000	Bulb vegetables	0.05*–0.1	0.002	0.013–0.49	8	0.047
0230000	Fruiting vegetables	0.05*–0.5	0.002	0.007–0.48	52	0.01
0240000	Brassica vegetables (excluding brassica roots	0.5–1	0.002	0.003–0.9	85	0.025

⁴² Commission Regulation (EU) 2017/626 of 31 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products. OJ L 96, 7.4.2017, p. 1–43.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Cypermethrin (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
	and brassica baby leaf crops)					
0250000	Leaf vegetables, herbs and edible flowers	0.05*-2	0.002	0.007-14.901	177	0.067
0260000	Legume vegetables	0.7	0.002	0.019-0.86	9	0.038
0270000	Stem vegetables	0.05*-2	0.002	0.004-3.9	39	0.028
0300000	Pulses (dried)	0.05*	0.003	0.012-0.033	2	0.023
0400000	Oilseeds and oil fruits	0.05*-0.2	0.001	0.016-0.08	5	0.044
0500000	Cereals	0.3-2	0.001	0.006-3.1	172	0.033
0632000	Herbal infusions from leaves and herbs	0.01*	0.005	0.01-0.24	6	0.04
0700000	Hops (dried)	30	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.05*-1	0.005	<LOQ	0	<LOQ
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
	Fodder beet roots	NA	ND	ND	ND	ND
	Sugar beet tops	NA	ND	ND	ND	ND
	Fodder beet tops	NA	ND	ND	ND	ND
	Turnip tops	NA	ND	ND	ND	ND
	Fodder bean and pea vines	NA	ND	ND	ND	ND
	Alfalfa forage	NA	ND	ND	ND	ND
	Trefoil & vetch forage	NA	ND	ND	ND	ND
	Cereal forage	NA	ND	ND	ND	ND
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of cypermethrin is not expected)						
Food						
0110000	Citrus fruits	2	0.002	0.01-0.34	71	0.03
0120000	Tree nuts	0.05*	0.005	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.05*-1	0.002	0.008-0.5	14	0.025
0290000	Algae and prokaryotes organisms	0.05*	0.01	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*-0.5	0.005	0.01-4.94	20	0.046
0800000	Spices (dried)	0.1*-3	0.01	0.02-0.51	3	0.36
1040000	Honey and other apiculture products	0.05*	0.001	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2017/626 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.3.3.2-2b: Occurrence of cypermethrin from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Cypermethrin (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0130000	Pome fruits	1	0.002	<LOQ	0	<LOQ
0140000	Stone fruits	2	0.001	0.016–0.063	4	0.033
0150000	Berries and small fruits	0.05*–0.5	0.001	0.009–0.42	34	0.04
0160000	Miscellaneous fruits	0.05*–2	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.05*	0.002	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.05*–0.1	0.01	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.05*–0.5	0.002	0.014–0.27	7	0.056
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.5–1	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.05*–2	0.005	0.01–1.1	16	0.094
0260000	Legume vegetables	0.7	0.001	<LOQ	0	<LOQ
0270000	Stem vegetables	0.05*–2	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.05*	0.008	0.03	1	0.03
0400000	Oilseeds and oil fruits	0.05*–0.2	0.002	0.011–0.16	17	0.043
0500000	Cereals	0.3–2	0.0001	0.008–1.8	100	0.046
0632000	Herbal infusions from leaves and herbs	0.01*	ND	ND	ND	ND
0700000	Hops (dried)	30	0.05	<LOQ	0	<LOQ
0900000	Sugar plants	0.05*–1	0.008	<LOQ	0	<LOQ
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
	Fodder beet roots	NA	ND	ND	ND	ND
	Sugar beet tops	NA	ND	ND	ND	ND
	Fodder beet tops	NA	ND	ND	ND	ND
	Turnip tops	NA	ND	ND	ND	ND
	Fodder bean and pea vines	NA	ND	ND	ND	ND
	Alfalfa forage	NA	ND	ND	ND	ND
	Trefoil & vetch forage	NA	ND	ND	ND	ND
	Cereal forage	NA	ND	ND	ND	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of cypermethrin is not expected)						
Food						
0110000	Citrus fruits	2	0.002	<LOQ	0	<LOQ
0120000	Tree nuts	0.05*	0.01	<LOQ	0	<LOQ
0140000	Stone fruits	2	0.001	0.016–0.063	4	0.033
0280000	Fungi, mosses and lichens	0.05*–1	0.005	0.108–0.15	3	0.13
0290000	Algae and prokaryotes organisms	0.05*	ND	ND	ND	ND
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*–0.5	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.1*–3	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.001	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2017/626 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of cypermethrin in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 10,185 samples were collected and analysed for cypermethrin from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 8,522 (83.67%) were unprocessed and 1,663 (16.33%) processed commodities. No residues were quantified in 10,176 samples out of the 10,185 samples (99.91%). In nine out of the 10,185 samples (0.09%) cypermethrin was found at or above the analytical LOQ but below or at the MRL. No MRLs exceeded in samples from organic production. These findings are summarised in Appendix B, Table B-3.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.3.3.2-3a for unprocessed and in Table 3.3.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on cypermethrin in feed labelled as organic were submitted to EFSA.

Table 3.3.3.2-3a: Occurrence of cypermethrin from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Cypermethrin (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	2	0.002	<LOQ	0	<LOQ
0120000	Tree nuts	0.05*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	1	0.002	<LOQ	0	<LOQ
0140000	Stone fruits	2	0.002	0.039–0.062	2	0.051
0150000	Berries and small fruits	0.05*–0.5	0.002	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.05*–2	0.002	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.05*	0.002	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.05*–0.1	0.002	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.05*–0.5	0.002	0.041	1	0.041
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.5–1	0.002	0.13	1	0.13
0250000	Leaf vegetables, herbs and edible flowers	0.05*–2	0.002	<LOQ	0	<LOQ
0260000	Legume vegetables	0.7	0.002	<LOQ	0	<LOQ
0270000	Stem vegetables	0.05*–2	0.002	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.05*–1	0.002	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.05*	0.01	<LOQ	0	<LOQ

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Cypermethrin (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0300000	Pulses (dried)	0.05*	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.05*-0.2	0.001	<LOQ	0	<LOQ
0500000	Cereals	0.3-2	0.001	0.01-0.013	3	0.01
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*-0.5	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	30	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.1*-3	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.05*-1	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.005	<LOQ	0	<LOQ

*Limit of quantification in Reg. (EC) No 396/2005.

a) Maximum Residue Level in Reg. (EU) No 17/626 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.3.3.2-3b: Occurrence of cypermethrin from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Cypermethrin (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	2	0.002	<LOQ	0	<LOQ
0120000	Tree nuts	0.05*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	1	0.002	<LOQ	0	<LOQ
0140000	Stone fruits	2	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.05*-0.5	0.001	0.012-0.015	2	0.014
0160000	Miscellaneous fruits	0.05*-2	0.002	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.05*	0.01	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.05*-0.1	ND	ND	ND	ND
0230000	Fruiting vegetables	0.05*-0.5	0.003	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.5-1	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.05*-2	0.01	<LOQ	0	<LOQ
0260000	Legume vegetables	0.7	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.05*-2	0.01	<LOQ	0	<LOQ

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Cypermethrin (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0280000	Fungi, mosses and lichens	0.05*-1	0.01	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.05*	ND	ND	ND	ND
0300000	Pulses (dried)	0.05*	0.01	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.05*-0.2	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.3-2	0.0001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*-0.5	0.001	<LOQ	0	<LOQ
0700000	Hops (dried)	30	ND	ND	ND	ND
0800000	Spices (dried)	0.1*-3	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.05*-1	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.001	<LOQ	0	<LOQ

*Limit of quantification in Reg. (EC) No 396/2005; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2017/626 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of cypermethrin in the EU Organic Farming Information System

The EU OFIS reported 51 findings for cypermethrin in 2021 and 2022 and one finding of alpha-cypermethrin; 12 of the products sampled and analysed had EU origin and 39 were of non-EU origin. One sample from non-EU origin was quantified for alpha-cypermethrin. Residues were found in one sample of citrus fruits (limes), two samples of stone fruits (plums), eight samples of berries and small fruits (table grapes, strawberries and blueberries), six samples of miscellaneous fruits (avocados, bananas and pomegranates), three samples of leaf vegetables, herbs and edible flowers (thyme – oregano), one sample of legume vegetables (lentils), 13 samples of oilseeds and oil fruits (linseeds, peanuts, sesame seeds, sunflower seeds, rapeseeds, mustard seeds, olives for oil production and oil palms kernels), eight sample of cereals (buckwheat and other pseudocereals – quinoa and wheat), six samples of teas, coffee, herbal infusions, cocoa and carobs (herbal infusions, teas, coffee beans, mate, anise and cinnamon), two samples of spices (aniseed and cinnamon) and one sample of processed apiculture products (beeswax). The only sample analysed for alpha-cypermethrin was teas, coffee, herbal infusions, cocoa and carobs (tea – black). The concentrations of cypermethrin residues were above LOQ but below MRL in 47 samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005³. MRLs were exceeded in four samples. The highest concentration was reported for a sample of mate from non-EU origin, with the quantified level of 0.46 mg/kg. These findings are summarised in Table 3.3.3.2-4.

Table 3.3.3.2-4: Occurrence of cypermethrin from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
Cypermethrin including other mixtures of constituent isomers (sum of isomers)				
0163010	Avocados	0.05*	0.018 – Avocado	ND
0163050	Pomegranates	0.05*	0.124 – Pomegranate	ND
0401050	Sunflower seeds	0.2	0.01; 0.079 – Sunflower seeds	ND
0401060	Rapeseeds/canola seeds	0.2	0.039 – Rapeseeds	ND
0401080	Mustard seeds	0.1	0.011 – Mustard seeds	ND
0500090	Wheat	2	0.14; 0.13 – Wheat	ND
0630000	Herbal infusions	0.1*	ND	0.01; 0.037 – Herbal infusion
0830010	Cinnamon	0.1*	0.007 – Cinnamon	ND
1040000	Honey and other apiculture products	0.05*	ND	0.066 – Beeswax
Samples of non-EU origin				
Alpha-cypermethrin				
0610000	Teas	0.5	ND	0.036 – Tea (black)
Cypermethrin including other mixtures of constituent isomers (sum of isomers)				
0110040	Limes	2	0.052 – Limes	ND
0140040	Plums	2	0.059 – Cherry	0.015 – Plums (dehydrated)
0151010	Table grapes	0.5	0.029; 0.025; 0.00614; 0.039 – Raisins/sultanas	0.01 – Raisins paste
0152000	Strawberries	0.07	0.015; 0.021 – Strawberries	ND
0154010	Blueberries	0.05*	0.019 – Barberries	ND
0163010	Avocados	0.05*	0.031 – Avocado (Hass) 0.017; 0.019 – Avocado	ND
0163020	Bananas	0.05*	0.02 – Bananas	ND
0256070	Thyme	2	ND	0.011; 0.011; 0.016 – Oregano
0260050	Lentils	0.7	0.026 – Lentils (red split)	ND
0401010	Linseeds	0.2	0.019 – Linseed	ND
0401020	Peanuts/groundnuts	0.1	0.023 – Peanut kernels	ND
0401040	Sesame seeds	0.2	0.008; 0.011; 0.006 – Sesame seeds	ND
0402010	Olives for oil production	0.05*	ND	0.018; 0.025 – Olive oil (extra virgin)
0402020	Oil palms kernels	0.05*	ND	0.018 – Argan oil (roasted) 0.026 – Argan oil
0500020	Buckwheat and other pseudocereals	0.3	0.014 – Quinoa (black) 0.027 – Quinoa (white) 0.02; 0.014; 0.016; 0.025 – Quinoa	ND
0610000	Teas	0.5	ND	0.033 – Tea (black)
0620000	Coffee beans	0.1*	0.053 – Coffee beans	ND
0632030	Mate/maté	0.1*	ND	0.096 – Moringa (powder) 0.46 – Mate
0810010	Anise/aniseed	0.1*	0.005 – Anis	ND

*Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2017/626 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of cypermethrin in untreated samples (control samples) from residue trials

One quantified finding was observed for cypermethrin in a control sample analysed in the context of a residue trial on winter wheat from the UK. The reported residue concentration was 0.06 mg/kg (Austria, 2021a). Quantified residues were also detected in control (untreated) samples from supervised residue trials on wheat grain in Belgium. Concentrations in the bran were 0.034 mg/kg between 1–7 days, and in the flour, concentrations were 0.034 mg/kg at 1 day and 0.032

mg/kg at 7 days (Belgium, 2022). These findings might relate to possible cross-contamination from the mill apparatus (Belgium, 2022).

However, no evidence-based explanations on the causes for these occurrences in control (untreated) samples were provided in the above-mentioned evaluation reports.

- Could the presence of cypermethrin and/or its residues be due to biocide use?

Cypermethrin is applied in biocidal products that function as insecticide to preserve wood and control pests. Mitigation measures are proposed to prevent environmental exposure to cypermethrin (ECHA, 2017). The summary of product characteristics of authorised biocidal products includes risk mitigation measures to restrict the storage of industrial treated timber wood to hard standing, to not treat wooden structures close to the water ecosystem or to use the substance only in areas that are not expected to be submersed or become wet.

Biocidal products containing cypermethrin are formulated at concentrations of 0.2–10% (w/w)⁴³. PEC values have been calculated to predict the potential contamination of water and soil for different scenarios (e.g. outdoor use in rural or urban areas). The highest estimated PEC_w was 2.71 µg/L and the highest PEC_{soil} was 0.008 mg/kg. These PECs are covered by those estimated for agricultural uses of the substance (see Section 3.3.3.6).

Based on the above, it can be concluded that the release of residues of cypermethrin in the water and/or soil after biocidal use cannot be excluded.

3.3.3.3 Behaviour in food and feed products

- What key physico-chemical properties of cypermethrin are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of cypermethrin are reported in Table 3.3.3.3.

Cypermethrin is considered a fat-soluble substance and it exhibits low to moderate persistence in soil (see Section 3.3.3.5). Regarding sorption to soil, the high value of $K_{F,oc}$ in Table 3.3.3.3 indicates that the substance is immobile in soil (EFSA, 2018c).

The maximum calculated PEC_w for cypermethrin for the representative uses was 0.23 µg/L (spray application to potatoes; 1 × 50 g a.s./ha) (EFSA, 2018c).

Cypermethrin is stable under pasteurisation (20 min at 90°C, pH 4), boiling, brewing and baking (60 min at 100°C, pH 5). Under sterilisation conditions (20 min at 120°C, pH 6), significant degradation and formation of (1R/S,3R/S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-1-carboxylic acid (DCVA) and 3-phenoxybenzaldehyde occurs (EFSA, 2023f). Therefore, the concentration of residues of cypermethrin cannot be excluded under conditions of pasteurisation, boiling, brewing and baking. Considering that cypermethrin may degrade under some food/feed processing conditions, a potential formation of degradation products would not be captured by the analytical methods because these products are not included in the residue definition for monitoring and, therefore, are not analysed. This would be expected to result in a decrease in

⁴³ <https://echa.europa.eu/information-on-chemicals/biocidal-active-substances/-/disas/substance/100.052.567>

the measured residues in the processed commodity when compared with the raw commodity. On the other hand, some processes such as drying may result in higher concentrations of residues in the processed commodities. Therefore, both possibilities (decrease or increase of cypermethrin residues) are plausible in this case, depending on the process.

Cypermethrin has a low vapour pressure ($<10^{-5}$ Pa at 20°C) EFSA, 2018c).

Table 3.3.3.3: Physico-chemical properties of cypermethrin (EFSA, 2018c)

Structural formula	<i>cis</i>-isomers <i>trans</i>-isomers
Chemical name IUPAC	Cypermethrin is a mix of the eight possible isomers above represented: (RS)-alpha-cyano-3-phenoxybenzyl-(1RS,3RS,1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate.
Appearance (state purity)	Pale yellow viscous liquid (room temperature) (97.9%, <i>cis/trans</i> : 43.0/54.9) Yellow viscous transparent liquid (20°C) (95.97%, <i>cis/trans</i> : 43.2/56.8)
Melting point (state purity)	Onset 41.2°C, peak 47.3°C (98.3%, <i>cis/trans</i> : 37.6/62.4)
Boiling point	Not applicable (decomposition)
Temperature of decomposition	Decomposition between 220 and 370°C (98.6%, <i>cis/trans</i> : 41.7/56.9)
Vapour pressure (state temperature, state purity)	6.78×10^{-6} Pa at 20°C (98.6%, <i>cis/trans</i> : 41.7/56.9)
Henry's law constant (state temperature)	≥ 0.31 Pa m ³ mol ⁻¹ (at 20°C)
Solubility in water (state temperature, state purity and pH)	< 9 µg/L at 20°C (pH=6 and pH=4) (98.3%, <i>cis/trans</i> : 37.6/62.4) ≤ 10.6 µg/L at 20°C (pH=8.6) (98.6%, <i>cis/trans</i> : 41.7/56.9)
Partition coefficient (state temperature, pH and purity)	Log <i>P</i> _{ow} range of discrete isomer pairs: 5.55 to 5.83 at 25°C (No influence of pH)
Partition coefficient (octanol/air)	Log <i>P</i> _{oa} = 11.7 (EPISuite KOAWIN v1.10) (Debler et al., 2024)
Atmospheric half-life	DT ₅₀ of 5.99 hours derived by the Atkinson model (AOPWIN version 4.11). OH (12 h) radical concentration assumed = 1.5×10^6 OH/cm ³
Dissociation constant (state purity)	No dissociation in the environmental pH range
Soil adsorption (geometric mean)	<i>K</i> _{Foc} = 194,425 mL/g
Hydrolytic degradation (>10%)	pH 4: At 25°C: Cypermethrin stable for 29 days At 50°C: Cypermethrin stable for 5 days pH 7: At 25°C: Cypermethrin stable for 29 days At 50°C: 4.73 d (1st order) DT₅₀ = 3.5 d and DT₉₀ = 11.5 d for total cypermethrin DT₅₀ = 2.6–5.5 d (1st order, χ^2 = 4.4–17.3 %) for the eight isomers, arithmetic mean 3.7 ± 1.0 d pH 9: At 50°C: 1.9 h (1st order), not tested at other temperatures since half-life is <2.4 h at 50°C At 20°C:

	DT ₅₀ = 3.8 and DT ₉₀ = 12.7 d for total cypermethrin DT ₅₀ = 3.0–6.0 d (1st order, χ^2 = 6.6–8.3 %) for the eight isomers, arithmetic mean 4.3 ± 1.4 d

DT₅₀ – Disappearance time of 50% of the substance in field studies; DT₉₀ – Disappearance time of 90% of the substance in field studies;
pH – Potential of Hydrogen; P_{ow} – Octanol/water Partition Coefficient; P_{oa} – Octanol/air Partition Coefficient

3.3.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from the soil surface at which it is applied).

The highest drift of cypermethrin to neighbouring fields may occur during its applications to fruit crops (up to 29.2%), hops (19.33%), vineyards and vegetables (up to 8.02%) and field crops (up to 2.77%). Drift values should be considered the rate received by neighbouring fields, expressed as a percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. buffer zones or spray drift-reducing nozzles).

If organic crops are present adjacent to the conventional crops treated, measurable residues of cypermethrin in the untreated crop cannot be excluded. However, since the nature of the potential adjacent crops and their possible growth stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

The use of cypermethrin in granular form has been identified (EFSA, 2023f), which necessitates consideration of potential dust drift. Although these granules are relatively large and will not contribute to drift themselves, small dust particles that are small enough to be taken downwind by the wind may break off. Deposition percentile values were considered for neighbouring fields, distinguishing between seed treatments (up to 17%) and granule applications (9.6%) for different crops and techniques (EFSA, 2013a). According to Adriaanse et al. (2022), the use of techniques (deflectors), size of the dust particles and average wind speed were the most important factors determining the amount of dust drift.

3.3.3.5 Accumulated/historical residue levels in soil

- What is the persistence of cypermethrin and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

According to available data (EFSA, 2018c), DT₉₀ of cypermethrin in soil has a worst-case field value of 104 days, indicating that cypermethrin is not expected to accumulate in soil over successive seasons.

This is supported by one confined rotational crop study applying cypermethrin to soil where wheat, sugar beet, lettuce and cotton were planted at an overdose rate of 1 kg a.s./ha (20 N).

The study showed no residues of cypermethrin are expected in crops grown in rotation if the substance is applied according to the respective GAPs⁴ (EFSA, 2018c, 2023f).

Based on the above, uptake of residues of cypermethrin from plants planted or sown in soil previously treated with cypermethrin is considered unlikely. This is also valid for organic crops, when planted in fields that previously used cypermethrin for conventional agriculture, considering that it requires at least 2 years after the last chemical treatment in order for organic crops to be planted in such areas.²

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Cypermethrin is not expected to accumulate in soil.

3.3.3.6 Residues from water used for irrigation

- Is there evidence that residues of cypermethrin present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for cypermethrin in water samples were considered:

- The EEA-WATERQUALITY³⁹ database (data retrieved on 10 April 2024) reports 364 analytical results from water samples collected in Austria (1 sample), Belgium (1 sample), Bulgaria (7 samples), Croatia (2 samples), Estonia (3 samples), France (46 samples), Germany (35 samples), Ireland (134 samples), Italy (127 samples) and the Netherlands (8 samples) between 2018 and 2020;
- The EMPODAT database (data retrieved on 21 March 2024) reports 81 analytical results from surface water samples collected in Bulgaria (1 sample), Germany (1 sample), Hungary (1 sample) and the Netherlands (78 samples) between 2018 and 2020;
- The NAIADES database (data retrieved on 2 April 2024) reports 60,950 analytical results from surface water samples collected in France from 2020 to 2022.

Among the 61,395 analytical results for cypermethrin, 954 were disregarded as found to report quantitative values below the analytical LOQ. Therefore, the number of water samples considered is 60,441.

Based on the screening process described in section 'Data and methodologies', for 99.9% of water samples analysed and reported in EEA-WATERQUALITY, EMPODAT and NAIADES (60,362 samples), the residue concentrations were below the screening Cw of 0.09 µg/L.

For 0.1% of samples (79 out of 60,441 samples), the residue concentrations were found to be at or above the screening Cw of 0.09 µg/L and the potential transfer of residues to plant commodities if water containing residues at these levels is used for irrigation cannot be excluded.

Overall, considering that for 99.9% of water samples analysed and reported in EEA-WATERQUALITY, EMPODAT and NAIADES (60,441 samples), the residue concentrations were below the screening Cw of 0.09 µg/L, it can be concluded that transfer of cypermethrin residues from water to plant commodities when this water is used to irrigate the plant is unlikely.

3.3.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *cypermethrin*, *industry/industrial*, and *air/atmosphere*) did not identify any relevant European study.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water. Based on conservative estimations of the possible transfer of residues from water used for irrigation to plant commodities, the transfer of residues of cypermethrin from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

Literature review was carried out to gather relevant information. A search in the Scopus database (conducted on March 4, 2025, using the keywords *cypermethrin*, *industry/industrial*, and *water*) did not identify any relevant European study.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Based on information on the possible plant uptake of cypermethrin from EU soil, the transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 17, 2025, using the keywords *cypermethrin*, *industry/industrial*, and *soil/sediment*) did not identify any relevant European study.

3.3.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Uptake from organic fertilisers

In a study investigating pesticide residues in organic fertilisers, residues of cypermethrin and other pesticides were quantified (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). The authors attributed the origin of the residues to the use of plant protection products in the composted crop or to their presence in composted manure due to transfer from animal feed after digestion, their presence in straw used in stables or due to potential veterinary medicinal use²³. Analysis of solid organic fertilisers gave an average concentration of 0.162 mg/kg for cypermethrin in two out of 147 samples. Considering that (according to the authors) the use of completely free from residues organic fertilisers is currently unsustainable, transfer of cypermethrin residues from fertilisers used in organic production to organic products cannot be excluded. On the other hand, no residues of cypermethrin were found in any of the products of the crops discussed in the study (van der Blom et al., 2022, under 'Documentation as provided

to EFSA'). As assessed above (see Section 3.3.3.5), available information from rotational crop studies indicates that the uptake of cypermethrin from soil by the plants is very limited. It may be expected that the same would hold true for the uptake of the cypermethrin residues from compost added to soil.

Medium and long-range aerial transport of residues

In a study by Silva et al. (2023) carried out under the EU SPRINT project, the authors investigated the presence of cypermethrin in 20 outdoor air samples collected during the 2021 growing season across 10 study sites in Europe of organic and conventional agriculture (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). The study was carried out under the framework of the EU SPRINT project. Organic fields had not been treated for 5 consecutive years. Cypermethrin was quantified in one out of 20 targeted samples (5%) at a concentration of 23.9 ng m⁻³ in Portugal. This sample was coming from the area surrounding an organic field.

In another study carried out by Debler et al. (2024) under the framework of the EU SPRINT project, cypermethrin was quantified in air samples collected between April 2021 and June 2022 from one agricultural area of conventional farming in Portugal (vineyard). Information on the applied pesticides suggests that cypermethrin had not been applied to these crops. Still, cypermethrin was quantified in the surrounding area at aerial concentrations ranging from 15 to 18 pg/m³ for both total and particle-phase concentrations.

Based on the above, it can be concluded that the medium-range aerial transport of residues of cypermethrin cannot be excluded.

Use as veterinary medicine

According to the EU Veterinary Medicines Database^{24, 24}, cypermethrin is authorised as veterinary medicine for cats, dogs, horses, cattle, goat, sheep and Atlantic salmon. When cypermethrin is used in veterinary medicine, residues of cypermethrin are released into the environment. Conservative estimates of the possible transfer of residues of cypermethrin from water used for irrigation to plant commodities and information on the possible plant uptake of residues of cypermethrin from the EU soil suggest that the transfer of residues of cypermethrin from veterinary use is less likely.

3.3.4 Conclusions on cypermethrin

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use. Some of the residues quantified in the residue trials are higher than the current MRLs for the respective commodities. This is because these trials were evaluated in the more recent MRL review that has not been considered yet by the risk managers (see Section 3.3.3.2).
- Residue trials carried out to support the critical GAPs⁴ for cypermethrin, gave residue concentrations of up to 2.38 mg/kg in cereals and up to 4.9 mg/kg in trefoil and vetch forage. Concentrations in the ranges reported in Table 3.3.3.2-1 might be associated with active use of cypermethrin according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.

- Cypermethrin was quantified in the context of residue trials in several European countries in untreated (control) samples with the highest concentrations observed for one sample of winter wheat from the UK.
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for cypermethrin in unprocessed commodities with authorised uses ranged from 0.01 mg/kg in miscellaneous fruits and fruiting vegetables to 0.067 mg/kg in leaf vegetables, herbs and edible flowers.
- In unprocessed products labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 there were no commodity groups with five or more quantified findings.
- In organic processed commodities, residues of cypermethrin were not quantified in most commodities. In samples from processed products not labelled as organic with five or more quantified findings, the median concentrations of residues of cypermethrin ranged from 0.04 mg/kg in berries and small fruits to 0.094 mg/kg in leaf vegetables, herbs and edible flowers. Considering that cypermethrin may degrade under some food/feed processing conditions, a potential formation of degradation products would not be captured by the analytical methods because these products are not included in the residue definition for monitoring and, therefore, are not analysed. This would be expected to result in a decrease in the measured residues in the processed commodity when compared with the raw commodity. On the other hand, some processes such as drying may result in higher concentrations of residues in the processed commodities. Therefore, both possibilities (decrease or increase of cypermethrin residues) are plausible in this case, depending on the process.
- Overall, in commodities labelled as organic, cypermethrin was quantified in 0.09% of samples (9 out of 10,185 samples). This percentage is 11 times lower than the percentage reflecting the number of findings in samples not labelled as organic (0.98%) (see Appendix B, Tables B-3.1 and B-3.2). These results suggest that the occurrence of residues of cypermethrin in organic products is less likely when compared with the conventional commodities.
- Potential sources of the unintentional presence of residues of cypermethrin in commodities of plant origin are drift from crops grown in the vicinity, and the medium-range transfer of cypermethrin from air residues.
- Cypermethrin is not persistent in soil. Plant uptake of residues of cypermethrin from organic fertilisers or from soil containing residues is considered a less likely explanation for residues found in crops where cypermethrin has not been actively used.
- The transfer of cypermethrin from EU water sources used for irrigation to plant commodities is unlikely.
- Cypermethrin is also used in biocidal products and as veterinary medicine^{23, 24}. These applications may result in the release of residues of cypermethrin in the environment.
- Based on conservative estimations of the possible transfer of residues of cypermethrin from water used for irrigation to plant commodities and information on the possible plant

Findings of not authorised substances in organic products

uptake of residues of cypermethrin from the EU soil, the transfer of residues of cypermethrin from biocidal, veterinary and other non-pesticide uses as well as the transfer from industrial emissions to the environment and from the environment to plants and plant commodities is less likely.

The pathways of residues of cypermethrin to plants and plant commodities are summarised in Figure 3.

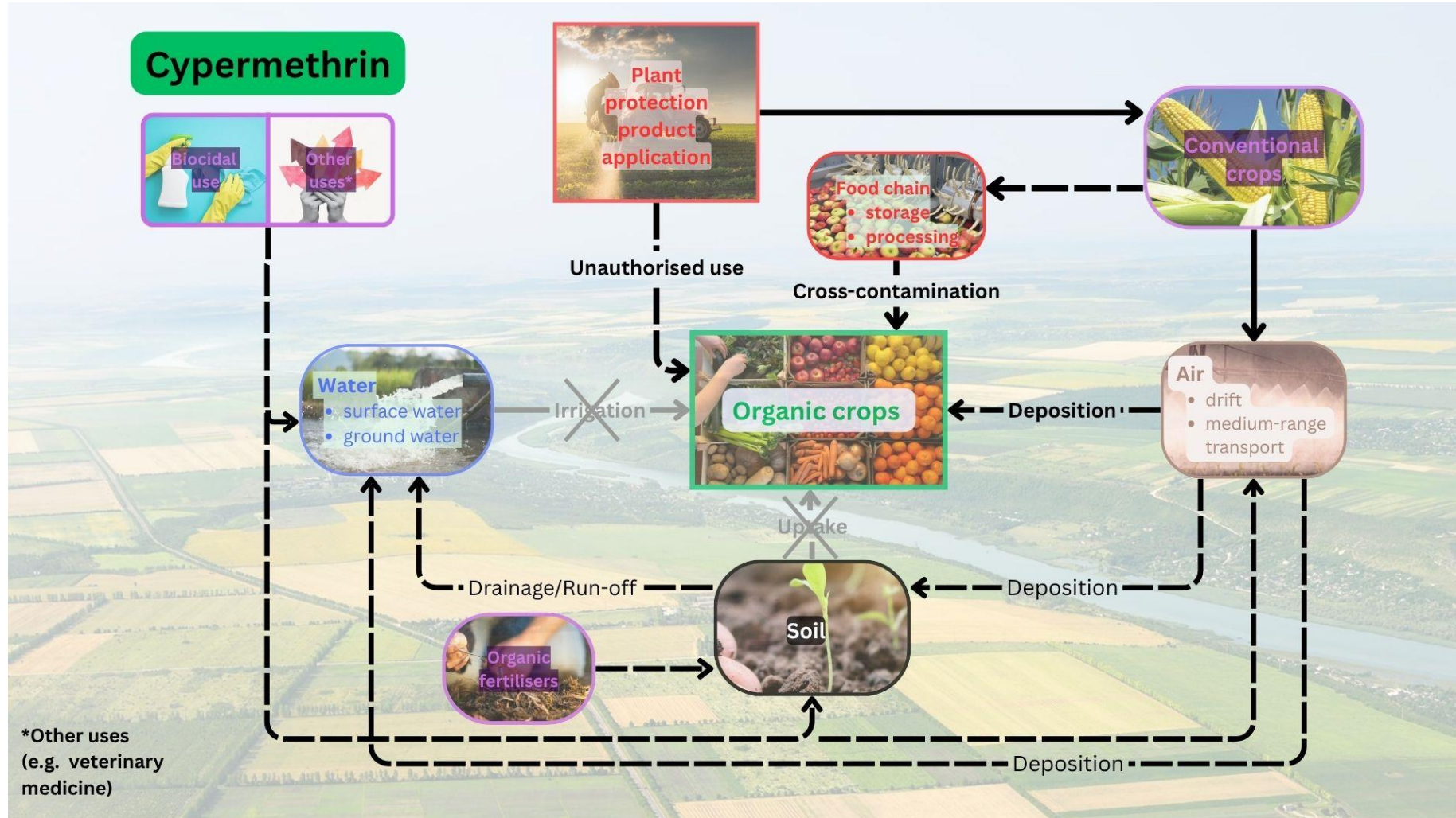


Figure 3: Pathways of residues of cypermethrin to plants and plant commodities

Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded

3.4 Imidacloprid

3.4.1 Method(s)

- What is/are the residues to be monitored for imidacloprid according to the residue definition for monitoring set in Regulation (EC) No 396/2005^{3,44}?

For the active substance 'imidacloprid', the residue definition for enforcement in food and feed of plant origin has been proposed as 'imidacloprid' in the EFSA MRL review (EFSA, 2019b). This residue definition is applicable to primary, rotational crops and processed products. This residue definition for enforcement is implemented in Regulation (EC) No 396/2005^{3,44}. The same residue definition is also applicable to honey.

Based on the above only residues of imidacloprid are to be monitored in foods of plant origin, honey and other apiculture products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

A multi-residue QuEChERS method combined with HPLC-MS/MS has been sufficiently validated for the monitoring of residues of imidacloprid in high water and high acid content, as well as dry commodities with an LOQ of 0.01 mg/kg (EFSA, 2019b).

Additionally, a single residue HPLC-MS/MS method and its independent laboratory validation (ILV) have been sufficiently validated for enforcing imidacloprid in matrices with high water, high acid, high oil content, and dry commodities, as well as hops. This method has an LOQ of 0.02 mg/kg in the four major matrices and 0.2 mg/kg in hops (EFSA, 2019b; Germany, 2024 under 'Documentation as provided to EFSA'). According to Erminia Schiano et al. (2024), residues of imidacloprid can be monitored in high oil content matrices such as olive oil using multi-residue LC-MS/MS method with an LOQ below 0.004 mg/kg.

Another HPLC-MS/MS method is validated for imidacloprid enforcement in cocoa beans (suitable for coffee beans as well), a matrix difficult to analyse, with an LOQ of 0.01 mg/kg. However, a confirmatory method and ILV are not provided (EFSA, 2019b).

A validated multi-residue LC-MS/MS method is available for quantifying imidacloprid residues in honey samples with an LOQ of 0.002 mg/kg (EFSA, 2019b; EURL, 2016, 2024 under 'Documentation as provided to EFSA'). A multi-residue citrate-buffered QuEChERS method based on LC-Q-TOF is validated to monitor residues of imidacloprid in honey at an LOQ of 0.005 mg/kg (EURL, 2024 under 'Documentation as provided to EFSA').

Overall, there are multi-residue HPLC-MS/MS methods available for the monitoring of imidacloprid residues in high water, high acid, high oil and dry plant commodities. LOQs for methods of analysis of imidacloprid residues in products of plant origin and honey range from 0.002 to 0.2 mg/kg with the lower sensitivities observed for hops.

⁴⁴ Commission Regulation (EU) 2021/1881 of 26 October 2021 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for imidacloprid in or on certain products. OJ L 380, 27.10.2021, p. 5–19.

3.4.2 Authorisation status and use

- Is imidacloprid currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has imidacloprid ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

a) Authorisations for plant protection use in conventional agriculture

Imidacloprid is not currently approved for plant protection use in conventional agriculture in the EU, but it used to be an approved active substance from 1 August 2009 to 1 December 2020, according to the EU Pesticides Database⁵ (accessed on 6 May 2024). Following the decision for the non-approval of imidacloprid⁴⁵, all authorisations for imidacloprid at Member State level have been withdrawn.

From 1 November 2020 to 21 May 2024, the following emergency authorisations⁵ have been granted at Member State level for imidacloprid as summarised in Table 3.4.2.

Table 3.4.2: Emergency authorisations of plant protection products in the EU containing imidacloprid since the withdrawal of the active substance.

EU Member State	Crop	Mode of application	Entry into force	Expiry date
Belgium	Escarole	Seed treatment	15/04/2021	12/08/2021
Belgium	Lettuce	Seed treatment	15/04/2021	12/08/2021
Belgium	Sugar beet	Seed treatment	01/11/2020	28/02/2021
Belgium	Sugar beet	Seed treatment	12/11/2020	10/03/2021
Belgium	Sugar beet	Seed treatment	13/11/2020	11/03/2021
Belgium	Sugar beet	Seed treatment	15/02/2021	14/06/2021
Belgium	Sugar beet	Seed treatment	19/04/2021	16/08/2021
Belgium	Sugar beet	Seed treatment	16/08/2021	13/12/2021
Belgium	Sugar beet	Seed treatment	01/12/2021	30/03/2022
Belgium	Sugar beet	Seed treatment	14/12/2021	12/04/2022
Belgium	Sugar beet	Seed treatment	15/02/2022	14/06/2022
Belgium	Sugar beet	Seed treatment	14/04/2022	11/08/2022
Belgium	Sugar beet	Seed treatment	12/08/2022	09/12/2022
Belgium	Sugar beet	Seed treatment	15/11/2022	14/03/2023
Belgium	Winter endive	Seed treatment	15/04/2021	12/08/2021
Denmark	Beets	Seed treatment	22/02/2021	30/05/2021
Denmark	Beets	Seed treatment	22/12/2021	13/04/2022
Finland	Sugar beet	Seed treatment	16/02/2021	15/06/2021
Finland	Sugar beet	Seed treatment	16/02/2022	15/06/2022
France	Sugar beet	Seed treatment	06/02/2021	06/06/2021
France	Sugar beet	Seed treatment	02/02/2022	02/06/2022
Poland	Sugar beet	Seed treatment	02/01/2021	01/05/2021
Romania	Common barley	Seed treatment	01/08/2022	28/11/2022
Romania	Common barley	Seed treatment	03/08/2023	30/11/2023
Romania	Corn	Seed treatment	25/01/2021	24/05/2021
Romania	Corn	Seed treatment	25/01/2022	24/05/2022
Romania	Corn	Seed treatment	23/01/2023	22/05/2023
Romania	Corn	Seed treatment	22/01/2024	21/05/2024
Romania	Sunflower	Seed treatment	25/01/2022	24/05/2022
Romania	Sunflower	Seed treatment	23/01/2023	22/05/2023
Romania	Sunflower	Seed treatment	22/01/2024	21/05/2024
Romania	Winter barley	Seed treatment	01/08/2022	28/11/2022
Romania	Winter barley	Seed treatment	03/08/2023	30/11/2023
Romania	Winter wheat	Seed treatment	01/08/2022	28/11/2022
Romania	Winter wheat	Seed treatment	03/08/2023	30/11/2023

⁴⁵ Commission Implementing Regulation (EU) 2018/783 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance imidacloprid. OJ L 132, 30.5.2018, p. 31–34

b) Authorisations for purposes other than plant protection

Biocidal use

Imidacloprid has been approved for biocidal use in the EU Member States, Iceland, Liechtenstein and Norway with Regulation (EU) No 528/2012⁷ since 7 July 2013. The expiry date of approval of the active substance is on 31 December 2025, as indicated by the ECHA website⁶ (accessed 3 June 2024). The application for the renewal of the approval of imidacloprid is under assessment.

According to the ECHA website⁶, at national level, imidacloprid has been authorised in Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden.

Other uses

A search carried out on the ECHA website⁹ on 6 June 2024 indicated three registrations for imidacloprid under REACH. One registration has been inactive since 2012. The other two registrations, submitted in 2021 and 2023, are active. The registration information confirms the manufacture of the substance and its use in formulation in the EU Member States¹¹, Iceland, Liechtenstein and Norway.

According to the EU Veterinary Medicines Database^{24, 24}, imidacloprid is authorised as veterinary medicine in cats, dogs, rabbits and ferrets.

- What is/was the actual use of imidacloprid? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of imidacloprid

Imidacloprid is an insecticide, acaricide and a product to control other arthropods that belong to the neonicotinoid/nitroguanidine compound group. It has systemic properties and acts by blocking postsynaptic nicotinic receptors in insect nervous systems (EFSA, 2019b).

Conditions of use and applicable crops

The uses reported in the EFSA MRL review for imidacloprid whilst the substance was still approved included applications from the northern and southern EU in food and feed commodities belonging to the following crop groups: citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds and oil fruits, cereals, hops (dried), sugar plants and fodder beet (EFSA, 2019b).

Different modes of application were registered for imidacloprid, including outdoor and indoor foliar sprays from sowing until harvest, outdoor seed treatments and outdoor and indoor soil treatments (EFSA, 2019b).

- Foliar applications were reported for commodities belonging to the following crop groups: citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous

fruits, root and tuber vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds and oil fruits, hops (dried), and grass. Application rates range from 0.03 kg a.s./ha to 0.30 kg a.s./ha for outdoor cultivation and from 0.1 kg a.s./ha to 0.15 kg a.s./ha for indoor cultivation (EFSA, 2019b).

- Seed treatments were reported for root and tuber vegetables, bulb vegetables, brassica vegetables (kohlrabies), leaf vegetables, herbs and edible flowers, stem vegetables (leeks), cereals, sugar plants and fodder beets. The reported application rates range from 0.01 kg a.s./100 kg seeds to 4.50 kg a.s./100 kg seeds (EFSA, 2019b).
- Soil treatments were reported for fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops) and leaf vegetables, herbs and edible flowers. The reported application rates range from 0.12 to 0.31 kg a.s./ha (EFSA, 2019b) or up to 0.01 kg a.s./unit⁴⁶ (cucumber).

b) Uses for purposes other than plant protection

Biocidal use

Products containing imidacloprid are reported to be used as insecticides in livestock installations and in residential and commercial buildings (indoor and/or outdoor). Biocidal products containing imidacloprid can be applied by both professional and non-professional users. Product application rates range from 2.15 mg a.s./m² to 10 mg a.s./m² (Germany, 2011) (see also 'authorisations for purposes other than plant protection/biocidal use').

Other uses

A search carried out on 6 June 2024 on the ECHA website⁹ showed three registrations under REACH for imidacloprid of which two are currently active (see 'authorisations for purposes other than plant protection/other uses').

Imidacloprid is a veterinary medicine^{23, 24} used in dogs, cats, rabbits and ferrets (see previous section).

3.4.3 Sources of residues in plants

3.4.3.1 Natural occurrence

- Is there evidence that imidacloprid occurs naturally? What is known about the natural origin of this substance?

Imidacloprid is a synthetic chemical, produced industrially through chemical processes (Lewis et al., 2016). No information on the potential natural presence of imidacloprid was found in the literature²².

3.4.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of imidacloprid per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of imidacloprid in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national

⁴⁶ Unit: 1000 plants corresponding to 10 mg/plant (EFSA, 2019b).

level are reported in Tables 3.4.3.2-1 to 3.4.3.2-4. The presence of residues in control (untreated) samples is also discussed in this section.

In all matrices and for both residue trials and results from monitoring, imidacloprid residue concentrations refer to the residue definition for enforcement (i.e. imidacloprid).

Occurrence of imidacloprid from residue trials carried out for the critical GAP per crop

Following product applications based on the critical GAPs⁴ reported to EFSA, residue levels of imidacloprid were below the LOQ in tree nuts, pulses (dried), cereals, hops (dried) and sugar plants (EFSA, 2019b).

Residues of imidacloprid were quantified in citrus fruits, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables and oilseeds and oil fruits (EFSA, 2019b).

Regarding feed commodities, residues of imidacloprid were below the LOQ in sugar beet tops, and fodder beet roots and tops and were quantified in cereal straw (EFSA, 2019b).

The results from residue trials carried out for the critical GAP per crop for imidacloprid in commodities for which uses were submitted to EFSA are summarised in Table 3.4.3.2-1 'Occurrence of imidacloprid from residue trials carried out for the critical GAP per crop'.

Table 3.4.3.2-1: Occurrence of imidacloprid from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Imidacloprid (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
Food				
0110000	Citrus fruits	0.9	0.067–0.25	0.17
0120000	Tree nuts	0.01*	<LOQ (0.01)	<LOQ (0.01)
1300000	Pome fruits	0.01*	<LOQ (0.01)–0.08 ^(c)	0.02
1400000	Stone fruits	0.01*	<LOQ (0.01)–0.11 ^(c)	0.06
0150000	Berries and small fruits	0.01*–5	<LOQ (0.01)–0.11	0.035
0160000	Miscellaneous fruits	0.01*	0.02–0.42 ^(c)	0.08
0210000	Root and tuber vegetables	0.01*	<LOQ (0.01)–0.02 ^(c)	0.01
0220000	Bulb vegetables	0.01*	<LOQ (0.01)–0.03 ^(c)	0.01
0230000	Fruiting vegetables	0.01*–0.9	<LOQ (0.01)–1.4 ^(c)	0.051
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	<LOQ (0.01)–0.17 ^(c)	0.01
0250000	Leaf vegetables, herbs and edible flowers	0.01*–0.05*	<LOQ (0.01)–0.95 ^(c)	0.049
0260000	Legume vegetables	0.01*–5	<LOQ (0.01)–0.25	0.075
0270000	Stem vegetables	0.01*	<LOQ (0.01)–0.14 ^(c)	0.09
0300000	Pulses (dried)	0.01*–2	<LOQ (0.01)	<LOQ (0.01)
0400000	Oilseeds and oil fruits	0.01*–0.5	0.01–0.44	0.14
0500000	Cereals	0.01*	<LOQ (0.01)	<LOQ (0.01)
0700000	Hops (dried)	15	<LOQ (0.2)	<LOQ (0.2)
0900000	Sugar plants	0.01*	<LOQ (0.01)	<LOQ (0.01)
Feed				
1200000	Cereal straw	NA	<LOQ (0.01)–0.1	0.01
	Fodder beet roots	NA	<LOQ (0.01)	<LOQ (0.01)
	Fodder beet tops	NA	<LOQ (0.01)	<LOQ (0.01)
	Sugar beet tops	NA	<LOQ (0.01)	<LOQ (0.01)

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; NR – no residue trials are available;

a) Maximum Residue Level in Reg. (EU) No 2021/1881 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA, 2019b; Concentrations above the MRL in the residue trials relate to residue trials carried out according to the (former) authorised EU outdoor use, before the expiry of the approval of imidacloprid in the EU (December 2020).

Occurrence of imidacloprid under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to imidacloprid are given by Regulation (EU) No 491/2014⁴⁷ for the years 2020 and 2021 and Regulation (EU) No 2021/1881⁴⁴ for the year 2022.

Regarding commodities not labelled as organic, 113,389 samples were collected and analysed for imidacloprid in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 104,136 (91.84%) were unprocessed and 9,253 (8.16%) processed commodities. No residues were quantified in 112,545 samples out of the 113,389 samples (99.26%). In 790 samples out of the 113,389 samples (0.70%) imidacloprid was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-4.1. MRLs were exceeded in 54 samples out of the 113,389 samples (0.05%). The highest concentration for samples exceeding the MRLs was 5.5 mg/kg in leaf vegetables, herbs and edible flowers (grape leaves and similar species).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of imidacloprid are summarised in Table 3.4.3.2-a for unprocessed and in Table 3.4.3.2-b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on imidacloprid in feed not labelled as organic were submitted to EFSA.

Table 3.4.3.2-a: Occurrence of imidacloprid monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Imidacloprid (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0110000	Citrus fruits	0.9	0.001	0.001–0.82	74	0.019
0120000	Tree nuts	0.01*	0.001	0.015	1	0.015
0130000	Pome fruits	0.01*	0.001	0.002–0.23	35	0.016
0140000	Stone fruits	0.01*	0.001	0.002–0.132	74	0.018
0150000	Berries and small fruits	0.01*–5	0.001	0.003–0.47	37	0.026
0160000	Miscellaneous fruits	0.01*	0.001	0.01–0.047	9	0.016
0210000	Root and tuber vegetables	0.01*	0.001	0.001–0.13	37	0.013

⁴⁷ Commission Regulation (EU) No 491/2014 of 5 May 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, azoxystrobin, cycloxydim, cyfluthrin, dinotefuran, fenbuconazole, fenvalerate, fludioxonil, fluopyram, flutriafof, fluxapyroxad, glufosinate-ammonium, imidacloprid, indoxacarb, MCPA, methoxyfenozide, penhiopyrad, spinetoram and trifloxystrobin in or on certain products. OJ L 146, 16.5.2014, p. 1–91.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Imidacloprid (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0220000	Bulb vegetables	0.01*	0.001	0.012–0.205	7	0.03
0230000	Fruiting vegetables	0.01*–0.9	0.001	0.001–1.016	314	0.028
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	0.001	0.001–0.498	32	0.012
0250000	Leaf vegetables, herbs and edible flowers	0.01*–0.05*	0.001	0.001–5.5	71	0.017
0260000	Legume vegetables	0.01*–5	0.001	0.015–0.046	4	0.031
0270000	Stem vegetables	0.01*	0.001	0.004–0.014	4	0.012
0300000	Pulses (dried)	0.01*–2	0.001	0.019–0.038	3	0.035
0400000	Oilseeds and oil fruits	0.01*–0.5	0.001	0.01–0.056	9	0.018
0500000	Cereals	0.01*	0.001	0.005–0.39	44	0.02
0700000	Hops (dried)	15	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*	0.005	<LOQ	0	<LOQ
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
	Fodder beet tops	NA	ND	ND	ND	ND
	Fodder beet roots	NA	ND	ND	ND	ND
	Sugar beet tops	NA	ND	ND	ND	ND

Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of imidacloprid is not expected)

0280000	Fungi, mosses and lichens	0.01*	0.001	0.01	1	0.01
0290000	Algae and prokaryotes organisms	0.01*	0.01	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*–1 ^{d)}	0.005	0.01–0.032	11	0.017
0800000	Spices (dried)	0.05*	0.005	0.007–0.088	12	0.014
1040000	Honey and other apiculture products	0.05*	0.001	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2021/1881 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) CXL in coffee beans.

Table 3.4.3.2-2b: Occurrence of imidacloprid from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Imidacloprid (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Imidacloprid (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.9	0.001	0.001–0.011	7	0.006
0120000	Tree nuts	0.01*	0.01	0.37	1	0.37
0130000	Pome fruits	0.01*	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*	0.002	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.01*–5	0.001	0.002–0.062	15	0.014
0160000	Miscellaneous fruits	0.01*	0.002	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*	0.01	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*–0.9	0.001	0.009–0.29	30	0.025
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*–0.05*	0.005	0.006–0.082	5	0.025
0260000	Legume vegetables	0.01*–5	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.01*–2	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–0.5	0.002	0.002	1	0.002
0500000	Cereals	0.01*	0.001	0.01–0.015	3	0.013
0700000	Hops (dried)	15	0.01	0.098	1	0.098
0900000	Sugar plants	0.01*	0.002	<LOQ	0	<LOQ
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
	Fodder beet tops	NA	ND	ND	ND	ND
	Fodder beet roots	NA	ND	ND	ND	ND
	Sugar beet tops	NA	ND	ND	ND	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of imidacloprid is not expected)						
0280000	Fungi, mosses and lichens	0.01*	0.005	0.14	1	0.14
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*–1	0.005	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*	0.005	0.13	1	0.13
1040000	Processed apiculture products	0.05*	0.001	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2021/1881 amending Annex II of Reg. (EC) No 396/2005;

b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of imidacloprid in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 10,264 samples were collected and analysed for imidacloprid from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 8,557 (83.37%) were unprocessed and 1,707 (16.63%) processed commodities. No residues were quantified in 10,258 samples out of the 10,264 samples (99.94%). In six samples out of the 10,264 samples (0.06%) imidacloprid was found at or above the analytical LOQ but below or at

the MRL. No samples labelled as organic were above MRLs. These findings are summarised in Appendix B, Table B-4.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.4.3.2-3a for unprocessed and in Table 3.4.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on imidacloprid in feed labelled as organic were submitted to EFSA.

Table 3.4.3.2-3a: Occurrence of imidacloprid from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Imidacloprid (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.9	0.001	0.069–0.08	2	0.075
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*	0.001	0.073	1	0.073
0150000	Berries and small fruits	0.01*–5	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*	0.001	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*–0.9	0.001	0.022	1	0.022
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	0.001	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*–0.05*	0.001	0.002	2	0.002
0260000	Legume vegetables	0.01*–5	0.001	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*	0.001	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.01*–2	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–0.5	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.01*	0.001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*–1	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	15	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.001	<LOQ	0	<LOQ

*Limit of quantification in Reg. (EC) No 396/2005.

a) Maximum Residue Level in Reg. (EU) No 2021/1881 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.4.3.2-3b: Occurrence of imidacloprid from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Imidacloprid (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.9	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.01*-5	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*	ND	ND	ND	ND
0230000	Fruiting vegetables	0.01*-0.9	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	0.001	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*-0.05*	0.005	<LOQ	0	<LOQ
0260000	Legume vegetables	0.01*-5	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.01	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0300000	Pulses (dried)	0.01*-2	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*-0.5	0.002	<LOQ	0	<LOQ
0500000	Cereals	0.01*	0.0001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*-1	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	15	ND	ND	ND	ND
0800000	Spices (dried)	0.05*	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.005	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2021/1881 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of imidacloprid in the EU Organic Farming Information System

The EU OFIS reported 30 findings for imidacloprid in 2021 and 2022. Four of the products sampled and analysed had EU origin and 26 were of non-EU origin. Residues were found in two samples of citrus fruit (oranges and limes), four samples of berries and small fruits (table grapes, strawberries and blueberries), eight samples of miscellaneous fruits (avocados, bananas and mangoes), three samples of fruiting vegetables (sweet peppers/bell peppers and okra/lady's fingers), two samples of leaf vegetables, herbs and edible flowers (thyme and basil and edible flowers), one sample of pulses (dried) (lupins/lupini beans), four samples of oilseeds and oil fruits (peanuts/groundnuts, sesame seeds, soyabeans and mustard seeds), 4 samples of teas,

coffee, herbal infusion, cocoa and carobs (teas and strawberries) and two samples of products or part of products exclusively used for animal feed production (rapeseed cake). The concentrations of imidacloprid residues were above LOQ but below MRL in 16 samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005³. MRLs exceeded in 12 samples. For the sample of products or part of products exclusively used for animal feed production (rapeseed cake), no MRL is applicable according to Reg. (EC) No 396/2005³. The highest concentration was reported for a sample of sweet peppers/bell peppers (pepper – black) from non-EU origin, with a quantified level of 0.18 mg/kg. These findings are summarised in Table 3.4.3.2-4.

Table 3.4.3.2-4: Occurrence of imidacloprid from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
0300040	Lupins/lupini beans	0.01*	0.049 – Lupine seed	ND
0401080	Mustard seeds	0.01*	0.019 – Mustard seed	ND
1200000	Products or part of products exclusively used for animal feed production	NA	ND	0.039; 0.039 – Rapeseed (cake) (feed-related matrix)
Samples of non-EU origin				
0110020	Oranges	0.9	ND	0.007 – Oranges (juice)
0110040	Limes	0.9	0.026 – Limes	ND
0151010	Table grapes	0.7	ND	0.073 – Raisins; 0.021 – Raisins (paste)
0152000	Strawberries	0.01*	0.073 – Strawberries	ND
0154010	Blueberries	5	ND	0.066 – Berry juice (powder)
0163010	Avocados	0.01*	0.012 – Avocado (Hass)	ND
0163020	Bananas	0.01*	0.011; 0.017; 0.021; 0.106 – Bananas	ND
0163030	Mangoes	0.01*	0.014; 0.015; 0.037 – Mangoes	ND
0231020	Sweet peppers/bell peppers	0.9	0.144; 0.18 – Peppers (sweet; black)	ND
0231040	Okra/lady's fingers	0.5	0.06 – Okra (beans)	ND
0256070	Thyme	0.05*	ND	0.06 – Oregano (rubbed)
0256080	Basil and edible flowers	0.05*	0.037 – Basil	ND
0401020	Peanuts/groundnuts	0.5	0.014 – Peanuts	ND
0401040	Sesame seeds	0.01*	0.011 – Sesame seeds	ND
0401070	Soyabeans	0.01*	0.007 – Soyabeans	ND
0610000	Teas	0.05*	ND	0.014; 0.02 – Teas (black; green)
0632010	Strawberry	0.05*	0.016 – <i>Equisetum arvense</i> /horsetail herb; 0.049 – Elderflowers	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable;

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2021/1881 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of imidacloprid in untreated samples (control samples) from residue trials

The evaluation report on the review of existing EU MRLs for imidacloprid (Germany, 2015b) noted the presence of imidacloprid residues in control (untreated) samples. Residues were quantified in barley (straw) samples from residue trials conducted in the United Kingdom³⁵ and Germany. Quantified findings were also observed in maize (whole plant) from Italy and in different plant portions of wheat (grain, ear, rest of the plant) from several trials carried out in

France and Italy. Additionally, residues of imidacloprid were measured in the control samples of apple from Germany and Spain as well as in pear, orange, bean and zucchini (courgettes) from Spain. Quantified findings were observed in one trial in cauliflower (curd) from Portugal and two trials in potato from Germany. Furthermore, residues of imidacloprid were observed in different trials in pepper from Germany, the Netherlands and Spain (Germany, 2015b; Portugal, 2016) and in lettuce (sowing seed) from Belgium, France and Germany (Germany, 2015b).

No evidence-based explanations on the causes for these occurrences in control (untreated) samples were provided in the above-mentioned evaluation reports.

Table 3.4.3.2-5: Summary of the quantitative findings for imidacloprid in control (untreated) samples from residue trials carried out for the critical GAP per crop

Crop	Country/Area	Residues (mg/kg)
Apple	Germany	Fruit: 0.02
	Spain	Fruit: 0.06
Barley	Germany	Straw: 0.06
	United Kingdom ³⁵	Straw: 0.06
Bean	Spain	Pod with seed: 0.015; 0.019
Cauliflower	Portugal	Curd: 0.02
Maize	Italy	Whole plant: 0.37
Orange	Spain	Fruit: 0.02
Pear	Spain	Fruit: 0.02, 0.04
	Germany	Fruit: 0.03
	Netherlands	Fruit: 0.05
Potato	Spain	Fruit: 0.03, 3 × 0.04
	Germany	Tuber: 2 × 0.012
Wheat	France (South)	Ear: 0.02; Grain: 0.02;
	Italy	Grain: 0.02; Rest of the plant: 0.02
Zucchini (courgettes)	Spain	Fruit: 0.03

- Could the presence of imidacloprid and/or its residues be due to biocide use?

Imidacloprid is applied as a biocidal insecticide in livestock installations, and in residential and commercial buildings. Mitigation measures are proposed to prevent environmental exposure to imidacloprid (Germany, 2011). These include proposals to restrict uses in livestock installations where emissions to a sewage treatment plant (STP) or direct emission to surface water cannot be prevented.

The products are applied as a granule or gel bait formulation at concentrations of 0.01–2.15% (w/w). PEC values have been calculated to predict the potential contamination of water and soil for different scenarios (e.g. outdoor application on paved surfaces with direct or indirect release) carried out by the Evaluation Member State; the highest values were 0.47 µg/L (PEC_w) and 0.004 mg/kg (PEC_{soil}). These PECs are covered by those estimated for agricultural uses of the substance (see Section 3.4.3.6).

Based on the above, it can be concluded that the release of residues of imidacloprid in the water and/or soil after biocidal use cannot be excluded.

3.4.3.3 Behaviour in food and feed products

- What key physico-chemical properties of imidacloprid are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of imidacloprid are reported in Table 3.4.3.3.

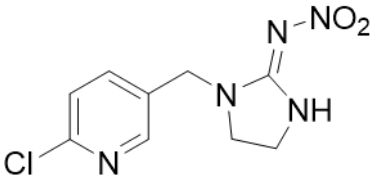
Imidacloprid exhibits moderate to high persistence in soil (see also Section 3.4.3.5). Regarding sorption to soil, the geometric mean of K_{Foc} in Table 3.4.3.3 indicates that the substance has medium mobility in soil (EFSA, 2008a).

The maximum calculated PEC_w for imidacloprid for the representative uses was 6.19 µg/L (spray application to apples; 1 × 70 g a.s./ha) (EFSA, 2014b).

Imidacloprid is hydrolytically stable under standard conditions of pasteurisation, baking/brewing/boiling and sterilisation (EFSA, 2008a). Considering that imidacloprid is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Imidacloprid is considered a very slightly volatile compound (vapour pressure = 10⁻¹⁰ Pa) (EFSA, 2008a).

Table 3.4.3.3: Physico-chemical properties of imidacloprid (EFSA, 2008a)

Structural formula	
Appearance (state purity)	Colourless crystals (99.8 %) or cream-coloured powder (98.5 %)
Melting point (state purity)	144°C (99.9 %)
Boiling point	NA
Temperature of decomposition	Decomposition starts at approx. 230°C (99.5 %)
Vapour pressure (state temperature, state purity)	20°C: 4 × 10 ⁻¹⁰ Pa 25°C: 9 × 10 ⁻¹⁰ Pa extrapolated from measurement between 50 and 70°C (99.9 %)
Henry's law constant (state temperature)	1.7 × 10 ⁻¹⁰ Pa m ³ mol ⁻¹ (20°C)
Solubility in water (state temperature, state purity and pH)	pH 4.0: 607 mg/L at 20°C (99.9%) pH 5.5: 613 mg/L at 20°C (99.9%) pH 9.0: 601 mg/L at 20°C (99.9%)
Partition coefficient (state temperature, pH and purity)	log P_{ow} = 0.57 at 20°C (99.8%)
Partition coefficient (octanol/air)	NA
Atmospheric half-life	DT ₅₀ = 0.85 hours derived by the Atkinson model. OH radical (12h) concentration assumed = 1 × 10 ⁶ cm ⁻³
Dissociation constant (state purity)	No dissociation within environmentally relevant pH range
Soil adsorption (geometric mean)	K_{Foc} = 210 mL/g
Hydrolytic degradation (>10%)	Hydrolytically stable (pH 5–7 at 25°C) Shows slow hydrolysis at pH 9 and 25°C (DT ₅₀ =1 year)

DT₅₀ – Disappearance time of 50% of the substance in field studies; NA – not applicable; pH – Potential of Hydrogen; Pow – Octanol/water Partition Coefficient

3.4.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

Imidacloprid has not been approved for plant protection purposes since 1 December 2020, therefore, drift from conventional to organic agriculture should not be expected. On the other hand, product authorisations at Member State level may not have been withdrawn between 2020 and 2022, therefore, potential drift from uses of the substance in conventional agriculture was considered.

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from soil surface at which it is applied).

The highest drift of imidacloprid to neighbouring fields may occur during its applications to fruit crops (up to 29.2%), hops (19.33%), vineyards and vegetables (up to 8.02%) and field crops (up to 2.77%). Drift values should consider the rate received by neighbouring fields, expressed as the percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. buffer zones or spray drift-reducing nozzles).

The use of imidacloprid in granular form has been identified (EFSA, 2013b), it was also authorised for use as a seed treatment, which necessitates consideration of potential dust drift. Although these granules are relatively large and will not contribute to drift themselves, small dust particles that are small enough to be taken downwind by the wind may break off. Deposition percentile values were considered for neighbouring fields, distinguishing between seed treatments (up to 17%) and granule applications (9.6%) for different crops and techniques (EFSA, 2013a). According to Adriaanse et al. (2022), the use of techniques (deflectors), size of the dust particles and average wind speed were the most important factors determining the amount of dust drift. If organic crops were present adjacent to the conventional crops treated between 2020 and 2022, measurable residues of imidacloprid in the untreated crop could not be excluded. However, since the nature of the potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

3.4.3.5 Accumulated/historical residue levels in soil

- What is the persistence of imidacloprid and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

According to available data (EFSA, 2008a, 2019b), the DT₉₀ of imidacloprid in soil, which was estimated from 14 field soil dissipation studies, has a worst-case field value of 956 days, indicating a potential for accumulation in soil and soil residues to remain after discontinued use of the substance.

Considering the persistence of imidacloprid in soil, confined and field rotational crop studies were carried out with bare soil to investigate the potential soil uptake of the substance by the plants. In addition, EFSA investigated not only the magnitude of residues based on primary applications of imidacloprid but also the potential carry-over from previously authorised uses (EFSA, 2019b). The results of these studies suggested that, based on the submitted GAPs⁴, significant uptake of residues from soil can only be expected in cereal straw. Significant residues in other commodities of plant origin are not expected if the substance is used according to the GAPs. For sweet peppers for which the available rotational crop studies did not cover the most critical GAP, risk mitigation measures were proposed, suggesting plantations in soil-less growing systems.

The above information suggests that significant residues of imidacloprid are not expected in most crops, except for cereal straw if the substance was used according to the submitted GAPs. Though the authorisation of the substance expired in 2020, there would have still been residues remaining in soil in many fields for the sampling years between 2020 and 2022, considering the soil has DT₉₀ in the available 14 field dissipation trials was up to 956 days. However, transfer of these residues to the plant commodities consumed by humans or livestock above the LOQ for monitoring is highly unlikely. This is also valid for organic crops planted in fields that were previously used for conventional agriculture, considering that it requires at least 2 years after the last chemical treatment in order for organic crops to be planted in such area³⁸. EFSA (2016a) had rotational crop trial residues data results indicating residues in pollen of up to 0.0025 mg/kg and in nectar up to 0.0035 mg/kg in crops of phacelia, winter oilseed rape, maize and mustard. This provides an indication of a potential for residues in honey and other apiculture products. However, based on the monitoring results reported in Section 3.4.3.2, such residues would be expected to be below the LOQ of the methods used for monitoring (0.001mg/kg).

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

The estimated plateau concentrations in soil for imidacloprid were 0.203 mg/kg soil, after a single year application and 0.348 mg/kg soil, over multiple year applications. These values are based on a maximum annual application rate of 2×0.31 kg/ha and suggest that imidacloprid can accumulate in soil (EFSA, 2019b). The DT₉₀ of imidacloprid ranging up to 956 days, suggests that imidacloprid can still be found in soil 3 years after its last application. Considering the transitional period for the withdrawal of authorisations for imidacloprid it can be expected that some residues of imidacloprid are still present in EU soil. On the other hand, data on the magnitude of residues in rotational crops indicate that, even if present, their uptake from soil should be insignificant (see previous paragraph).

Monitoring data for imidacloprid in soil are available from the LUCAS pesticides 2018 (JRC, 2023) on IPCHEM¹². According to Franco et al. (2024), imidacloprid was detected in 18% of sites included in the LUCAS soil survey, ranking among the most frequently identified pesticide residues in European soil.

The data from LUCAS pesticides show background levels of the substance in soil samples from 21 EU countries: Austria (5 samples), Belgium (2 samples), Bulgaria (71 samples), Cyprus (3 samples), Czechia (13 samples), Denmark (4 samples), Estonia (1 sample), Finland (2 samples), France (269 samples), Germany (7 samples), Greece (18 samples), Hungary (13 samples), Italy (40 samples), the Netherlands (7 samples), Poland (22 samples), Portugal (5 samples),

Romania (9 samples), Slovakia (4 samples), Spain (122 samples), Sweden (3 samples) and United Kingdom³⁵ (2 samples). The reported residues ranged from 0.001 mg/kg to 0.77 mg/kg. In LUCAS soil, the lack of information on the agricultural use history of the sites where soil was sampled precluded knowing whether the reported quantified findings were related to recent active use or historical levels in soil for imidacloprid.

Evidence on the occurrence of imidacloprid residues in soil is provided by Chiaia-Hernandez et al. (2017), who analysed 29 archived agricultural soil samples collected from 14 monitoring sites from 1995 to 2008 in Switzerland. The sites were selected from locations where crops had been regularly treated with pesticides. Selection was based on land use characteristics and long-term patterns of pesticide application. Imidacloprid was detected in 10 samples (34%) from cropland and orchard land use sites, with levels ranging from 0.004 to 0.138 mg/kg. The authors observed what they considered to be false positives in seven cropland sites and in three orchard sites. In 10% of cases the substance had been applied and detected, whilst in 24% of cases detection occurred without prior application. Additionally, minor transformation products of imidacloprid were detected in five samples (17%), and in two samples (7%), from all land use sites, including cropland, orchard, vegetable and viticulture.

In a study by Riedo et al. (2021) the presence of imidacloprid was analysed in soil samples from 60 agricultural sites with different management systems (conventional tillage, conventional without soil tillage, and organic) sampled in May 2016 for an on-farm study throughout Switzerland. Results showed the presence of imidacloprid in 59% of the samples at concentrations ranging from 0.00014 and 0.024 mg/kg in all types of soil, with higher levels in soil from conventional arable and vegetable farming. The concentrations in soil under organic production systems were reported to be <0.01 mg/kg in a total of 13 out of 40 samples (32.5%).

Additional evidence on the occurrence of imidacloprid in soil is provided by Silva et al. (2023) in a study carried out in the framework of the EU SPRINT project. The study assessed the presence of 209 pesticide residues in 100 soil samples from conventional agriculture and 63 soil samples from organic agriculture collected during the 2021 growing season across 10 study sites in Europe: Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark. Imidacloprid was detected in five conventional soil samples (5%) from Spain at concentrations ranging from 4.3 to 27.8 µg/kg.

Considering the available evidence, the plant uptake above the LOQ needed for the monitoring of imidacloprid from soil containing imidacloprid is not expected if the crop is grown in soil that contain residues at the levels quantified in these studies.

3.4.3.6 Residues from water used for irrigation

- Is there evidence that residues of imidacloprid present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for imidacloprid in water samples were considered:

- The EEA-WATERQUALITY³⁹³⁹³⁹ database (data retrieved on 10 April 2024) reports 52,632 analytical results from water samples collected in Belgium (980 samples), Croatia (10 samples), Cyprus (31 samples), Czechia (8,347 samples), Denmark (310 samples), Estonia (284 samples), Finland (71 samples), France (23,849 samples), Hungary (20 samples), Ireland (16 samples), Italy (17,544 samples), Latvia (6 samples), the

Netherlands (1,050 samples), Portugal (54 samples), Slovakia (8 samples), Slovenia (4 samples), Spain (12 samples) and Sweden (36 samples) between 2019 and 2020;

- The EMPODAT database (data retrieved on 2 April 2024) reports 15,350 analytical results from surface water samples collected in Austria (19 samples), Bulgaria (35 samples), Croatia (10 samples), Czechia (10 samples), Germany (30 samples), Hungary (50 samples), the Netherlands (15,140 samples), Romania (11 samples) and Slovakia (45 samples) between 2018 and 2020; 24 analytical results from groundwater samples collected in 2019 in Austria (4 samples), Bulgaria (4 samples), Croatia (4 samples), Hungary (4 samples), Romania (4 samples) and Slovakia (4 samples);
- The NAIADES database (data retrieved on 2 April 2024) reports 54,573 analytical results from surface water samples collected in France from 2020 to 2022.

Among the 122,561 analytical results for imidacloprid, 2004 were disregarded as found to report quantified residues below the LOQ and 3,667 were disregarded as found to report quantified residues equal to LOQs as high as 1 µg/L and above. Therefore, the number of water samples considered is 116,890.

Based on the screening process described in section 'Data and methodologies', for 99.8% of water samples analysed and reported in the above-mentioned databases (116,625 samples), the residue concentrations in these waters were below the screening Cw of 0.18 µg/L and, therefore, transfer of residues from water sources to plant commodities is unlikely.

For 0.2% of samples (265 out of 116,890 samples), the residue concentrations were found to be at or above the screening Cw of 0.18 µg/L and the potential transfer of residues to plant commodities if water containing residues at these levels is used for irrigation cannot be excluded.

The available data after the transitional period for the withdrawal of authorisations, suggest a reduction in the concentrations of imidacloprid in water.

In a study by Silva et al. (2023) carried out under the framework of the EU SPRINT project the authors assessed the presence of 209 pesticide residues in 58 water samples collected during the 2021 growing season across 10 study sites in Europe (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). Imidacloprid was detected in two samples (3% detection frequency) in Italy and Spain at concentrations of 0.004 and 0.006 µg/L, respectively.

Overall, considering that, for 99.8% of the water samples analysed and reported for imidacloprid in EEA-WATERQUALITY, EMPODAT and NAIADES (116,890 samples) and 100% of results of surface water samples analysed by Silva et al. (2023), the residue concentrations were below the screening Cw of 0.18 µg/L, it can be concluded that the transfer of imidacloprid residues from water sources to plant commodities when this water is used to irrigate the plant is unlikely.

3.4.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *imidacloprid, industry/industrial, and air/atmosphere*) identified only one European study, which was considered irrelevant for this section.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water. Based on conservative estimations of the possible transfer of residues from water used for irrigation to plant commodities, the transfer of residues of imidacloprid from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 7, 2025, using the keywords *imidacloprid, industry/industrial, and water*) identified two European studies which were considered irrelevant for this section.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Based on information on the possible plant uptake of imidacloprid from EU soil, the transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 17, 2025, using the keywords *imidacloprid, industry/industrial, and soil/sediment*) did not identify any relevant European study.

3.4.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Medium and long-range aerial transport of residues

In a study by López et al. (2022) the authors developed a comprehensive strategy to identify (unknown) pollutants in the particulate matter of ambient air (PM₁₀) and to characterise the pollutant profiles in different areas in Spain. In May 2021, the authors collected PM₁₀ air samples from three different areas: one industrial (Onda), one urban (Valencia-Viveros), and one rural (Burriana). A total of 15 samples (5 samples in each area) were collected. The presence of imidacloprid was confirmed in urban areas, with the maximum estimated concentration of 20.31 pg m⁻³. No additional details on possible sources were provided.

In a study investigating the potential transport of pesticide residues from apple-growing fields in South Tyrol (Vinschgau Valley) to higher altitudes, an analysis of soil showed the presence of imidacloprid at levels between the LOD and the LOQ in two out of 53 samples in the study (Brühl et al. 2024). These results indicate the plausibility of aerial transport (through aerosols) as a potential source of residues of imidacloprid in soil outside the treated areas.

Overall, medium-range transport of residues of imidacloprid from treated areas for which emergency authorisations apply to untreated plants cannot be excluded.

Use as veterinary medicine

The use of imidacloprid as veterinary medicine^{23, 24} might also result in the release of residues in the environment that could be taken up by plants. On the other hand, veterinary use of imidacloprid does not concern food-producing animals but only domestic animals, therefore, transfer of residues to agricultural soil and, from there, to plants is less likely. This conclusion is supported by the fact that the uptake of imidacloprid from soil is unlikely.

Other sources (not reported above)

Imidacloprid could also accumulate in urban water systems due to e.g. biocidal use and, from there, leach to soil and from soil to plants (Pinasseau et al., 2020).

3.4.4 Conclusions on imidacloprid

- Considering that imidacloprid has been a non-approved active substance as pesticide since January 2021 and that it does not occur naturally, quantified residues of imidacloprid are generally not expected to be found in food and feed of plant origin. In years 2020 to 2022, however, products containing imidacloprid were still on the EU market and used in conventional agriculture.
- Residue trials carried out to support the critical GAPs⁴ before the expiry date of the approval of imidacloprid, gave residue concentrations of up to 1.4 mg/kg in fruiting vegetables. Concentrations in the ranges reported in Table 3.4.3.2-1 might be associated with active use of imidacloprid according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.
- Imidacloprid was quantified in the context of residue trials in several European countries in untreated (control) samples with the highest concentration observed in one control sample of maize (whole plant) from Italy (0.37 mg/kg). The second highest value was 0.06 mg/kg in one apple sample from Spain and two samples of barley straw from the UK and Germany.
- Overall, residues of imidacloprid were not quantified in more than 99% of samples collected and analysed between 2020 and 2022 from produce both labelled and not labelled as organic crops.
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for imidacloprid in unprocessed commodities with authorised uses ranged from 0.012 mg/kg in brassica vegetables (excluding brassica roots and brassica baby leaf crops) to 0.03 mg/kg in bulb vegetables.
- In unprocessed products labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 there were no commodity groups with five or more quantified findings.
- In processed commodities, residues of imidacloprid were not quantified in any of the products labelled as organic and sampled under the EU monitoring programmes from 2020

to 2022. In samples from processed products not labelled as organic with five or more quantified findings, the median concentrations of residues of imidacloprid ranged from 0.006 mg/kg in citrus fruits to 0.025 mg/kg in fruiting vegetables and leaf vegetables, herbs and edible flowers. Considering that imidacloprid is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

- Imidacloprid is a persistent active substance and accumulates in soil. However, plant uptake from succeeding crops is not expected with the exception of cereal straw. Although this conclusion is valid for crops planted between 2020 and 2022 in soil treated at that time, it is unlikely for organic crops (for which a waiting period of 2 years is applicable) and will be even more unlikely in the coming years taking into consideration that the substance is no longer authorised.
- Following the withdrawal of authorisations for imidacloprid, transfer of residues due to drift is no longer expected, unless organic crops are in the vicinity to crops for which emergency authorisations apply (see Section 3.4.2). Transfer of residues from conventional to organic crops grown in the vicinity of each other cannot be excluded for the years 2020 to 2022 where imidacloprid was still authorised.
- Medium-range air transfer of residues of imidacloprid cannot be excluded.
- The transfer of imidacloprid residues from EU water sources used for irrigation to plant commodities is unlikely.
- Imidacloprid has been registered under REACH⁹; however, beyond manufacture and formulation, other uses (industrial, professional or consumer ones) are not confirmed in REACH registrations as of 6 June 2024.
- The use of imidacloprid as veterinary medicine^{23, 24} might also result in the release of residues in the environment that could be taken up by plants. On the other hand, veterinary use of imidacloprid does not concern food-producing animals but only domestic animals, therefore, transfer of residues to agricultural soil and, from there, to plants is less likely.
- Imidacloprid is also used in biocidal products and applications of biocidal products containing imidacloprid may result in the release of residues of imidacloprid into the environment.
- Conservative estimates of the possible transfer of residues of imidacloprid from water used for irrigation to plant commodities and information on the possible plant uptake of residues of imidacloprid from EU soil suggest that the transfer of residues of imidacloprid from biocidal, veterinary and other non-pesticide uses as well as transfer from industrial emissions to the environment and from the environment to plants and plant commodities is less likely.

The pathways of residues of imidacloprid to plants and plant commodities are summarised in Figure 4.

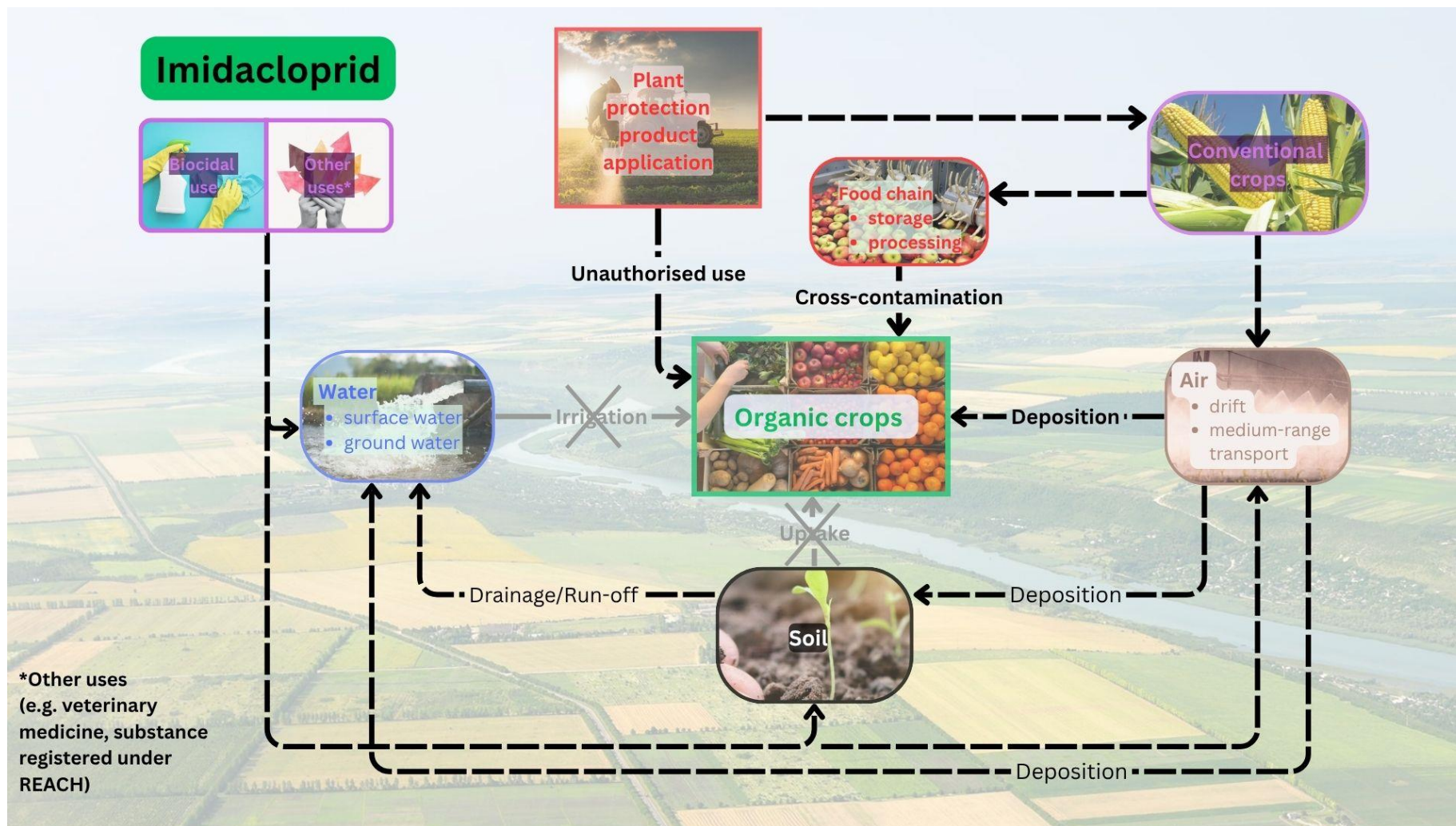


Figure 4: Pathways of residues of imidacloprid to plants and plant commodities

Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded

3.5 Boscalid

3.5.1 Method(s)

- What is/are the residues to be monitored per boscalid according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

For the active substance boscalid, the residue definition for enforcement in food and feed of plant origin as well as honey has been proposed as 'boscalid' in the EFSA reasonable opinions (EFSA, 2014c, 2019c). This residue definition for enforcement is implemented in Regulation (EC) No 396/2005³ and is applicable to primary, rotational crops, processed commodities, honey and other apiculture products.

Based on the above only residues of boscalid are to be monitored in foods of plant origin, honey and other apiculture products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

Multi-residue QuEChERS methods using HPLC-MS/MS are available for quantifying boscalid residues at or above the LOQ of 0.01 mg/kg in high water, high acid, high oil content, and dry commodities as well as honey (EFSA, 2014c, 2019c).

Another method using HPLC-MS/MS has also been validated for the analysis of boscalid in plant matrices of high water, high acid, and high oil content commodities but with lower sensitivity (LOQ of 0.05 mg/kg) (EFSA, 2014c).

Boscalid can also be quantified with a method utilising GC-MS at an LOQ of 0.01 mg/kg in high water, high acid content, and dry commodities, and an LOQ of 0.02 mg/kg in high oil content matrices (EFSA, 2014c).

Overall, there are multi-residue methods for the monitoring of residues of boscalid in high water, high acid, high oil content and dry plant commodities, as well as honey and other apiculture products. LOQs for methods of analysis of residues of boscalid in products of plant origin, honey and other apiculture products range from 0.01 to 0.05 mg/kg.

3.5.2 Authorisation status and use

- Is boscalid currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has boscalid ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

a) Authorisations for plant protection use in conventional agriculture

Boscalid has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of approval of the active substance is on 15 April 2026, as indicated by the EU Pesticides Database⁵ (accessed on 10 January 2024). The application for the renewal of the approval of boscalid is under assessment.

According to the EU Pesticides Database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Estonia, Greece,

Spain, France, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia.

b) Authorisations for uses other than plant protection

Biocidal use

Boscalid has not been approved for biocidal use in the EU Member States, Iceland, Liechtenstein and Norway, according to information from the ECHA website⁶ (accessed on 12 February 2024).

Other uses

According to the search carried out on the ECHA website⁹ on 6 June 2024, boscalid is currently not registered under REACH.

- What is/was the actual use of boscalid? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of boscalid

Boscalid is a fungicide that belongs to the carboxamide compound group and is used to protect plants against fungal pathogens. It targets the succinate dehydrogenase enzyme, disrupting the fungal respiratory chain. This disruption significantly impacts key stages of fungal development and reproduction such as spore germination, germ tube elongation, mycelial growth, and sporulation. Due to its effectiveness, boscalid is used to control a wide spectrum of fungal pathogens in multiple agricultural crops (EFSA, 2014c).

Conditions of use and applicable crops

The uses reported in the EFSA MRL review included applications in both northern and southern Europe. Uses were reported for commodities belonging to the following crop groups: pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds, cereals, hops (dried) (EFSA, 2014c).

After the EFSA MRL review in 2014, applications were submitted to EFSA to modify the existing MRLs for miscellaneous fruits, legume vegetables and honey and other apiculture products (EFSA, 2015c, 2019c, 2020a). Boscalid applications include outdoor and indoor foliar treatments in all those crop commodities except miscellaneous fruits. Application rates range from 50 g a.s./ha to 1000 g a.s./ha for foliar application (EFSA, 2014c, 2015c, 2020a). Post-harvest treatment (dipping) was recorded for cultivation of kiwi indoors with an application rate of 38 g a.s./hL (EFSA, 2014c).

b) Uses for purposes other than plant protection

Biocidal use

Boscalid is not approved for biocidal use, therefore, use of the substance in biocidal products is not expected (see also 'authorisations for purposes other than plant protection/biocidal use').

Other use

According to the ECHA website⁹, boscalid is not registered under REACH (see 'authorisations for purposes other than plant protection/other uses').

3.5.3 Sources of residues in plants

3.5.3.1 Natural occurrence

- Is there evidence that boscalid occurs naturally? What is known about the natural origin of this substance?

Boscalid is a synthetic fungicide, produced industrially through chemical processes (Lewis et al., 2016). No information on the potential natural presence of boscalid was found in the literature²².

3.5.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of boscalid per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of boscalid in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.5.3.2-1 to 3.5.3.2-4. Findings relating to residues in control (untreated) samples are also discussed in this section.

In all matrices and for both residue trials and results from monitoring, boscalid residue concentrations refer to the applicable residue definition for enforcement (i.e. boscalid).

Occurrence of boscalid from residue trials carried out for the critical GAP per crop

Following product applications based on the critical GAPs⁴ reported to EFSA, residue levels of boscalid were below the LOQ in pulses (dried) (EFSA, 2014c).

Residues of boscalid were quantified in pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, oil seeds, cereals, hops (dried) and honey and other apiculture products (EFSA, 2014c, 2015c, 2019c, 2020a).

Regarding feed commodities, residues of boscalid were quantified in cereal straw (EFSA, 2014c).

The results from residue trials carried out for the critical GAP per crop for boscalid in commodities for which uses were submitted to EFSA are summarised in Table 3.5.3.2-1 'Occurrence of boscalid from residue trials carried out for the critical GAP per crop'.

Table 3.5.3.2-1: Occurrence of boscalid from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Boscalid (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
Food				
0130000	Pome fruits	0.01*-2	0.15-1.20	0.38
0140000	Stone fruits	0.01*-5	<LOQ (0.05)-0.79	0.21
0150000	Berries and small fruits	5-15	0.12-6.4	0.95
0160000	Miscellaneous fruits	0.01*-5	0.37-2.38	0.81

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Boscalid (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
0210000	Root and tuber vegetables	2–4	<LOQ (0.05)–1.1	0.13
0220000	Bulb vegetables	0.5–6	<LOQ (0.01)–0.21	0.05
0230000	Fruiting vegetables	0.05–4	<LOQ (0.05)–1.3	0.19
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	5–9	<LOQ (0.05)–4.1	0.10
0250000	Leaf vegetables, herbs and edible flowers	0.01*–50	<LOQ (0.02)–29.0	0.86
0260000	Legume vegetables	0.06–5	<LOQ (0.05)–3.17	0.49
0270000	Stem vegetables	0.01*–9	<LOQ (0.05)–4.00	0.67
0300000	Pulses (dried)	3	<LOQ (0.05)	<LOQ (0.05)
0401000	Oilseeds	0.06–3	<LOQ (0.01)–0.33	0.05
0500000	Cereals	0.15–4	0.02–1.79	0.29
0700000	Hops (dried)	80	16.46–33.58	24.51
1040000	Honey and other apiculture products	0.15	0.01–0.08	0.06
Feed				
1200000	Cereal straw	NA	1.24–52.7	15.2

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable.

a) Maximum Residue Level in Reg. (EU) No 2022/1324 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA 2014c, 2015c, 2020a.

Occurrence of boscalid under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to boscalid are given by Regulation (EU) 2016/156⁴⁸ for the years 2020 and 2021 and Regulation (EU) 2021/590⁴⁹ for the years 2021 and 2022.

Regarding commodities not labelled as organic, 116,453 samples were collected and analysed for boscalid in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 106,975 (91.86%) were unprocessed and 9,478 (8.14%) processed commodities. No residues were quantified in 104,198 samples out of the 116,453 samples (89.48%). In 12,243 samples out of the 116,453 samples (10.51%) boscalid was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-5.1. MRLs were exceeded in 12 samples out of the 116,453 samples (0.01%). The highest concentration for samples exceeding the MRLs was 6.1 mg/kg in miscellaneous fruits (miscellaneous fruits with inedible peel, large – plums).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of boscalid are summarised in Table 3.5.3.2-2a for unprocessed and in Table 3.5.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on boscalid in feed not labelled as organic were submitted to EFSA.

⁴⁸ Commission Regulation (EU) 2016/156 of 18 January 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for boscalid, clothianidin, thiamethoxam, folpet and tolclofos-methyl in or on certain products. OJ L 31, 6.2.2016, p. 1–44.

⁴⁹ Commission Regulation (EU) 2021/590 of 12 April 2021 amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetonitrile, boscalid, cow milk, etofenprox, ferric pyrophosphate, L-cysteine, lambda-cyhalothrin, maleic hydrazide, mefenflupir, mefenflupir, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and triclopyr in or on certain products. OJ L 125, 13.4.2021, p. 15–41.

Table 3.5.3.2-2a: Occurrence of boscalid monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Boscalid (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b), c)} only (mg/kg)	Total no. of quantified results ^{d)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0130000	Pome fruits	0.01*-2	0.001	0.001-2.88	1,987	0.058
0140000	Stone fruits	0.01*-5	0.001	0.001-3.1	2,181	0.05
0150000	Berries and small fruits	5-15	0.001	0.001-7	2,339	0.085
0160000	Miscellaneous fruits	0.01*-5	0.001	0.001-1.1	56	0.034
0210000	Root and tuber vegetables	2-4	0.001	0.001-1.2	1,265	0.025
0220000	Bulb vegetables	0.5-6	0.001	0.001-1.284	195	0.026
0230000	Fruiting vegetables	0.05-4	0.001	0.001-1.9	793	0.031
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	5-9	0.001	0.001-6.128	674	0.027
0250000	Leaf vegetables, herbs and edible flowers	0.01*-50	0.001	0.001-21.2	1,741	0.051
0260000	Legume vegetables	0.06-5	0.001	0.001-1.74	181	0.036
0270000	Stem vegetables	0.01*-9	0.001	0.001-5.05	238	0.022
0300000	Pulses (dried)	3	0.002	0.008-0.201	22	0.014
0401000	Oilseeds ^{d)}	0.06-3	0.005	0.21- 0.042	2	0.032
0500000	Cereals	0.15-4	0.001	0.01-0.069	14	0.018
0700000	Hops (dried)	80	0.01	0.043-13.8	20	1.8
1040000	Honey and other apiculture products	0.15	0.001	0.011-0.19	15	0.019
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of boscalid is not expected)						
0110000	Citrus fruits	2	0.001	0.011-0.045	20	0.022
0120000	Tree nuts	0.05*-1	0.005	0.03-0.031	2	0.031
0280000	Fungi, mosses and lichens	0.01*	0.001	0.001-1.9	1	0.002
0290000	Algae and prokaryotes organisms	0.01*	0.01	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*-3	0.005	0.021-0.042	2	0.032
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.01*-40	0.005	0.024-0.09	6	0.046
0800000	Spices (dried)	0.4-0.9	0.005	0.012-0.018	2	0.015
0900000	Sugar plants	0.4-7	0.005	0.036	1	0.036

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2022/1324 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) Residues are not only related to direct use but can also be taken up from rotational crops; d) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Oilseeds, appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0401000 and non-use of the substance for all other commodities '040N000' that are reported under the 'broader' category 0400000 on the table. This creates an inconsistency in the results indicating non-uses which are overestimated.

Table 3.5.3.2-2b: Occurrence of boscalid from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Boscalid (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b), c)} only (mg/kg)	Total no. of quantified results ^{d)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0130000	Pome fruits	0.01*-2	0.001	0.012-0.31	4	0.02
0140000	Stone fruits	0.01*-5	0.002	0.003-0.125	7	0.013
0150000	Berries and small fruits	5-15	0.001	0.001-16	405	0.021
0160000	Miscellaneous fruits	0.01*-5	0.002	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	2-4	0.001	0.018-0.1	3	0.027
0220000	Bulb vegetables	0.5-6	0.01	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.05-4	0.001	0.001-0.2	22	0.027
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	5-9	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*-50	0.002	0.026-8	11	0.083
0260000	Legume vegetables	0.06-5	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*-9	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	3	0.002	<LOQ	0	<LOQ
0401000	Oilseeds ^{d)}	0.06-3	0.002	0.027-0.035	2	0.031
0500000	Cereals	0.15-4	0.001	0.01-0.079	4	0.011
0700000	Hops (dried)	80	0.01	0.054-19	5	5.5
1040000	Honey and other apiculture products	0.15	0.001	0.001-0.057	28	0.004
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of boscalid is not expected)						
0110000	Citrus fruits	2	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.05*-1	0.01	0.016	1	0.016
0280000	Fungi, mosses and lichens	0.01*	0.005	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0400000	Oilseeds and oil fruits	0.01*-3	0.002	0.027-0.035	2	0.031
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.01*-40	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.4-0.9	0.01	0.013	1	0.013
0900000	Sugar plants	0.4-7	0.002	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2022/1324 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) residues are not only related to direct use but can also be taken up from rotational crops; d) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Oilseeds, appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0401000 and non-use of the substance for all other commodities '040N000' that are reported under the 'broader' category 0400000 on the table. This creates an inconsistency in the results indicating non-uses which are overestimated.



Occurrence of boscalid in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 10,411 samples were collected and analysed for boscalid from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 8,654 (83.12%) were unprocessed and 1,757 (16.88%) 0.440 processed commodities. No residues were quantified in 10,365 samples out of the 10,411 samples (99.56%). In 46 samples out of the 10,411 samples (0.44%) boscalid was found at or above the analytical LOQ but below or at the MRL. No MRLs exceeded in samples from organic production. These findings are summarised in Appendix B, Table B-5.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.5.3.2-3a for unprocessed and in Table 3.5.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on boscalid in feed labelled as organic were submitted to EFSA.

Table 3.5.3.2-3a: Occurrence of boscalid from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Boscalid (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b), c)} only (mg/kg)	Total no. of quantified results ^{d)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	2	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.05*–1	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*–2	0.001	0.024–0.174	4	0.053
0140000	Stone fruits	0.01*–5	0.001	0.002–0.054	4	0.019
0150000	Berries and small fruits	5–15	0.001	0.035–0.21	5	0.086
0160000	Miscellaneous fruits	0.01*–5	0.001	0.018	1	0.018
0210000	Root and tuber vegetables	2–4	0.001	0.001–0.019	7	0.003
0220000	Bulb vegetables	0.5–6	0.001	0.001–0.044	6	0.016
0230000	Fruiting vegetables	0.05–4	0.001	0.001–0.1	2	0.051
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	5–9	0.001	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*–50	0.001	0.001–1.7	11	0.003
0260000	Legume vegetables	0.06–5	0.001	0.011	1	0.011
0270000	Stem vegetables	0.01*–9	0.001	0.016	1	0.016
0280000	Fungi, mosses and lichens	0.01*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	3	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–3	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.15–4	0.001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.01*–40	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	80	0.01	0.3	1	0.3
0800000	Spices (dried)	0.4–0.9	0.01	<LOQ	0	<LOQ

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Boscalid (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b), c)} only (mg/kg)	Total no. of quantified results ^{d)}	Median of results from samples with quantified residues only (mg/kg)
0900000	Sugar plants	0.4–7	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.15	0.005	0.008	1	0.008

*Limit of quantification in Reg. (EC) No 396/2005;

a) Maximum Residue Level in Reg. (EU) No 2022/1324 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) residues are not only related to direct use but can also be taken up from rotational crops; d) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.5.3.2-3b: Occurrence of boscalid from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Boscalid (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b), c)} only (mg/kg)	Total no. of quantified results ^{d)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	2	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.05*–1	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*–2	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*–5	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	5–15	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*–5	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	2–4	0.01	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.5–6	ND	ND	ND	ND
0230000	Fruiting vegetables	0.05–4	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	5–9	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*–50	0.01	<LOQ	0	<LOQ
0260000	Legume vegetables	0.06–5	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*–9	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.01	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0300000	Pulses (dried)	3	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–3	0.002	<LOQ	0	<LOQ
0500000	Cereals	0.15–4	0.0001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.01*–40	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	80	ND	ND	ND	ND
0800000	Spices (dried)	0.4–0.9	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.4–7	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.15	0.001	0.002–0.006	2	0.004

*Limit of quantification in Reg. (EC) No 396/2005; ND – no data available.

Findings of not authorised substances in organic products

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2022/1324 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) residues are not only related to direct use but can also be taken up from rotational crops; d) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of boscalid in the EU Organic Farming Information System

The EU OFIS reported 29 findings for boscalid in 2021 and 2022. Nineteen of the products sampled and analysed had EU origin and 10 were of non-EU origin. Residues were found in 13 samples of berries and small fruits (strawberries, raspberries, blueberries and mixed fruits – other), one sample of root and tuber vegetables (carrots), six samples of bulb vegetables (garlic and garlic – Violet Spring), three samples of leaf vegetables, herbs and edible flowers (roman rocket/rucola and chive), one sample of oilseeds and oil fruits (sunflower seeds), one sample of herbal infusions from leaves and herbs (strawberry – wormwood), two samples of hops (hops) and two samples of products or part of products exclusively used for animal feed production (hop pellets). The concentrations of boscalid residues were above LOQ but below MRL in all 29 samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005³. No MRLs exceeded. The highest concentration was reported for a sample of hops pellets of EU origin, with the quantified level of 0.74 mg/kg. These findings are summarised in Table 3.5.3.2-4.

Table 3.5.3.2-4: Occurrence of boscalid from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
<i>Samples of EU origin</i>				
0152000	Strawberries	6	0.02; 0.012 – Strawberries	0.018; 0.018 – Strawberry purée
0153030	Raspberries (red and yellow)	10	ND	0.025 – Raspberries crumble
0213020	Carrots	2	ND	0.019 – Carrots (dehydrated)
0220010	Garlic	5	0.026; 0.036; 0.005; 0.05 – Garlic 0.189; 0.016 – Garlic (Violet Spring)	ND
0251060	Roman rocket/rucola	50	0.05; 0.05 – Rocket	ND
0256020	Chives	50	0.023 – Chives roots	ND
0632010	Strawberry	0.9	0.038 – Wormwood	ND
0700000	Hops	80	0.3 – Hops	ND
1200000	Products or part of products exclusively used for animal feed production	NA	ND	0.3; 0.74 – Hops pellets
<i>Samples of non-EU origin</i>				
0152000	Strawberries	6	0.066; 0.041; 0.019; 0.041 – Strawberries	ND
0154010	Blueberries	15	0.017 – Freeze Dried Bilberry 0.01 – Blueberries	ND
0401050	Sunflower seeds	1	0.009 – Sunflower seeds	ND
0700000	Hops	80	0.032 – Hops	ND

*Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2022/1324 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').



Occurrence of boscalid in untreated samples (control samples) from residue trials

Quantified findings in control (untreated) samples were observed for boscalid in residue trials from Germany that were carried out in indoor black currants. Concentrations were measured in fruits at 2×0.16 , 0.24 and 0.44 mg/kg (Germany, 2014a).

No evidence-based explanations on the causes for these occurrences in control (untreated) samples were provided in the above-mentioned evaluation report.

- Could the presence of boscalid and/or its residues be due to biocide use?

Boscalid is not approved for biocidal use, therefore, residues due to biocidal use are not expected for boscalid.

3.5.3.3 Behaviour in food and feed products

- What key physico-chemical properties of boscalid currently not authorised for EU organic farming are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of boscalid are reported in Table 3.5.3.3.

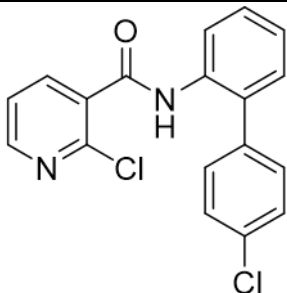
Boscalid exhibits a very high persistence in soil (see Section 3.5.3.5). Regarding sorption to soil, the range of K_{Foc} in Table 3.5.3.3 indicates that the substance has low mobility in soil (EC, 2008).

The maximum calculated PEC_w for boscalid for the representative uses was 12.85 µg/L (spray application to winter oil seed rape; 1×250 g a.s./ha) (Slovakia, 2018)⁵⁰.

Boscalid was found to be stable under the standard conditions of pasteurisation, baking, brewing, boiling and sterilisation (EFSA, 2014c). Considering that boscalid is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Boscalid has low vapour pressure (10^{-7} Pa at 20°C) (EFSA, 2014c).

Table 3.5.3.3: Physico-chemical properties of boscalid (EFSA, 2014c; EC, 2008)

Structural formula	

⁵⁰ Information on PEC_w included in the Rapporteur Assessment Report under public consultation has not undergone peer-review by EFSA.

Appearance (state purity)	White crystalline solid, odourless (minimum 99.4 %)
Melting point (state purity)	143–144°C (99.7%)
Boiling point	NA
Temperature of decomposition	NA
Vapour pressure (state temperature, state purity)	7.2×10^{-7} Pa at 20°C
Henry's law constant (state temperature)	5.178×10^{-5} Pa m ³ /mol
Solubility in water (state temperature, state purity and pH)	4.6 mg/L at 20°C (99.4 %) No dissociation in water, therefore no pH dependency
Partition coefficient (state temperature, pH and purity)	Log Pow = 2.96 (pH 7.1, 21°C) No dissociation in water, therefore no pH dependency
Partition coefficient (octanol/air)	Log Poa = 12.7 (EPISuite KOAWIN v1.10) (Debler et al. 2024)
Atmospheric half-life	DT ₅₀ : < 1.1 d AOPWIN Version 1.88, [OH radicals] = 8×10^5 molecules/cm ³
Dissociation constant (state purity)	No dissociation in water
Soil adsorption (range)	K _{Foc} = 507–1110 mL/g
Hydrolytic degradation (>10%)	Stable at pH 4, pH 7 and pH 9.

DT₅₀ – Disappearance time of 50% of the substance in field studies; NA – not applicable; pH – Potential of Hydrogen; Pow – Octanol/water Partition Coefficient; Poa – Octanol/air Partition Coefficient

3.5.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from the soil surface at which it is applied).

The highest drift of boscalid to neighbouring fields may occur during its applications to fruit crops (up to 29.2 %), hops (19.33 %), vineyards and vegetables (up to 8.02 %) and field crops (up to 2.77 %). Drift values should take into consideration the rate received by neighbouring fields, expressed as the percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. buffer zones or spray drift-reducing nozzles).

If organic crops are present adjacent to the conventional crops treated, measurable residues of boscalid in the untreated crop cannot be excluded (above all if the treated crops are fruit trees). However, since the nature of the potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

3.5.3.5 Accumulated/historical residue levels in soil

- What is the persistence of boscalid and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

According to available data (EFSA, 2014c), the DT₅₀ of boscalid in soil has a worst-case field value of 746 days with the associated DT₉₀ not being reported, though it is stated that there was biphasic decline. The DT₉₀ would be expected to be higher (uncertain but >2,500 days which is around what would be expected for a first-order (and not biphasic) decline) indicating a potential for accumulation in soil after discontinued use of the substance.

The potential plant uptake of residues of boscalid from soil previously treated with boscalid was investigated in field rotational crop studies submitted to EFSA and in the context of evaluation of the Joint Meeting on Pesticide Residues (JMPR) (EFSA, 2014c; WHO/FAO, 2010). Results from studies carried out in Europe, the US and Japan and reported by JMPR (WHO/FAO, 2010) showed that boscalid applications in bare soil with annual application rates ranging from 2.0 to 2.15 kg a.s./ha, result in plant uptake of boscalid from this soil: root and tuber vegetables (0.05 and 0.37 mg/kg), brassica vegetables (0.035 and 0.05 mg/kg), sweet corn cobs (0.05 mg/kg), pulses and oilseeds (0.05 and 0.06 mg/kg), cereal grains (0.05 and 0.12 mg/kg), root crop leaves and tops (0.05 and 0.84 mg/kg), various legume animal feed (0.08 and 1.46 mg/kg) and cereal straw and fodder (0.21 and 6.8 mg/kg) (EFSA, 2014c).

In Regulation (EC) No 396/2005³ a default MRL (0.05 mg/kg) was established for annual crops for which no use is anticipated in order to cover uptake from soil due to the legal use of the substance to another crop (EFSA, 2014c). In the EFSA MRL review MRL proposals were made for rotational crops based on rough estimates that are subject to considerable uncertainties.

Based on the above, transfer of boscalid in plants planted or sown in soil previously treated with boscalid cannot be excluded in organic crops, even if they are planted 2 years after the last chemical treatment, as required by the regulatory provisions for organic agriculture².

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Boscalid accumulates in soil (EFSA, 2014c).

Monitoring data for boscalid in soil are available from the LUCAS pesticides 2018 (JRC, 2023) on IPCHEM¹². According to Franco et al. (2024), boscalid was detected in 20% of sites included in the LUCAS soil survey, ranking among the most frequently identified pesticide residues in European soil.

The data from LUCAS soil show background levels of the substance in soil samples from 23 EU countries: Austria (2 samples), Belgium (6 samples), Bulgaria (17 samples), Cyprus (2 samples), Czechia (31 samples), Denmark (35 samples), Estonia (13 samples), France (319 samples), Germany (54 samples), Greece (12 samples), Hungary (26 samples), Ireland (1 sample), Italy (35 samples), Latvia (8 samples), Lithuania (17 samples), the Netherlands (11 samples), Poland (28 samples), Portugal (2 samples), Romania (2 samples), Slovakia (1 sample), Slovenia (1 sample), Spain (38 samples) and Sweden (3 samples). The reported residue levels in soil ranged from 0.0011 mg/kg to 0.67 mg/kg. The highest value corresponds to a soil sample from Belgium. In LUCAS soil, the lack of information on the agricultural use history of the sites where soil was sampled precluded knowing whether the reported quantified findings were related to recent active use or historical levels in soil for boscalid.

In a study by Riedo et al. (2021) the presence of boscalid was analysed in soil samples from 60 agricultural sites with different management systems (conventional tillage, conventional without soil tillage, and organic) sampled in May 2016 for an on-farm study throughout Switzerland. Results showed the presence of boscalid in 24% of the samples at concentrations ranging from 0.00092 to 0.11 mg/kg in all types of soil, with higher levels in soil from no-till and conventional arable farming. The concentrations in soil under organic farming systems were reported to be <0.005 mg/kg in a total of two out of 40 samples (5%).

Further evidence of boscalid levels in soil was provided by Silva et al. (2023) in a study carried out under the framework of the EU SPRINT project. The study assessed the presence of 209 pesticide residues in 100 soil samples from conventional agriculture and 63 soil samples from organic agriculture collected during the 2021 growing season across 10 study sites in Europe: Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark. Boscalid was quantified in 37 conventional soil samples (37%) from all countries but Slovenia at concentrations ranging from 2.9 to 413.7 µg/kg and 11 soil samples under organic farming systems (17%) from Croatia, Denmark, France and Italy at concentrations ranging from 6 to 47.1 µg/kg. The highest concentrations were found in conventional soil from Portugal and soil under organic farming systems from France.

Considering that boscalid is very persistent in the soil, that plant uptake of boscalid from soil containing residues is plausible and that boscalid was found in soil of organic agriculture, it can be concluded that the uptake of residues of boscalid by organic crops planted in such soil cannot be excluded. If boscalid is quantified in organic crops, an analysis of the soil the plants were grown in is recommended.

3.5.3.6 Residues from water used for irrigation

- Is there evidence that residues of boscalid present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for boscalid in water samples were considered:

- The EEA-WATERQUALITY³⁹ database (data retrieved on 10 April 2024) reports 2,186 analytical results from water samples collected in Estonia (21 samples), France (498 samples), Italy (1,228 samples), the Netherlands (433 samples) and Sweden (5 samples) between 2018 and 2020;
- The EMPODAT database (data retrieved on 21 March 2024) reports 553 analytical results from surface water samples collected in the Netherlands between 2017 and 2019; 18 analytical results from groundwater samples collected in 2019 in Austria (3 samples), Bulgaria (3 samples), Croatia (3 samples), Hungary (3 samples), Romania (3 samples) and Slovakia (3 samples);
- The NAIADES database (data retrieved on 21 March 2024) reports 103 analytical results from surface water samples collected in France from 2020 to 2022.

Based on the screening process described in section 'Data and methodologies', for 70% of water samples analysed and reported in the above-mentioned databases (1988 samples), the residue concentrations in these waters were below the screening Cw of 0.11 µg/L and, therefore, transfer of residues from water sources to plant commodities is unlikely.

For 30% of samples (854 out of 2,842 results), the residue concentrations were found to be at or above the screening Cw of 0.11 µg/L and the potential transfer of residues to plant commodities if water containing residues at these levels is used for irrigation cannot be excluded. Since Cw is a screening value derived from worst-case calculations it requires experimental evidence in order to confirm or rule out the potential transfer of residues from the specific water sources. Therefore, if boscalid is quantified in organic commodities, analysis of the water source used to irrigate the plant is recommended.

The high number of samples exceeding the screening Cw for boscalid was investigated. It was noticed that 100% of samples reported in NAIADES (103 samples) and 100% of samples reported in EMPODAT (553 samples) were exceeding the screening Cw. In contrast, only 9% of samples from EEA-WATERQUALITY (198 out of 2,186 samples) were exceeding the screening Cw. This, combined with the fact that some sites were monitored multiple times during the study period, suggests that samples reported in NAIADES and EMPODAT were collected based on more risk-based strategies, aiming for positive findings.

In a study by Silva et al. (2023) carried out under the framework of the EU SPRINT project the authors assessed the presence of 209 pesticide residues in 58 water samples collected during the 2021 growing season across 10 study sites in Europe (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). Boscalid was detected in four samples (7% detection frequency) from France, Portugal and Spain at concentrations ranging between 0.018 and 0.91 µg/L. Only one sample from Portugal was found to contain residues above 0.1 µg/L.

Overall, the available evidence suggests that the transfer of residues of boscalid from water sources to plant commodities when this water is used to irrigate the plant, cannot be excluded.

3.5.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *boscalid*, *industry/industrial*, and *air/atmosphere*) did not identify any relevant European study.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water.

A mapping exercise was conducted by overlaying georeferenced water sampling data from IPCHEM (2020–2022) with georeferenced data on chemical industry facilities from the European Industrial Emissions Portal. Of the 854 relevant water samples (exceeding the screening value, as reported in Table 1), 164 were collected between 2020–2022. For the conducted spatial analysis, it is important to note that these numbers reflect the total number of sampling events rather than distinct sampling locations, as some sites were monitored multiple times during the study period. Of these 164 samples, none was located within a 1 km radius of a chemical facility, whilst 13 fell within a 5 km radius. No clear spatial association was identified.

A literature review was conducted to gather additional relevant information. A search in the Scopus database conducted on February 7, 2025, using the keywords *boscalid*, *industry/industrial*, and *water*) identified one article with potentially relevant information.

In a study by Sayed et al. (2021), the authors assessed the presence of 111 pesticides in wastewater samples at three vegetable and two potato processing companies located in Flanders (Belgium). Washed, peeled and/or cut, and frozen fries and vegetables were the main end products of the companies. Samples were collected over 1 year (2019–2020), resulting in a total of 52 water samples (26 untreated influent water samples and 26 treated water samples). All treatment plants consisted of a primary, secondary and potentially tertiary treatment unit before discharging the treated water. Boscalid was found to be predominant in the vegetable industry, found in the three processing companies. Boscalid was detected above 0.1 µg/L in 24 of 26 samples of the untreated influent water with a maximum of 8.79 µg/L for boscalid. For the treated water, boscalid residues were measured above 0.1 µg/L in 17 of 26 samples, with a maximum of 18.32 µg/L. According to the authors, pesticide residues in wastewater from the vegetable industry could originate from a mix of different crops. Also, the possible accumulation of pesticide residues could take place when reusing treated water within the same production processes.

Overall, a mapping of the locations of water samples on IPCHEM that were analysed for boscalid with georeferenced data from the EEA's industrial emissions portal did not show associations between environmental occurrence and industrial activity in the surrounding areas. The one study from the literature showing a transfer of residues from industrial activity to environmental water sources does not provide insight into the potential transfer of residues from water to plants.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Although plant uptake of boscalid from soil containing boscalid cannot be excluded, there is no evidence showing that residues from industrial emissions are transferred to soil at levels that might be taken up by plants and their products.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 17, 2025, using the keywords *boscalid*, *industry/industrial*, and *soil/sediment*) did not identify any relevant European study.

3.5.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Medium and long-range aerial transport of residues

In a study by Figueiredo et al. (2021), the authors investigated pesticide presence in air samples during periods of use and non-use of boscalid in the surrounding area (up to 500 m distance) from the agricultural field (bulb field) in the Netherlands between May 2016 and December 2017. Aerial concentrations of boscalid appeared to decrease between use and non-use periods. Comparable aerial concentrations were reported for locations close to the agricultural areas and at a 500 m distance. According to the authors, boscalid's persistence in soil ($DT_{50} > 1$ year)

combined with its atmospheric persistence ($DT_{50} < \text{half-day}$) leads to a continuous release of residues to the atmosphere and to an even distribution of boscalid in the broader area.

Silva et al. (2023) investigated the presence of boscalid in 20 outdoor air samples collected during the 2021 growing season across 10 study sites in Europe of organic and conventional agriculture (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). The study was carried out under the framework of the EU SPRINT project. Organic fields had not been treated for 5 consecutive years. Boscalid was quantified in three out of 20 targeted samples at concentrations of 53.9 ng m^{-3} in Czechia and 165 ng m^{-3} in Portugal from the surrounding area of conventional fields, and at a concentration of 33.3 ng m^{-3} in Portugal from the surrounding area of an organic field. The presence of positive findings (17%) in air suggests that transfer of boscalid to nearby plants cannot be excluded.

In a study investigating the potential transport of pesticide residues from apple-growing fields in South Tyrol (Vinschgau Valley) to higher altitudes, an analysis of the soil showed an average concentration of 0.013 mg/kg for boscalid in six out of the 53 samples analysed (Brühl *et al.*, 2024). These results indicate the plausibility of aerial transport (through aerosols) as a potential source of residues of boscalid in soil outside the treated areas.

In another study published by Debler et al. (2024) under the EU SPRINT project, boscalid was quantified in air samples from two agricultural areas of conventional farming in Portugal (vineyard) and the Netherlands (potatoes, onions and sugar beet) collected between April 2021 and June 2022. Aerial concentrations ranged between 18 and 23 pg/m^3 in Portugal (5% detection frequency) and between 14 and 18 pg/m^3 in the Netherlands (3% detection frequency). Note was taken that the Dutch agricultural areas had not undergone boscalid treatment before sample collection in the surrounding area and measurement.

In a study by Mayer et al. (2024) residues of boscalid were quantified in air samples from 29 sampling sites classified as rural, coastal, mountain and polar. The samples were collected from 15 EU countries i.e. Austria, Czechia, Estonia, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Poland, Slovakia, Spain and Sweden, Switzerland and the United Kingdom during the main pesticide application period in spring 2020. To investigate aerial transport in polar sites, air samples from the European Arctic were also collected. Results showed the presence of boscalid at levels from 0.6 to 4 pg m^{-3} in the rural sites, from 0.8 to 9 pg m^{-3} in the coastal sites and from 0.9 to 11 pg m^{-3} in the mountain sites (the exact concentration ranges are not reported in the paper). The maximum concentration was quantified in a mountain area in Slovakia. For the rural area, the maximum concentrations were quantified in Germany, France and Spain, whilst for the coastal area, the highest concentration was reported in Spain. Boscalid was not quantified in the Arctic sites. The total frequency of findings for all areas was below 50% (the exact % detection frequency is not reported in the paper).

Overall, the results of these studies indicate that aerial transport (through aerosols) of boscalid outside treated agricultural areas cannot be excluded.

Uptake from organic fertilisers

In a study investigating pesticide residues in organic fertilisers, residues of boscalid and other pesticides were quantified (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). The authors attributed the origin of the residues to the presence of plant protection products in the composted crop or in composted manure due to transfer from animal feed after digestion, or in straw used in stables. Analysis of solid organic fertilisers gave an average

concentration of 0.312 mg/kg for boscalid in two out of 147 samples. Considering that (according to the authors) the use of completely free from residues organic fertilisers is currently unsustainable, transfer of boscalid residues from fertilisers used in organic production to organic products cannot be excluded. On the other hand, no residues of boscalid were found in any of the products of the crops discussed in the study (van der Blom et al., 2022, under 'Documentation as provided to EFSA').

3.5.4 Conclusions on boscalid

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use.
- Residue trials carried out to support the critical GAPs⁴ for boscalid, gave residue concentrations of up to 33.6 mg/kg in hops (dried) and up to 52.7 mg/kg in cereal straw. Concentrations in the ranges reported in Table 3.5.3.2-1 might be associated with active use of boscalid according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.
- Boscalid was quantified in untreated (control) black currant samples in the context of residue trials carried out in Germany. The highest concentration observed was 0.44 mg/kg.
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for boscalid in unprocessed commodities with authorised uses ranged from 0.014 mg/kg in pulses (dried) to 1.8 mg/kg in hops (dried).
- In organic commodities that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings, the median concentrations for boscalid in unprocessed commodities ranged from 0.003 mg/kg in root and tuber vegetables, leaf vegetables, herbs and edible flowers to 0.086 mg/kg in berries and small fruits.
- Without additional information on the individual samples' history and context, it is not possible to conclude if quantified results in organic commodities are associated with active use or the unintentional presence of boscalid.
- In organic processed commodities, residues of boscalid were quantified in two of the samples analysed. In samples from processed products not labelled as organic with five or more quantified findings, the median concentrations of residues of boscalid ranged from 0.004 mg/kg in honey to 5.5 mg/kg in hops (dried). Considering that boscalid is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.
- Overall, in commodities labelled as organic, boscalid was quantified in 0.44% of samples (46 out of 10,411 samples). This percentage is approximately 24 times lower than the percentage reflecting the number of findings in samples not labelled as organic (10.52%)

(see Appendix B, Tables B-5.1 and B-5.2). These results suggest that the occurrence of residues of boscalid in organic products is less likely when compared with the conventional commodities.

- Other potential sources of residues are drift from conventional crops grown in the vicinity or from medium-range aerial transfer of residues over distances up to 1000km through aerosol transport.
- Boscalid is persistent in soil. Studies assessed by EFSA on crops growing in rotation showed that plant uptake of boscalid from soil containing residues cannot be excluded. Therefore, potential sources of the unintentional presence of residues of boscalid in commodities of plant origin are plant uptake from soil that had been treated with boscalid in the past. If boscalid is quantified in organic crops, analysis of the soil in which the plants were grown is recommended.
- Transfer of residues from boscalid-containing water to plant commodities via irrigation cannot be excluded. If boscalid is quantified in organic commodities, analysis of the water source used to irrigate the plants is recommended.
- Plant uptake of residues of boscalid from organic fertilisers is considered a less likely explanation for residues found in crops where boscalid has not been actively used.
- A mapping of the locations of samples analysed for boscalid on IPCHEM with georeferenced data from the EEA's industrial emissions portal did not show associations between environmental occurrence and industrial activity in the surrounding areas. The one study from the literature showing a transfer of residues from industrial activity to environmental water sources does not provide insight into the potential transfer of residues of boscalid from water to plants and although plant uptake of boscalid from soil containing boscalid cannot be excluded, there is no evidence showing that residues from industrial emissions are transferred to soil at levels that might be taken up by plants and their products.

The pathways of residues of boscalid to plants and plant commodities are summarised in Figure 5.



Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded



3.6 Tebuconazole

3.6.1 Method(s)

- What is/are the residues to be monitored for the active substance tebuconazole according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

For the active substance tebuconazole, the residue definition for enforcement in food and feed of plant origin has been provisionally proposed by EFSA as the sum of enantiomers of tebuconazole, pending the outcome of a comprehensive risk assessment approach for triazole metabolites (TDMs), i.e. triazole alanine, triazole lactic acid, triazole acetic acid and 1,2,4-triazole (EFSA, 2014d, 2018d). TDMs are common metabolites of tebuconazole and several other triazole active substances and their presence may also relate to the use of some fertilisers (EFSA, 2018d). Therefore, findings of TDMs in food and feed are not necessarily associated with the use of tebuconazole.

The residue definition for enforcement proposed by EFSA is applicable to primary, rotational crops and processed products (EFSA, 2014d).

In Regulation (EC) No 396/2005³, the residue definition for enforcement for plant commodities is implemented as 'tebuconazole'. The same residue definition is also applicable to honey and other apiculture products.

Since TDMs are not included in the residue definition for enforcement and are, therefore, not monitored, only residues of tebuconazole in food and feed of plant origin, honey and other apiculture products will be considered in this technical report.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

A multi-residue QuEChERS method using HPLC-MS/MS is validated for the monitoring of residues of tebuconazole at or above the LOQ of 0.01 mg/kg in high water content, acidic, high oil and dry commodities (EFSA, 2018e). The method quantifies residues of tebuconazole as the sum of its enantiomers.

Another multi-residue method (DFG-S19) has been sufficiently validated in high water content, acidic, high oil content, and dry commodities. This method achieves an LOQ of 0.02 mg/kg utilising full scan GC-MS (EFSA, 2011b, 2014d).

According to the EURL for Residues of Pesticides (EURL, 2024, under 'Documentation as provided to EFSA'), a multi-residue citrate-buffered QuEChERS method based on LC-MS/MS is validated to monitor tebuconazole residues in honey samples at an LOQ of 0.002 mg/kg. Higher sensitivities can be achieved by utilising multi-residue LC-Q-TOF methods (LOQ: 0.001 mg/kg).

Overall, multi-residue methods are available for the monitoring of residues of tebuconazole in high water, high acid, high oil content and dry plant commodities, as well as in honey and other apiculture products. LOQs for methods of analysis of tebuconazole residues range from 0.001 to 0.02 mg/kg.



3.6.2 Authorisation status and use

- Is tebuconazole currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has tebuconazole ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

a) Authorisations for plant protection use in conventional agriculture

Tebuconazole has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of approval of the active substance is on 15 August 2026, as indicated in the EU Pesticides Database⁵ (accessed 9 January 2024). The application for the renewal of the approval of tebuconazole is under assessment.

According to the EU Pesticides Database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, France, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, and Slovakia.

b) Authorisations for purposes other than plant protection

Biocidal use

Tebuconazole has been approved for biocidal use in the EU Member States, Iceland, Liechtenstein and Norway in accordance with Regulation (EU) No 528/2012⁷. The approval relates to the use of the substance as a film preservative (from 1 July 2015 to 30 June 2025), as a wood preservative (from 1 April 2010 to 30 June 2026), and as a construction material preservative (from 1 July 2015 to 30 June 2025), as indicated in the ECHA website⁶ (accessed on 6 June 2024). The application for the renewal of the approval of tebuconazole as a wood preservative is under assessment.

According to the ECHA website⁶, at national level, tebuconazole has been authorised for use as a wood preservative in biocidal product formulations in Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden.

Other uses

A search carried out on the ECHA website⁹ (accessed 6 June 2024) showed that tebuconazole had one registration under REACH which has been inactive since 2012 due to cease of manufacture/import.

- What is/was the actual use of tebuconazole? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of tebuconazole

Tebuconazole is a systemic fungicide within the triazole class (EFSA, 2011b). It acts as an ergosterol biosynthesis inhibitor (EBI), preventing the production of ergosterol which is essential for fungal growth. This disruption effectively suppresses fungal growth, preventing further



infection and/or invasion of host tissues. Tebuconazole is widely used against various fungal pathogens in many agricultural crops (EFSA, 2010a, 2011b, 2012e, 2013c, 2015e).

Tebuconazole has also been approved as a plant growth regulator (EC, 2014b).

Conditions of use and applicable crops

The uses reported in the EFSA MRL review for tebuconazole included applications from the northern and southern EU in food and feed commodities belonging to the following crop groups: citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds and oil fruits, cereals, hops (dried), seed spices (dried), sugar plants and grass (EFSA, 2011b).

After the EFSA MRL review, applications were submitted to modify the existing MRLs or support new uses for citrus fruits (except oranges), miscellaneous fruits (table olives), fruiting vegetables, leaf vegetables, herbs and edible flowers, legume vegetables (beans with pods), oilseeds and oil fruits, cereals and herbal infusions (EFSA, 2012e, 2013c, 2015d,e, 2017a, 2018e).

Note was taken that food uses in legume vegetables and feed uses in grass were not supported by data (see Section 3.6.3.2 'Active use (all legitimate uses of the substance)').

Tebuconazole treatment included outdoor and indoor foliar applications, seed and post-harvest treatments:

- Foliar applications were reported for commodities belonging to the following crop groups: tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits (table olives), root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds and oil fruits, cereals, herbal infusions (dried), hops (dried), seed spices (dried) and sugar plants (sugar beet) and grass (EFSA, 2011b, 2012e, 2013c, 2014d, 2015d,e, 2017a, 2018e). Application rates range from 30 g a.s./ha to 562.5 g a.s./ha for outdoor cultivation and from 62.50 g a.s./ha to 375 g a.s./ha for indoor cultivation (EFSA, 2011b).
- Post-harvest treatments were reported for citrus fruits (EFSA, 2011b, 2012e). Application rates for indoor cultivation range from 2.58 g a.s./ton to 161.25 g a.s./ton (EFSA, 2011b, 2012e).
- Seed treatment was reported for bulb vegetables with an application rate of 2 a.s./dt seeds and for cereals with an application rate ranging from 3 g a.s./dt seeds and 6 g a.s./ha to 3.75 g a.s./100 kg seeds and 180–250 kg seed/ha (EFSA, 2011b, 2014d).

b) Uses for purposes other than plant protection

Biocidal use

Products containing tebuconazole were identified for use as fungicide wood preservatives in the pre-treatment of timber and protective treatment of wood applied *in situ*, used indoors and/or outdoors. The products are used by industrial as well as professional and non-professional users, including treatments such as vacuum impregnation with applications rates ranging from 50 g a.s./m³ to 100 g a.s./m³ and spraying/dipping applications from 0.15 g a.s./m² to 1 g a.s./m²



(Denmark, 2007) (see also 'authorisations for purposes other than plant protection/biocidal use').

Other uses

According to the search carried out on ECHA website⁹ there is 1 REACH (inactive) registration dossier available for tebuconazole since 2012.

3.6.3 Sources of residues in plants

3.6.3.1 Natural occurrence

- Is there evidence that tebuconazole occurs naturally? What is known about the natural origin of this substance?

Tebuconazole is a synthetic chemical produced industrially through chemical processes (Lewis et al., 2016; Wu et al., 2023; Folorunso et al., 2024). No information on the potential natural presence of tebuconazole was found in the literature²².

3.6.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of tebuconazole per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of tebuconazole in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.6.3.2-1 to 3.6.3.2-4. Findings relating to residues in control (untreated) samples are also discussed in this section.

In all matrices and for both residue trials and results from monitoring, tebuconazole residue concentrations refer to the applicable residue definition for enforcement (i.e. tebuconazole).

Occurrence of tebuconazole from residue trials carried out for the critical GAP per crop

Following product applications based on the critical GAPs⁴ reported to EFSA, residue levels of tebuconazole were below the LOQ in tree nuts (EFSA, 2011b).

Residues of tebuconazole were quantified in citrus fruits, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops) and leaf vegetables, herbs and edible flowers, stem vegetables, pulses (dried), oilseeds and oil fruits, cereals, hops (dried and hop pellets) and seed spices (black caraway) (EFSA, 2011b, 2012e, 2013c, 2014d, 2015d,e, 2018e). Regarding feed commodities, residues of tebuconazole were quantified in cereal straw (EFSA, 2011b, 2015d, 2018e).

Although EU GAPs were reported for all uses indicated under 3.6.2 'Conditions of use and applicable crops', data on residue trials for legume vegetables and grass were not submitted and evaluated in the EFSA MRL review (EFSA, 2011b).

These findings are summarised in Table 3.6.3.2-1 'Occurrence of tebuconazole from residue trials carried out for the critical GAP per crop'.

Table 3.6.3.2-1: Occurrence of tebuconazole from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Tebuconazole occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
Food				
0110000	Citrus fruits	0.9–5	0.25–1.75	1.19
0120000	Tree nuts	0.05	<LOQ (0.05)	<LOQ (0.05)
0130000	Pome fruits	0.3–0.5	0.06–0.26	0.11
0140000	Stone fruits	0.02*–1	0.03–0.74	0.14
0150000	Berries and small fruits	0.02*–1.5	0.03–1.20	0.18
0160000	Miscellaneous fruits	0.02*–1.5	<LOQ (0.05)–0.31	0.10
0210000	Root and tuber vegetables	0.02*–0.5	0.02–0.34	0.10
0220000	Bulb vegetables	0.02*–2	<LOQ (0.01)–0.32	0.02
0230000	Fruiting vegetables	0.02*–0.9	<LOQ (0.02)–0.46	0.08
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.02*–0.7	<LOQ (0.01)–1.33 ^{c)}	0.05
0250000	Leaf vegetables, herbs and edible flowers	0.02*–2	<LOQ (0.05)–1.00	0.13
0260000	Legume vegetables ^{d)}	0.02*–2	NR	-
0270000	Stem vegetables	0.02*–0.6	<LOQ (0.05)–0.44	0.16
0300000	Pulses (dried)	0.2–0.3	<LOQ (0.01)–0.17	0.05
0400000	Oilseeds and oil fruits	0.02*–2	<LOQ (0.01)–0.31	0.06
0500000	Cereals	0.02*–2	<LOQ (0.01)–1.10	0.05
0630000	Herbal infusions ^{e)}	0.05*–15	0.39–6.0	2.79
0700000	Hops (dried)	40	5.8–21.0	9.7
0810000	Seed spices (dried)	1.5	0.24–0.68	0.40
Feed				
1200000	Cereal straw	NA	0.09–17.0	1.9
	Grass	NA	NR	-
	Sugar beet top	NA	NR	-

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; NR – no residue trials are available; '-': not estimated due to lack of data.

a) Maximum Residue Level in Reg. (EU) No 2018/1514 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA, 2011b, 2012e, 2013c, 2014d, 2015d,e, 2017a and 2018e; c) Residues exceeding the MRL are related to trials conducted on Chinese cabbage, where a consumer risk was identified (EFSA, 2011b). Consequently, the MRL was set at the specific LOQ of 0.02* mg/kg⁵¹ for the commodity sub-group of leafy brassica; d) For uses not supported by data, the MRLs were lowered to the LOQ, except for beans (with or without pods) and peas (without pods); e) Uses in herbal infusions were supported from residue trials in fresh herbs and applying a dehydration factor (EFSA, 2018e).

Occurrence of tebuconazole under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to tebuconazole are given by Regulation (EU) 2018/1514⁵² for the years 2020–2022.

Regarding commodities non-labelled as organic, 114,697 samples were collected and analysed for tebuconazole in plant commodities, honey and other apiculture products under a monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 105,957 (92.4%) were unprocessed and 8,740 (7.6%) were processed commodities. No residues were quantified in 109,395 out of the 114,697 samples (95.38%). In 5,243 out of the 114,697 samples (4.57%) tebuconazole was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-6.1. MRLs were exceeded in 59 out

⁵¹ Commission Regulation (EU) No 61/2014 of 24 January 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyromazine, fenpropidin, formetanate, oxamyl and tebuconazole in or on certain products. OJ L 22, 25.1.2014, p. 1–32.

⁵² Commission Regulation (EU) 2018/1514 of 10 October 2018 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin, acibenzolar-S-methyl, clopyralid, emamectin, fenhexamid, fenpyrazamine, fluzifop-P, isofetamid, *Pasteuria nishizawae* Pn1, talc E553B and tebuconazole in or on certain products. OJ L 256, 12.10.2018, p. 8–32.

of the 114,697 samples (0.05%). The highest concentrations for samples exceeding the MRLs were 1.6 mg/kg in berries and small fruits (gooseberries (green, red and yellow)) and 1.9 mg/kg in berries and small fruits (table and wine grapes).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.6.3.2-2a for unprocessed and in Table 3.6.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on tebuconazole in feed not labelled as organic were submitted to EFSA.

Table 3.6.3.2-2a: Occurrence of tebuconazole from monitoring data submitted from EU Member States¹¹ Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Tebuconazole (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0110000	Citrus fruits	0.9–5	0.001	0.007–0.27	11	0.017
0120000	Tree nuts	0.05	0.005	<LOQ	0	<LOQ
0130000	Pome fruits	0.3–0.5	0.001	0.001–1	919	0.028
0140000	Stone fruits	0.02*–1	0.001	0.001–0.8	2,539	0.03
0150000	Berries and small fruits	0.02*–1.5	0.001	0.001–1.9	387	0.069
0160000	Miscellaneous fruits	0.02*–1.5	0.001	0.001–0.06	13	0.018
0210000	Root and tuber vegetables	0.02*–0.5	0.001	0.001–0.23	321	0.019
0220000	Bulb vegetables	0.02*–2	0.001	0.001–0.38	50	0.014
0230000	Fruiting vegetables	0.02*–0.9	0.001	0.001–0.77	207	0.028
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.02*–0.7	0.001	0.001–1.5	156	0.025
0250000	Leaf vegetables, herbs and edible flowers	0.02*–2	0.001	0.001–1.7	64	0.026
0260000	Legume vegetables	0.02*–2	0.001	0.005–0.26	20	0.022
0270000	Stem vegetables	0.02*–0.6	0.001	0.002–1.4	182	0.024
0300000	Pulses (dried)	0.2–0.3	0.003	0.005–0.081	9	0.019
0400000	Oilseeds and oil fruits	0.02*–2	0.005	0.010–0.109	9	0.013
0500000	Cereals	0.02*–2	0.001	0.003–0.29	231	0.019
0630000	Herbal infusions ^{d)}	0.05*–15	0.005	0.011–0.079	4	0.022
0700000	Hops (dried)	40	0.005	0.01	1	0.01
0810000	Seed spices (dried)	1.5	0.005	0.042–0.11	3	0.068
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
	Grass	NA	ND	ND	ND	ND
	Sugar beet top	NA	ND	ND	ND	ND
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of tebuconazole is not expected)						
Food						
0280000	Fungi, mosses and lichens	0.02*	0.001	0.011	1	0.011



Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Tebuconazole (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0290000	Algae and prokaryotes organisms	0.02*	0.005	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs ^{d)}	0.05*–15	0.001	0.011–0.022	5	0.014
0800000	Spices (dried)	0.05*–1.5	0.005	0.042–0.11	5	0.064
0900000	Sugar plants	0.02*	0.005	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.1*	0.005	0.01–0.012	2	0.011

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2018/1514 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Herbal infusions appear in both higher and lower parts of the table to indicate the use of the substance for commodities 06300000 and non-use of the substance for all other commodities '06N0000' that are reported under the 'broader' category 0600000 on the table. This creates an inconsistency where the results indicating non-uses are overestimated.

Table 3.6.3.2-2b: Occurrence of tebuconazole from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Tebuconazole (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0110000	Citrus fruits	0.9–5	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.05	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.3–0.5	0.001	0.01	1	0.01
0140000	Stone fruits	0.02*–1	0.005	0.005–0.052	7	0.011
0150000	Berries and small fruits	0.02*–1.5	0.001	0.001–0.2	67	0.02
0160000	Miscellaneous fruits	0.02*–1.5	0.004	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.02*–0.5	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.02*–2	0.01	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.02*–0.9	0.001	0.01–0.49	21	0.07
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.02*–0.7	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.02*–2	0.002	0.005–0.206	11	0.024
0260000	Legume vegetables	0.02*–2	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.02*–0.6	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.2–0.3	0.008	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.02*–2	0.002	0.006–0.11	30	0.017



Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Tebuconazole (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0500000	Cereals	0.02*-2	0.002	0.002-0.025	28	0.012
0630000	Herbal infusions ^{d)}	0.05*-15	0.01	0.048	1	0.048
0700000	Hops (dried)	40	0.005	<LOQ	0	<LOQ
0810000	Seed spices (dried)	1.5	0.01	0.31	1	0.31
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
	Sugar beet top	NA	ND	ND	ND	ND
	Grass	NA	ND	ND	ND	ND

Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of tebuconazole is not expected)

Food						
0280000	Fungi, mosses and lichens	0.02*	0.005	0.01	1	0.01
0290000	Algae and prokaryotes organisms	0.02*	ND	ND	ND	ND
0600000	Teas, coffee, herbal infusions, cocoa and carobs ^{d)}	0.05*-15	0.005	0.048	1	0.048
0800000	Spices (dried)	0.05*-1.5	0.005	0.31	1	0.31
0900000	Sugar plants	0.02*	0.005	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.1*	0.005	0.0101	1	0.01

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2018/1514 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Herbal infusions appear in both higher and lower parts of the table to indicate the use of the substance for commodities 06300000 and non-use of the substance for all other commodities '06N0000' that are reported under the 'broader' category 0600000 on the table. This creates an inconsistency where the results indicating non-uses are overestimated.

Occurrence of tebuconazole in monitoring results 2020–2022 in plant commodities, honey and other apicultural products labelled as organic

Regarding organic production, 10,315 samples were collected and analysed for tebuconazole from plant commodities, honey and other apicultural products labelled as organic under a monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 8,587 (83.25%) were unprocessed and 1,728 (16.75%) processed commodities. No residues were quantified in 10,300 out of the 10,315 samples (99.85%). In 15 out of the 10,315 samples (0.15%) tebuconazole was found at or above the analytical LOQ but below or at the MRL. No samples labelled as organic were above MRLs. These findings are summarised in Appendix B, Table B-6.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.6.3.2-3a for unprocessed and in Table 3.6.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on tebuconazole in feed labelled as organic were submitted to EFSA.



Table 3.6.3.2-3a: Occurrence of tebuconazole from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Tebuconazole (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.9–5	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.05	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.3–0.5	0.001	0.006–0.034	5	0.023
0140000	Stone fruits	0.02*–1	0.001	0.002–0.057	3	0.022
0150000	Berries and small fruits	0.02*–1.5	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.02*–1.5	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.02*–0.5	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.02*–2	0.001	0.004–0.054	5	0.025
0230000	Fruiting vegetables	0.02*–0.9	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.02*–0.7	0.001	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.02*–2	0.001	<LOQ	0	<LOQ
0260000	Legume vegetables	0.02*–2	0.001	<LOQ	0	<LOQ
0270000	Stem vegetables	0.02*–0.6	0.001	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.02*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.02*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.2–0.3	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.02*–2	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.02*–2	0.001	0.108	1	0.108
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*–15	0.003	<LOQ	0	<LOQ
0700000	Hops (dried)	40	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*–1.5	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.02*	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.1*	0.005	<LOQ	0	<LOQ

*Limit of quantification in Reg. (EC) No 396/2005;

a) Maximum Residue Level in Reg. (EU) No 2018/1514 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).



Table 3.6.3.2-3b: Occurrence of tebuconazole from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Tebuconazole (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.9–5	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.05	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.3–0.5	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.02*–1	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.02*–2	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.02*–1.5	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.02*–0.5	0.01	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.02*–0.1	ND	ND	ND	ND
0230000	Fruiting vegetables	0.02*–0.9	0.002	0.034	1	0.034
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.02*–0.7	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.02*–2	0.005	<LOQ	0	<LOQ
0260000	Legume vegetables	0.02*–2	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.02*–0.6	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.02*	0.005	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.02*	ND	ND	ND	ND
0300000	Pulses (dried)	0.2–0.3	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.02*–2	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.02*–2	0.002	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*–15	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	40	ND	ND	ND	ND
0800000	Spices (dried)	0.05*–1.5	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.02*	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.1*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2018/1514 amending Annex II of Reg. (EC) No 396/2005;

b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of tebuconazole in the EU Organic Farming Information System

The EU OFIS reported 27 quantified results for tebuconazole in 2021 and 2022, from which 19 of the products sampled and analysed had EU origin and eight were of non-EU origin. Residues were found in one sample from tree nuts (pistachios), 1 sample of stone fruits (plum), 3 samples of berries and small fruits (grapes), 5 samples from root and tuber vegetables (carrots), 7 samples of bulb vegetables (garlic), 1 sample of fruiting vegetables (chilli), 3 samples of leaf vegetables, herbs and edible flowers (spinach, grape leaves and thyme), 1 sample of fungi, mosses and lichens (mushrooms), 1 sample of oilseeds and oil fruits (sunflower seeds), 3 samples of teas, coffee, herbal infusions, cocoa and carobs (herbal infusions from leaves and

herbs and ginseng) and one sample of products or part of products exclusively used for animal feed production (alfalfa pellets for animals). The concentrations of tebuconazole residues were above LOQ but below MRL in 23 samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005³. MRLs exceeded in three samples. For the sample of products or part of products exclusively used for animal feed production (alfalfa pellets), no MRL is applicable according to Reg. (EC) No 396/2005³. The highest concentration was reported for a sample of carrot juice of EU origin, with the quantified level of 187.82 mg/kg. These findings are summarised in Table 3.6.3.2-4.

Table 3.6.3.2-4: Occurrence of tebuconazole from the EU OFIS in the years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
<i>Samples of EU origin</i>				
0120100	Pistachios	0.05	0.011 – Pistachios	ND
0213020	Carrots	0.4	0.039; 0.067; 0.088 – Carrots	187.82 – Carrot (juice) 0.025 – Carrots (dehydrated)
0220010	Garlic	0.1	0.008; 0.016; 0.025; 0.016 – Garlic	0.016 – Garlic (powder) 0.032; 0.009 – Garlic (Violet Spring) (drying)
0231020	Sweet peppers/bell peppers	0.6	0.08 – Chilli	ND
0252010	Spinaches	0.02*	ND	0.023 – Spinach (powder)
0253000	Grape leaves and similar species	0.02*	ND	0.006 – Grape leaves (stuffed vine leaves)
0280000	Fungi, mosses and lichens	0.02*	ND	0.016 – Mushrooms (substrate)
0632000	Herbal infusions from leaves and herbs	15	0.036 – Wormwood	
1200000	Products or part of products exclusively used for animal feed production	NA	ND	0.012 – Alfalfa pellets (Luzerne) (Feed-related matrix)
<i>Samples of non-EU origin</i>				
0140040	Plums	1	ND	0.012 – Plum (dehydrated)
0151010	Table grapes	0.5	ND	< 0.01, 0.011, 0.061 – Sultanas (dried)
0256070	Thyme	2	ND	0.013 – Oregano (rubbed)
0401050	Sunflower seeds	0.02*	0.008 – Sunflower seeds	ND
0632000	Herbal infusions from leaves and herbs	15	0.11 – Equisetum arvense/horsetail herb	ND
0633020	Ginseng	0.15	0.018 – Ginseng (roots white) for infusion	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities;

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2018/1514 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of tebuconazole in untreated samples (control samples) from residue trials

Quantified findings in control (untreated) samples were observed for tebuconazole in two residue trials from Germany that were carried out in parsley and savory. The quantified levels were 0.022 mg/kg in parsley and 0.015 mg/kg in savory (Germany, 2018). Additionally, one quantified finding in the control sample from supervised residue trials carried out in Germany was found in spring barley (green material) at 0.16 mg/kg (Denmark, 2010).

No evidence-based explanations on the causes for these occurrences in control (untreated) samples were provided in the above-mentioned evaluation reports.



- Could the presence of tebuconazole and/or its residues be due to biocide use?

Tebuconazole is applied as a biocidal fungicide used in wood preservative treatments for timber and wood *in situ*. Mitigation measures are proposed to prevent environmental exposure to tebuconazole, these include proposals to prevent losses to drains during application or restrict the storage of industrial treated timber to hard standing (Denmark, 2007).

Products are applied as water-based or solvent-based formulations at concentrations of 0.6% w/w. PEC values have been calculated to predict the potential contamination of water and soil from the unintentional release of residues of tebuconazole after biocidal application, which describes a worst-case scenario for brushing a bridge over a small pond for *in situ* applications (Denmark, 2007). These PECs that describe a worst-case scenario very localised and with a direct application of the product, are covered by those estimated for agricultural uses of the substance (see Section 3.6.3.6.).

In a study by Jeanvoine et al. (2017) the authors investigated the usage of azole fungicides, namely propiconazole and tebuconazole mixtures, for wood treatment in sawmills and presence of azole-resistant strains in the environment. Twenty sawmills were prospected in Franche-Comté from September 2014 to April 2016. A total of 15 sawmills of the 20 studied treated wood by short dipping several stacked boards into a tank containing azole fungicide only composed of propiconazole or propiconazole and tebuconazole mixture. In total, 10 air samples and 30 substrate samples (shavings, sawdust, organic matter decomposition, earth soil type or effluent) were taken in each sawmill. The authors observed that quantities of tebuconazole substrates taken near the dripping tank were significantly higher than those of substrates taken in three other locations (far from the tank, outside, and no treatment). Average tebuconazole quantity in substrates ranged from 0.01–4000 µg g⁻¹. The authors concluded that despite fungicide use recommendations, residues can spread throughout the environment, notably around processing tanks, and can subsequently contaminate water, air and soil.

Based on the above, release of residues of tebuconazole in the water and/or soil after biocidal use cannot be excluded.

3.6.3.3 Behaviour in food and feed products

- What key physico-chemical properties of tebuconazole are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of tebuconazole are reported in Table 3.6.3.3.

Identified residues can be attributed to the two tebuconazole enantiomers. This is in line with the proposed residue definition for enforcement (EFSA, 2014d).

Tebuconazole exhibits moderate to medium persistence in soil (see also Section 3.6.3.5) (EFSA, 2014d). Regarding sorption to soil, the geometric mean of K_{Foc} in Table 3.6.3.3 indicates that the substance has medium mobility in soil (EFSA, 2014d).

Spray applications of tebuconazole to winter cereals (2 × 250 g/ha) result in PEC_w values up to 3.043 µg/L (EFSA, 2014d).



There is evidence that tebuconazole is hydrolytically stable under conditions simulating boiling, pasteurisation and sterilisation (EFSA, 2011b, 2014d). Considering that tebuconazole is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Tebuconazole has a low vapour pressure ($<10^{-5}$ Pa at 25°C) (EFSA, 2014d).

Table 3.6.3.3: Physico-chemical properties of tebuconazole

Structural formula	
Appearance (state purity)	Pure material: colourless crystals (99.5%) Technical material: yellowish crystalline powder (purity not specified)
Melting point (state purity)	105°C (99.9%)
Boiling point	Thermal decomposition is reached before boiling point.
Temperature of decomposition	DTA-measurement: Exothermal reaction above 350°C. TGA-measurement: A weight loss was observed above 165°C. (99.5%)
Vapour pressure (state temperature, state purity)	Purity: 99.1% 1.3×10^{-6} Pa at 20°C (extrapolated) 3.1×10^{-6} Pa at 25°C (extrapolated)
Henry's law constant (state temperature)	1×10^{-5} Pa m ³ /mol at 20°C (calculated)
Solubility in water (state temperature, state purity and pH)	Temperature: 20°C. Purity: 99.5% 38 mg/L at pH 5.3 36 mg/L at pH 7.2 36 mg/L at pH 9.4
Partition coefficient (state temperature, pH and purity)	$\log P_{ow} = 3.7$ at 20°C, pH 7 (purity 99.1 %) Effect of pH was not investigated since there is no dissociation in water in the environmentally relevant pH range
Partition coefficient (octanol/air)	$\log P_{oa} = 11.9$ (EPISuite KOAWIN v1.10) (Debler et al. 2024)
Atmospheric half-life	DT ₅₀ of 2.6 days derived by the Atkinson model (version 1.4). OH (24 h) concentration assumed = 0.5×10^6 molecules/cm ³
Dissociation constant (state purity)	Temperature: not stated. Purity: not stated pKa: Tebuconazole is a very weak base which can only be completely protonised in non-aqueous systems in the presence of very strong acids. It is not possible to specify a pK value for water
Soil adsorption (geometric mean)	K _{Foc} = 494 mL/g
Hydrolytic degradation (>10%)	Stable within pH 5–9 at 25°C for 28 days

DT₅₀ – Disappearance time of 50% of the substance in field studies; DTA – Differential Thermal Analysis; NA – not applicable; pH – Potential of Hydrogen; pKa – Acid Dissociation Constant; Pow – Octanol/water Partition Coefficient; Poa – Octanol/air Partition Coefficient; TGA – Thermo-Gravimetric Analysis



3.6.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from the soil surface at which it is applied).

The highest drift of tebuconazole to neighbouring fields may occur during its applications to fruit crops (up to 29.2 %), hops (19.33 %), vineyards and vegetables (up to 8.02 %) and field crops (up to 2.77 %). Drift values should take into consideration the rate received by neighbouring fields, expressed as a percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. buffer zones or spray drift-reducing nozzles).

If organic crops are present adjacent to the conventional crops treated, measurable residues of tebuconazole in the untreated crop cannot be excluded (above all if the treated crops are fruit trees). However, since the nature of the potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

Tebuconazole is used as a seed treatment, which necessitates consideration of potential dust drift. Deposition percentile values were considered for neighbouring fields, up to 17% for different crops and techniques (EFSA, 2013b). According to Adriaanse et al. (2022), the use of techniques (deflectors), size of the dust particles and average wind speed were the most important factors determining the amount of dust drift.

3.6.3.5 Accumulated/historical residue levels in soil

- What is the persistence of tebuconazole and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

Since, according to available data DT₉₀ of tebuconazole in field trials (carried out in seven different sites around Europe) is < 1 year (worst-case field DT₉₀ = 304 days), tebuconazole is not expected to accumulate in soil over successive seasons. This is further confirmed by the results of the available field rotational crop studies conducted with radiolabelled tebuconazole which demonstrated that residues of the parent tebuconazole above LOQ are unlikely to occur in rotational wheat after use according to intended practices (EFSA, 2014d).

Based on the above, tebuconazole uptake from soil is not expected in organic crops, even if planted in fields in which tebuconazole was previously used for conventional agriculture, considering that it requires at least 2 years after the last chemical treatment in order for organic crops to be planted in such areas.²



- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Based on results from field studies where plateau concentrations were found as low as 0.1 mg/kg after 3 years of tebuconazole application at an annual rate of 750 g/ha, accumulation of tebuconazole in soil is not expected (EFSA, 2014d).

Monitoring data for tebuconazole in soil are available from the LUCAS pesticides 2018 (JRC, 2023) on IPCHEM¹²¹². According to Franco et al. (2024), tebuconazole was detected in 26% of sites included in the LUCAS soil survey, ranking among the most frequently identified pesticide residues in European soil.

The data from the LUCAS pesticides 2018 on IPCHEM¹² show background levels of the substance in soil samples from 22 EU countries: Austria (11 samples), Belgium (3 samples), Bulgaria (52 samples), Cyprus (1 sample), Czechia (72 samples), Denmark (25 samples), Estonia (15 samples), Finland (14 samples), France (237 samples), Germany (49 samples), Greece (6 samples), Hungary (34 samples), Ireland (1 sample), Italy (34 samples), Latvia (15 samples), Lithuania (30 samples), the Netherlands (10 samples), Poland (90 samples), Portugal (1 sample), Romania (11 samples), Slovakia (14 samples) and Spain (148 samples) at levels ranging from 0.002 mg/kg to 0.031 mg/kg (average values) and from 0.002 to 0.4 mg/kg (maximum values). In LUCAS soil, the lack of information on the agricultural use history of the sites where soil was sampled precluded knowing whether the reported quantified findings were related to recent active use or historical levels in soil for tebuconazole.

Evidence on the presence of tebuconazole residues in soil is provided by Chiaia-Hernandez et al. (2017), who analysed 29 archived agricultural soil samples collected from 14 monitoring sites from 1995 to 2008 in Switzerland. The sites were selected from locations where crops had been regularly treated with pesticides. Selection was based on land use characteristics and long-term patterns of pesticide application. Tebuconazole was detected in eight samples (28%) from cropland and viticulture land use sites, with levels ranging from 0.001 to 0.089 mg/kg. Tebuconazole was applied and detected in 21% of cases, whilst it was not applied but detected in 7% of cases. Additionally, several minor transformation products of tebuconazole were identified in five samples (17%) and three samples (10%), from all land use sites, including cropland, orchard, vegetable and viticulture.

In a study by Riedo et al. (2021) soil samples from 60 agricultural sites in Switzerland with different management systems (conventional tillage, conventional without soil tillage, and organic) were analysed for residues of tebuconazole. The samples were collected in May 2016 for an on-farm study throughout the country. Results showed the presence of tebuconazole in 33% of the samples at concentrations ranging from 0.00038 to 0.040 mg/kg in all types of soil, with higher levels in soil from conventional arable farming. The concentrations in soil under organic farming systems were reported to be <0.005 mg/kg in a total of four out of 40 samples (10%).

Additional evidence on the occurrence of tebuconazole in soil is provided by Silva et al. (2023) in a study carried out in the framework of the EU SPRINT project. The study assessed the presence of 209 pesticide residues in 100 soil samples from conventional agriculture and 63 soil samples from organic agriculture collected during the 2021 growing season across 10 study sites



in Europe: Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark. Tebuconazole was detected in 29 conventional soil samples (29%) from Switzerland, Czechia, Croatia, Italy, Portugal and Slovenia at concentrations ranging from 0.0059 to 0.109 mg/kg and two soil samples under organic farming systems (3%) from Italy at concentrations of 0.0098 to 0.013 mg/kg. The highest levels were found in conventional soil from Czechia.

Considering the available evidence, plant uptake of tebuconazole from soil containing tebuconazole is not expected even if the crop is grown in soil that contain residues at the levels quantified in these studies.

3.6.3.6 Residues from water used for irrigation

- Is there evidence that residues of tebuconazole present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for tebuconazole in water samples were considered:

- The EEA-WATERQUALITY³⁹³⁹ database (data retrieved on 10 April 2024) reports 2,404 analytical results from water samples collected in Belgium (4 samples), Czechia (1202 samples), Denmark (1 sample), Estonia (5 samples), France (103 samples), Hungary (2 samples), Ireland (3 samples), Italy (687 samples), Latvia (2 samples), the Netherlands (295 samples), Poland (50 samples), Slovakia (3 samples), Slovenia (2 samples), Spain (37 samples) and Sweden (8 samples) between 2019 and 2021;
- The EMPODAT database (data retrieved on 5 April 2024) reports 18,782 analytical results from surface water samples collected in Austria (19 samples), Bulgaria (35 samples), Croatia (10 samples), Czechia (10 samples), Germany (30 samples), Hungary (50 samples), the Netherlands (18,571 samples), Romania (12 samples) and Slovakia (45 samples) between 2017 and 2019; 24 analytical results from groundwater samples collected in 2019 in Austria (4 samples), Bulgaria (4 samples), Croatia (4 samples), Hungary (4 samples), Romania (4 samples) and Slovakia (4 samples);
- The NAIADES database (data retrieved on 2 April 2024) reports 54,902 analytical results from surface water samples collected in France from 2020 to 2022.

Among the 76,089 analytical results for tebuconazole, 885 were disregarded as found to report quantitative values below the analytical LOQ. Therefore, the number of water samples considered is 75,204.

Based on the screening process described in section 'Data and methodologies', for 99.5% of water samples analysed and reported in the above-mentioned databases (74,833 samples), the residue concentrations in these waters were below the screening Cw of 0.24 µg/L and, therefore, transfer of residues from water sources to plant commodities if water containing residues at these levels is used for irrigation is unlikely.

For 0.5% of samples (371 out of 75,204 results), the residue concentrations were or above the screening Cw of 0.24 µg/L and the potential transfer of residues to plant commodities cannot be excluded.

In a study by Silva et al. (2023) carried out under the framework of the EU SPRINT project the authors assessed the presence of 209 pesticide residues in 58 water samples collected during



the 2021 growing season across 10 study sites in Europe (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). Tebuconazole was quantified in 28 samples (48% detection frequency) from all countries except Switzerland and Croatia at concentrations ranging from 0.001 to 0.061 µg/L. These water concentrations would not be expected to transfer residues of tebuconazole to plant commodities.

Overall, considering that for 99.5% of water samples analysed and reported for tebuconazole in EEA-WATERQUALITY, EMPODAT and NAIADES (75,204 samples) and 100% of results of surface water samples analysed by Silva et al. (2023), the residue concentrations were below the screening Cw of 0.24 µg/L, it can be concluded that the transfer of tebuconazole residues from water sources to plant commodities when this water is used to irrigate the plant is unlikely.

3.6.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *tebuconazole*, *industry/industrial*, and *air/atmosphere*) identified two European studies, which were considered irrelevant for this section.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water. A literature review was carried out to gather relevant information. A search in the Scopus database (conducted on March 4, 2025, using the keywords *tebuconazole*, *industry/industrial*, and *water*) identified two articles with potentially relevant information.

In a study by Stamatis et al. (2010), the presence of five fungicides was investigated in river water samples from the Acheloos River (Greece) and wastewater from a nearby wastewater treatment plant which receives the effluents of the plant. Tebuconazole has been quantified in all samples at concentrations up to 1.89 µg/L. Higher specific loads were observed in wastewater treatment plants where stormwater and domestic/industrial wastewater were treated. According to the authors, since tebuconazole is used for the preservation of wood and coatings and it may be leached from treated materials during rain events, input via these pathways may be expected. However, no evidence was provided in the paper to support this argument.

In a study by Kahle et al. (2008), the presence of azole fungicides was investigated in domestic wastewater and water from several lakes in Switzerland. Tebuconazole was detected in both wastewater and lake water, with higher loads and wastewater influent at the maximum concentration of 0.01 µg/L. According to the author, tebuconazole is used in the area in agriculture as well as for urban/industrial uses as biocides in wood or coating preservatives. However, no evidence was provided in the article to support this argument.

Overall, none of the available studies provides evidence to support the transfer of residues from industrial emissions to water sources at levels that may transfer residues into plants and their products. Based on conservative estimations of the possible transfer of residues of tebuconazole from water used for irrigation to plant commodities, the transfer of residues of tebuconazole



from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on 5 March 2025, using the keywords *tebuconazole*, *industry/industrial*, and *soil/sediment*) identified one European study that was considered relevant for this section.

In a study by Masiá et al. (2013), the presence of 50 pesticides was investigated in water and sediment samples from the Guadalquivir River Basin in Spain in 2010 and 2011. Tebuconazole was quantified only in sediment samples from 2011 at a maximum concentration of 12.7 ng/g (13% detection frequencies). According to the authors, urban/industrial wastewaters and runoff were among the factors contributing to these residue concentrations. However, no evidence was provided in the paper to support this argument.

The poor information from the literature does not allow for a conclusion on the possible transfer of residues from industrial emissions to plants. The poor plant uptake of tebuconazole from soil indicates that the transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely.

3.6.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Medium and long-range aerial transport of residues

When plant protection products containing tebuconazole are sprayed, medium and long-range transport of tebuconazole through air in aerosols cannot be completely excluded. Despite its relatively low vapour pressure (10^{-6} Pa at 20°C), tebuconazole has an atmospheric half-life of 2.6 days and, when applied as a spray to oilseeds, cereals and berries and small fruits (grapes), it could potentially undergo long-range transport to areas where it has not been used (FOCUS, 2008). This is not expected when tebuconazole is used for seed treatment due to the substance's low volatility (EFSA, 2014d).

Figueiredo et al. (2021) investigated pesticide presence in air samples during periods of use and non-use of tebuconazole in the surrounding area (up to 500 m distance) from the agricultural field (bulb field) in the Netherlands between May 2016 and December 2017. Tebuconazole concentrations were higher during the use periods. Comparable median concentrations of tebuconazole were reported between locations close to the agricultural areas and at a 500 m distance. Wind direction and nearby agricultural fields, including other crops being sprayed, were also reported by the authors among the parameters that affect air pesticide concentrations.

Silva et al. (2023) investigated the presence of tebuconazole in 20 outdoor air samples collected during the 2021 growing season across 10 study sites in Europe of organic and conventional agriculture (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). The study was carried out under the framework of the EU SPRINT project. Organic fields had not been treated for 5 consecutive years. Tebuconazole was quantified in six out of 20 targeted samples (30%) from Czechia, Portugal, Spain and Slovenia at a maximum concentration of 136 ng m⁻³ in Portugal. Three out of six samples with quantified



residues had been collected in the surrounding areas of organic fields in Czechia (30 ng m^{-3}), Portugal (136 ng m^{-3}) and Slovenia (24.2 ng m^{-3})

A study monitoring aerial transport for a series of active substances used in apple fields in the South Tyrol (IT) shows that aerial aerosol transport of residues is responsible for the presence of residues in vegetation outside of the treated fields (Brühl et al., 2024). Whereas tebuconazole is not investigated in this study, results of the similar substance difenoconazole (also of low volatility) show the plausibility of this route of transport as a potential source of residues of this kind of substances in vegetation outside of the treated areas.

In another study published by Debler et al. (2024) under the EU SPRINT project, tebuconazole was quantified in the particle phase of air samples collected between April 2021 and June 2022 from an agricultural area of conventional farming in the Netherlands (potatoes, onions and sugar beet). Tebuconazole was found in 14% of the samples at total concentrations that ranged from 16 to 80 pg/m^3 . Note was taken that the agricultural area had not undergone tebuconazole treatment before samples were collected from the surrounding area and measurement.

In a study by Mayer et al. (2024) residues of tebuconazole were quantified in air samples from 29 sampling sites classified as rural, coastal, mountain and polar. The samples were collected from 15 EU countries i.e. Austria, Czechia, Estonia, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Poland, Slovakia, Spain and Sweden, Switzerland and the United Kingdom during the main pesticide application period in spring 2020. To investigate aerial transport in polar sites, air samples from the European Arctic were also collected. Results showed the presence of tebuconazole at levels from 0.05 to 100 pg m^{-3} in the rural sites, from 0.9 to 20 pg m^{-3} in the coastal sites and from 0.2 to 30 pg m^{-3} in the mountain sites (the exact concentration ranges are not reported in the paper). The maximum concentration was quantified in a rural area located in Germany. For the coastal area, the maximum concentration was quantified in the United Kingdom, whilst for the mountain area, the highest concentration was reported in Slovakia. Tebuconazole levels at remote mountain areas were similar in scale, within an order of magnitude, compared with those at other sites. Tebuconazole was not quantified in the Arctic sites. The total frequency of findings for all areas was above 50% (the exact % detection frequency is not reported in the paper).

Overall, the results of these studies suggest that tebuconazole transfer via aerial transport outside the treated areas cannot be excluded.

Uptake from organic fertilisers

In a study investigating pesticide residues in organic fertilisers, residues of tebuconazole and other pesticides were quantified (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). The authors attributed the origin of the residues to the presence of plant protection products in the composted crop or in composted manure due to transfer from animal feed after digestion, or in straw used in stables. Analysis of solid organic fertilisers gave an average concentration of 0.547 mg/kg for tebuconazole in 11 out of 147 samples. Further analysis carried out by different producers, showed several detections of triazole fungicides in organic fertilisers (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). Considering that (according to the authors) the use of completely free from residues organic fertilisers is currently unsustainable, transfer of tebuconazole residues from fertilisers used in organic production to organic products cannot be excluded. On the other hand, no residues of tebuconazole were found in any of the products of the crops discussed in the study (van der Blom et al., 2022, under



'Documentation as provided to EFSA'). As assessed above (see Section 3.6.3.5), available information from rotational crop studies indicates that the uptake of tebuconazole from soil by plants is very limited. It may be expected that the same would hold true for the uptake of the tebuconazole residues from soil compost.

3.6.4 Conclusions on tebuconazole

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use. In Chinese cabbage, the residues quantified in the residue trials were higher than the implemented MRL, at that time, for the respective commodity. This is because a concern was identified by EFSA for the specific use and, consequently, the MRL was set at the LOQ of 0.02* mg/kg for this commodity group (see Section 3.6.3.2).
- Residue trials carried out to support the critical GAPs⁴ for tebuconazole, gave residue concentrations of up to 6.0 mg/kg in herbal infusions, 21 mg/kg in hops, and up to 17 mg/kg in cereal straw. Concentrations in the ranges reported in Table 3.6.3.2-1 might be associated with active use of tebuconazole according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.
- Tebuconazole was quantified in the context of residue trials in three untreated (control) samples from Germany with the highest concentration observed in one sample of spring barley (0.16 mg/kg).
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for tebuconazole in unprocessed commodities with authorised uses ranged from 0.013 mg/kg in oilseeds and oil fruits to 0.069 mg/kg in berries and small fruits.
- In organic commodities that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for tebuconazole in unprocessed commodities with authorised uses ranged from 0.023 mg/kg in pome fruits to 0.025 mg/kg in bulb vegetables.
- Without additional information on the individual samples' history and context, it is not possible to conclude if quantified results for tebuconazole in organic commodities are associated with active use or unintentional presence.
- In organic processed commodities, residues of tebuconazole were quantified in one sample of fruiting vegetables analysed under the pesticide residues monitoring programme between 2020 and 2022. In samples from processed products not labelled as organic with five or more quantified findings, the median concentrations of residues of tebuconazole ranged from 0.011 mg/kg in stone fruits to 0.07 mg/kg in fruiting vegetables. Considering that tebuconazole is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels



can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

- Overall, in commodities labelled as organic, tebuconazole was quantified in 0.15% of samples (15 out of 10,315 samples). This percentage is around 31 times lower than the percentage reflecting the number of findings in samples not labelled as organic (4.6%) (see Appendix B, Tables B-6.1 and B-6.2). These results suggest that the occurrence of residues of tebuconazole in organic products is significantly less likely when compared with the conventional commodities.
- Potential sources of the unintentional presence of residues of tebuconazole in commodities of plant origin are spray drift, dust drift and/or aerosol aerial transport of residues.
- Tebuconazole is moderately persistent in soil. However, not all substances accumulating in soil are taken up by plants. Studies assessed by EFSA on crops growing in rotation showed that plant uptake of residues of tebuconazole from organic fertilisers or from soil where tebuconazole has not been actively used is unlikely.
- The transfer of tebuconazole residues from EU water sources used for irrigation to plant commodities is unlikely.
- Tebuconazole is also used in biocidal products and biocidal products containing tebuconazole may result in the release of residues of tebuconazole into the environment.
- Conservative estimates of the possible transfer of residues of tebuconazole from water used for irrigation to plant commodities and information on the possible plant uptake of residues of tebuconazole from EU soil suggest that the transfer of residues of tebuconazole from biocidal and other non-pesticide uses as well as the transfer from industrial emissions to the environment and from the environment to plants and plant commodities is less likely.

The pathways of residues of tebuconazole to plants and plant commodities are summarised in Figure 6.

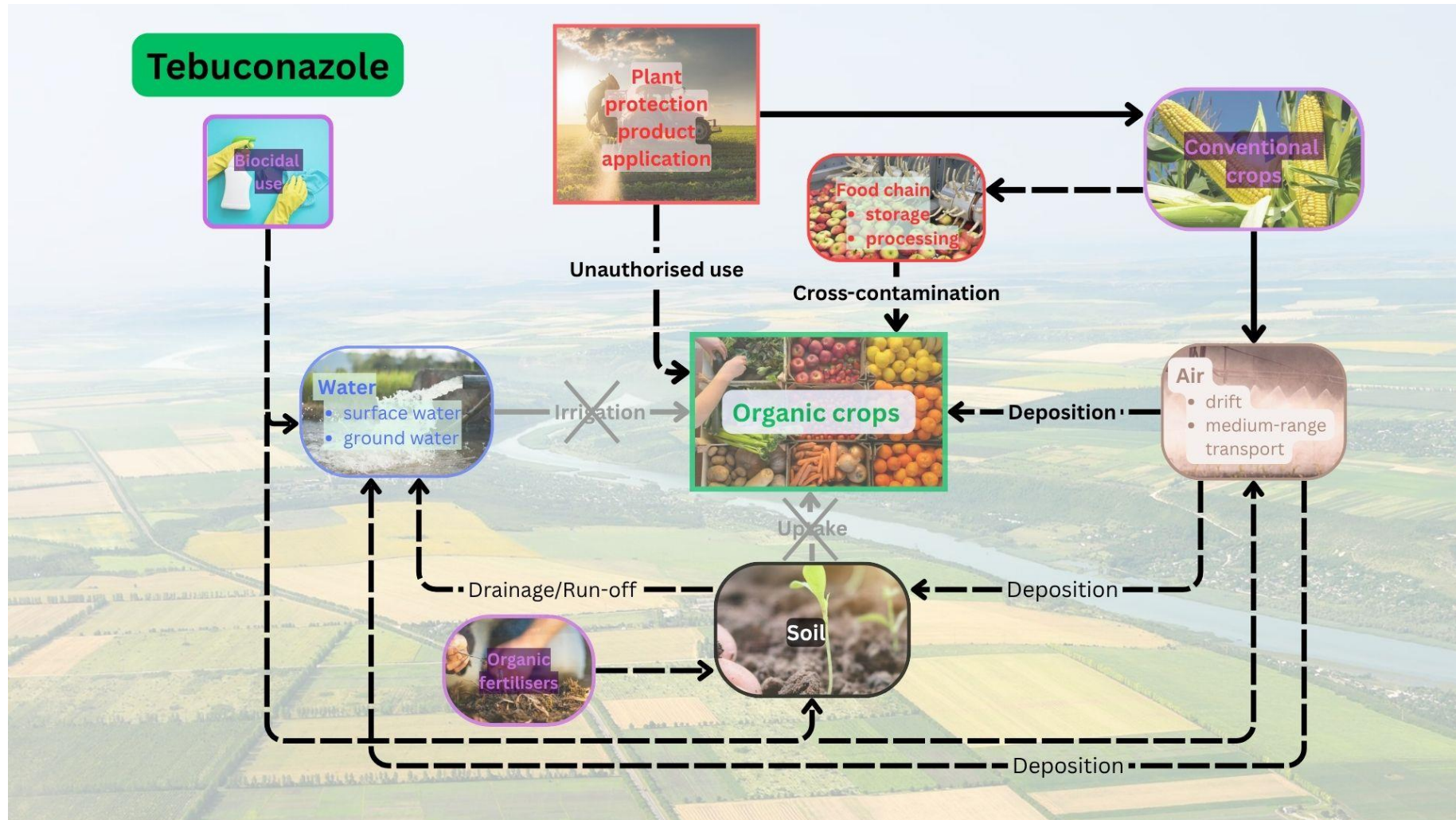


Figure 6: Pathways of residues of tebuconazole to plants and plant commodities

Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded

3.7 Folpet

3.7.1 Method(s)

- What is/are the residues to be monitored for the active substance folpet according to the residue definition (RD) for monitoring set in Regulation (EC) No 396/2005³?

For the active substance folpet, the applicable residue definition for enforcement in Reg. (EC) No 396/2005³ for food and feed of plant origin has been proposed as 'sum of folpet and phthalimide, expressed as folpet'. This residue definition is applicable to primary crops, rotational crops and processed products (EFSA, 2022e). The same residue definition is implemented in Reg. (EC) No 396/2005³ for honey and other apiculture products.

In the more recent EFSA peer review conclusions for folpet, it was proposed to change the residue definition for enforcement in commodities of plant origin from folpet (sum of folpet and phthalimide expressed as folpet) to folpet only (EFSA, 2023g). It is reported, however, that neither folpet nor phthalimide are good markers for the monitoring of residues of folpet in root crops (EFSA, 2023g).

Considering that this report deals with results from 2020 to 2022, the residue definition currently implemented in Reg. (EC) 396/2005³ will be considered for folpet, i.e. the sum of folpet and phthalimide, expressed as folpet for foods of plant origin, honey and other apiculture products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

Since the residue definition to be considered is folpet (sum of folpet and phthalimide, expressed as folpet), then methods of analysis for both folpet and phthalimide (as a sum and individually) will be discussed under this section.

Folpet and phthalimide analysis:

Multi-residue analytical methods based on HPLC-MS/MS and GC-MS are reported for the monitoring of residues of folpet and phthalimide in plant matrices of high-water content, dry commodities, green and dried hop cones. For folpet, LOQs were 0.05 mg/kg in high water content, dry commodities, green and dried hop cones, and 0.1 mg/kg in cereal straw. For phthalimide, LOQs were 0.01 mg/kg in high water content commodities, dry commodities (cereal grain), cereal straw, green and dry cones. Note was taken that GC-MS was not sufficiently specific for folpet residues in high water content commodities (EFSA, 2014e, 2017b, 2022e; France, 2024 under 'Documentation as provided to EFSA').

Single residue GC-ECD and GC-MSD methods can be utilised for analysing folpet and phthalimide in high acid content commodities with an LOQ of 0.02 mg/kg for folpet and 0.05 mg/kg for phthalimide, respectively (EFSA, 2013d; Austria, 2024 under 'Documentation as provided to EFSA').

A single residue analytical method based on GC-MS is available for the measurement of residues of folpet and phthalimide in high oil content commodities, with an LOQ of 0.05 mg/kg for each compound (EFSA, 2014e; France, 2024 under 'Documentation as provided to EFSA').

A multi-residue analytical method (QuEChERS), based on HPLC-MS/MS is available for the enforcement of folpet and phthalimide, with an LOQ of 0.01 mg/kg for both analytes in dry content matrices (EFSA, 2021b).

Folpet analysis:

According to the latest peer review conclusions, residues of folpet can be monitored in food and feed by LC-MS/MS with an LOQ of 0.01 mg/kg for all commodity groups of food and feed matrices of plant origin (EFSA, 2023g).

A multi-residue QuEChERS method in combination with GC-MS has been developed and reported for the determination of residues of folpet with an LOQ of 0.05 mg/kg in high water content and 0.005 mg/kg in high acid content commodities (EFSA, 2011c, 2014e). The method can also analyse folpet in high oil content and dry matrices although these matrices are characterised by poor method validation datasets (EFSA, 2014e).

GC-MS methods can also be used to analyse folpet residues in oily, dry and acidic commodities with an LOQ of 0.01 mg/kg (EFSA, 2011c, 2023g). GC coupled with ECD gives lower sensitivities in high water content, high acid content and high oil content matrices (LOQ of 0.05 mg/kg) (EFSA, 2011c).

A single residue citrate-buffered QuEChERS method based on GC-MS/MS is validated for monitoring folpet residues in honey samples at an LOQ of 0.002 mg/kg (EURL, 2024 under 'Documentation as provided to EFSA').

Phthalimide analysis:

Phthalimide can be quantified in high water content matrices with an LOQ of 0.01 mg/kg based on GC-MS/MS (EFSA, 2022e). Suitable methods but with higher sensitivities have been reported for phthalimide in previous EFSA reasoned Opinions dealing with high water content commodities. Both methods are based on GC-MS and have LOQs of 0.02 mg/kg (EFSA, 2017b) and 0.05 mg/kg (EFSA, 2011c).

In the context of the MRL review, an analytical method (and ILV) based on GC-MS was reported for the analysis of phthalimide in high acid content matrices, with an LOQ of 0.05 mg/kg (EFSA, 2014e).

A multi-residue LC-MS/MS method, reported by Oulkar et al. (2019), is validated for the analysis of phthalimide residues in plant commodities with high water and acid content, at an LOQ of 0.05 mg/kg. Cunha et al. (2007) developed a multi-residue GC-MS method with an LOQ of 0.075 mg/kg for the determination of phthalimide residues in high oil content plant commodities.

Phthalimide residues can be monitored in honey samples at an LOQ of 0.005 mg/kg using a single residue citrate-buffered QuEChERS method based on LC-MS/MS (EURL, 2024 under 'Documentation as provided to EFSA').

Summary of methods of analysis of folpet (RD)

Overall, multi-residue methods of analysis are available for the monitoring of residues of folpet and phthalimide in high water, high acid content and dry commodities, as well as in green and dried hop cones according to the residue definition for enforcement currently in place. For folpet only, a multi-residue method has been validated for analysis in high water and high acid content

commodities. For phthalimide only, multi-residue methods have been validated for analysis in high water, high acid and high oil content matrices. For the analysis of residues of folpet and phthalimide in honey and other apiculture products single residue methods are available.

The LOQs of the methods of analysis intended for enforcement purposes of folpet range from 0.002 to 0.075 mg/kg, depending on the food/feed matrix. In the 2023 EFSA peer review conclusions, an LOQ of 0.01 mg/kg was validated for food and feed matrices of plant origin. For phthalimide, LOQs range from 0.01 mg/kg for high water content commodities, dry commodities (cereal grain), cereal straw, green and dried cones to 0.05 mg/kg for high acid and high oil content commodities. Residues of folpet and phthalimide can be monitored in honey and other apiculture products with single residue methods at a sum LOQ of 0.012 mg/kg.

3.7.2 Authorisation status and use

- Is folpet currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has folpet ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

a) Authorisations for plant protection use in conventional agriculture

Folpet has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of approval of the active substance is on 31 October 2039, as indicated by the EU Pesticides Database⁵ (accessed 27 November 2024).

According to the EU Pesticides Database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Greece, Spain, France, Croatia, Hungary, Ireland, Italy, Luxembourg, Latvia, the Netherlands, Poland, Portugal, Romania, Sweden, Slovenia, and Slovakia.

b) Authorisations for purposes other than plant protection

Biocidal use

Folpet has been approved for biocidal use in the EU Member States, Iceland, Liechtenstein and Norway in accordance with Regulation (EU) No 528/2012⁷. The approval relates to the use of the substance as a preservative for products during storage (from 1 January 2016 to 31 December 2025), as a film preservative (from 1 October 2016 to 30 September 2026), and as a fibre, leather, rubber and polymerised materials preservative (from 1 October 2016 to 30 September 2026), as indicated in the ECHA website⁶ (accessed on 6 June 2024).

According to the ECHA website⁶, at national level, folpet has been authorised for use in fibre, leather, rubber and polymerised materials preservative formulations in Belgium, France, Hungary, Italy, Luxembourg, and the Netherlands until 2 April 2031.

Phthalimide, a substance included in the residue definition for enforcement purposes, has not been approved for biocidal use according to ECHA.

Other uses

According to the search carried out on the ECHA website⁹ on 6 June 2024, folpet is not currently registered under REACH.

Three registration dossiers under REACH are available for phthalimide; two have remained active since 2010 and 1 has been inactive as of 2021 (cease manufacture/import). Both active registrations indicate the manufacture of the substance in the EU Member States¹¹, Iceland, Liechtenstein and Norway. One of the active registrations indicates the industrial use of the substance as an intermediate in chemical synthesis; details of the products of synthesis are not known. Professional use as a laboratory agent is also indicated in the registration data.

- What is/was the actual use of folpet? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of folpet

Folpet is a fungicide and belongs to the group of phthalimide fungicides. Folpet is a contact fungicide that controls a wide range of fungi. It inhibits many oxidative enzymes, carboxylases and enzymes involved with phosphate metabolism and citrate synthesis by interfering with the respiratory process in fungi via binding to sulphur-hydrogen bonds (EFSA, 2014e).

Conditions of use and applicable crops

The uses reported in the EFSA MRL review included outdoor foliar spraying to control various pests in northern and southern Europe in food and feed commodities belonging to the following crop groups: berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, oil fruits, cereals and hops (dried) (EFSA, 2014e).

After the EFSA MRL review, more applications were submitted to EFSA to support new uses or modify the existing MRLs in pome fruits (apple and pear), leaf vegetables, herbs and edible flowers (lettuce) and cereals (EFSA, 2017b, 2021b, 2022e). These additional applications were also involving outdoor foliar spraying.

Application rates for foliar (outdoor) treatment ranged from 0.45 kg a.s./ha to 4 kg a.s./ha (EFSA, 2014e, 2017b, 2021b, 2022e, 2023g). Indoor foliar treatment was also reported for tomatoes only. Application rate for foliar (indoor) treatment of tomatoes was up to 1.60 kg a.s./ha (EFSA, 2014e).

b) Uses for purposes other than plant protection

Biocidal use

One product containing folpet was identified for use as a fungicide preservative of plastic material for several end products articles used indoors and/or outdoors in Belgium, France, Hungary, Italy, Luxembourg, and the Netherlands. The product is used by professionals and is incorporated during the manufacture of the material. It is applied as a powder formulation at concentrations of 0.3–1.5% (w/w) (Netherlands, 2021c) (see also 'authorisations for purposes other than plant protection/biocidal use').

Phthalimide, a substance included in the residue definition for enforcement purposes, has not been approved for biocidal use.

Other uses

According to a search carried out on the ECHA website⁹ (accessed on 6 June 2024), folpet is not currently registered under REACH. For phthalimide, 3 REACH registration dossiers (2 of them are currently active, one inactive since the end of June 2021 due to the cessation of manufacture/import). The active registration dossiers indicate the manufacture and industrial use of phthalimide as an intermediate in synthesis in the EU Member States¹¹, Iceland, Liechtenstein and Norway. Professional or consumer use of the substance in the EU Member States¹¹, Iceland, Liechtenstein and Norway is not confirmed by available registration data with the exception of professional laboratory use.

Phthalimide (transformation product and analytical marker of folpet) has numerous industrial uses as intermediate in the synthesis of primary amines and several other types of organic compounds. Phthalimide is the constituent of other plant protection active substances such as phosmet or ditalimfos (Cunha et al., 2007; Allmaier and Schmid, 1986). Phthalimide is also a constituent moiety of several existing drugs (e.g. thalidomide, taltrimide). Several other derivatives of phthalimides are also being investigated for their biological and pharmacological properties (Fernandes et al., 2023). Eventually, phthalimide-containing compounds may, upon degradation or metabolism, release free phthalimide.

3.7.3 Sources of residues in plants

3.7.3.1 Natural occurrence

- Is there evidence that folpet occurs naturally? What is known about the natural origin of this substance?

Folpet is a synthetic fungicide, produced industrially through chemical processes (Lewis et al., 2016) and no information on the potential natural presence of folpet was found in the literature²².

However, its transformation product and analytical marker, phthalimide can occur naturally in burning coal heaps. When found in its natural crystalline form phthalimide is considered a mineral named Kladnoite (Rost, 1942; Matzat, 1972). Its natural occurrence is rare and considered not relevant to explain residues of phthalimide in cultivated plants.

3.7.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of folpet per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of folpet in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.7.3.2-1 to 3.7.3.2-4. Findings relating to residues in control (untreated) samples are also discussed in this section.

In all matrices and for both residue trials and results from monitoring, folpet residue concentrations refer to the residue definition for enforcement (i.e. the sum of folpet and phthalimide, expressed as folpet).

Occurrence of folpet from residue trials carried out for the critical GAP per crop

When applied at the critical GAPs⁴ reported to EFSA, residue levels of the sum of folpet and phthalimide expressed as folpet were below the LOQ in miscellaneous fruits (table olives), root

and tuber vegetables (radishes and salsify), bulb vegetables and olives for oil production (EFSA, 2014e).

Quantified residues of the sum of folpet and phthalimide expressed as folpet were found in pome fruits (apples), berries and small fruits, fruiting vegetables, leaf vegetables (lettuces), cereals and hops (dried) (EFSA, 2011c, 2014e, 2017b, 2021b, 2022e, 2023g). Regarding feed commodities, quantified residues of the sum of folpet and phthalimide expressed as folpet were found in cereal straw (EFSA, 2014e, 2021b, 2023g).

The residue trials carried out for the sum of folpet and phthalimide also allowed studying the occurrence of the individual substances, folpet and phthalimide. These results are reported below.

Residues of folpet were below the LOQ in root and tuber vegetables and legume vegetables (fresh beans, without pods) (EFSA, 2014e; Germany, 2014b).

Quantified residues of folpet were found in pome fruits (apples) (EFSA, 2017b, France, 2017c), berries and small fruits (Austria, 2013a, 2023; EFSA, 2011c, 2014e, 2023g), miscellaneous fruits (table olives) (EFSA, 2014e; Italy, 2014), bulb vegetables (EFSA, 2011c, 2014e), fruiting vegetables (Austria, 2023a; EFSA, 2011c, 2014e, 2023g), brassica vegetables (excluding brassica roots and brassica baby leaf crops) (EFSA, 2014e), leaf vegetables (EFSA, 2014e, 2022e; Spain, 2020d), olives for oil production (EFSA, 2014e, Italy, 2014), cereals (Austria, 2023a; EFSA, 2014e, 2021b, 2023g; France, 2014a) and hops (dried) (EFSA, 2014e, Germany, 2014b). Regarding feed commodities, quantified residues of folpet were found in cereal straw (EFSA, 2014e, 2021b, 2023g; France, 2014a, 2016b).

For phthalimide, residues were below LOQ in pome fruits (apples) (EFSA, 2017b, France, 2017c), miscellaneous fruits (table olives) (EFSA, 2014e; Italy, 2014), root and tuber vegetables (EFSA, 2014e, Germany, 2014b), bulb vegetables (EFSA, 2011c, 2014e) and olives for oil production (EFSA, 2014e; Italy, 2014).

Quantified residues of phthalimide were found in berries and small fruits (Austria, 2013a, 2023; EFSA, 2011c, 2014e, 2023g), fruiting vegetables (Austria, 2023a; EFSA, 2011c, 2014e, 2023g), leaf vegetables (EFSA, 2014e, 2022e; Spain, 2020d) and cereals (Austria, 2023a; EFSA, 2014e, 2021b, 2023g; France, 2014a). Regarding feed commodities, quantified residues of phthalimide were found in cereal straw (France, 2014a, 2016b; EFSA, 2014e, 2021b, 2023g).

These findings are summarised in Table 3.7.3.2-1 'Occurrence of folpet from residue trials carried out for the critical GAP per crop'.



Findings of not authorised substances in organic products

Table 3.7.3.2-1: Occurrence of folpet from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Folpet (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop					
			Sum of folpet and phthalimide, expressed as folpet		Folpet		Phthalimide	
			Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)
Food								
0130000	Pome fruits	0.03*-0.3	<LOQ (0.06)-0.19	0.06	<LOQ (0.02)-0.15	0.02	<LOQ (0.02)	<LOQ (0.02)
0150000	Berries and small fruits	0.03*-20	<LOQ (0.12)-9.0	2.4	<LOQ (0.02)-6.3	1.8	<LOQ (0.05)-2.45	0.26
0160000	Miscellaneous fruits ^{c)}	0.03*-0.15*	<LOQ (0.15)	<LOQ (0.15)	<LOQ (0.05)-0.05	0.05	<LOQ (0.05)	<LOQ (0.05)
0210000	Root and tuber vegetables	0.03*-0.06*	<LOQ (0.04)	<LOQ (0.04)	<LOQ (0.02) - <LOQ (0.05)	<LOQ (0.02)	<LOQ (0.01) - <LOQ (0.02)	<LOQ (0.01)
0220000	Bulb vegetables	0.03*	<LOQ (0.12)	<LOQ (0.12)	<LOQ (0.02)-0.91	0.05	<LOQ (0.05)	<LOQ (0.05)
0230000	Fruiting vegetables	0.03*-5	<LOQ (0.12)-2.8	0.48	<LOQ (0.01)-2.4	0.48	<LOQ (0.05)-0.2	0.05
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.03*	NR	-	<LOQ (0.05)-0.05	0.05	NR	-
0250000	Leaf vegetables, herbs and edible flowers	0.03*-1.5	<LOQ (0.02)-0.86	0.19	<LOQ (0.01)-5.1	0.06	<LOQ (0.01)-0.9	0.05
0260000	Legume vegetables	0.03*	NR	-	<LOQ (0.05)	<LOQ (0.05)	NR	-
0402010	Olives for oil production	0.15*	<LOQ (0.15)	<LOQ (0.15)	<LOQ (0.05)-0.05	0.05	<LOQ (0.05)	<LOQ (0.05)
0500000	Cereals	0.07*-2	<LOQ (0.11)-2.17 ^{d)}	0.21	<LOQ (0.01)-0.84	0.02	<LOQ (0.05)-0.81	0.1
0700000	Hops (dried)	400	52-192	82	13-74	54	NR	-
Feed								
1200000	Cereal straw	NA	<LOQ (0.13)-19.6	1.5	0.07-11.3	1.2	<LOQ (0.05)-6.9	0.32

* Limit of quantification in Reg. (EC) No 396/2005; NR – no residue trial data is available; NA – not applicable; '-': not estimated due to lack of data.

a) Maximum Residue Level in Reg. (EU) 2023/1042 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA, 2011c, 2012f, 2013d, 2014e, 2017b, 2021b, 2022e and 2023g; c) Uses in table olives were supported from residue trials in olives for oil production (EFSA, 2014e; Italy, 2014); d) Residues quantified above the MRLs come from the EFSA peer review for folpet (EFSA, 2023g) that has not been considered by risk managers yet.

Occurrence of folpet (RD) under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to folpet are given by Regulation (EU) 2018/832⁵³ for the samples taken in years 2020 and 2021 and Regulation (EU) 2022/93³⁴ for samples taken in year 2022. Results were reported by the Member States for the sum of folpet and phthalimide, expressed as folpet, therefore, it is not possible to know whether these residues are due to residues of folpet, residues of phthalimide, or both, as in the residue trials.

Regarding commodities not labelled as organic, 55,190 samples were collected and analysed for folpet (RD) (i.e. the sum of folpet and phthalimide expressed as folpet) in plant commodities, honey and other apiculture products under a monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 52,280 (94.73%) were unprocessed and 2,910 (5.27%) were processed commodities. No residues were quantified in 54,798 out of the 55,190 samples (99.29%). In 381 out of the 55,190 samples (0.69%) folpet (RD) was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-7.1. MRLs were exceeded in 11 out of the 55,190 samples (0.02%). The highest concentration for samples exceeding the MRLs was 2.453 mg/kg in pome fruits (pears).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of folpet (RD) are summarised in Table 3.7.3.2-2a for unprocessed, and in Table 3.7.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on folpet (RD) in feed not labelled as organic were submitted to EFSA.

Table 3.7.3.2-2a: Occurrence of folpet from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Folpet (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0130000	Pome fruits	0.03*–0.3	0.002	0.01–2.453	50	0.022
0150000	Berries and small fruits	0.03*–20	0.002	0.005–6.3	101	0.03
0160000	Miscellaneous fruits	0.03*–0.15*	0.002	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.03*–0.06*	0.002	0.005–0.058	7	0.017
0220000	Bulb vegetables	0.03*	0.002	0.013	1	0.013
0230000	Fruiting vegetables	0.03*–5	0.002	0.011–0.245	4	0.051
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.03*	0.002	0.011–0.951	7	0.032

⁵³ Commission Regulation (EU) 2018/832 of 5 June 2018 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cymoxanil, deltamethrin, difenoconazole, fenamidone, flubendiamide, fluopicolide, folpet, fosetyl, mandestrobin, mepiquat, metazachlor, propamocarb, propargite, pyrimethanil, sulfoxaflor and trifloxystrobin in or on certain products. OJ L 140, 6.6.2018, p. 38–86.



Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Folpet (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0250000	Leaf vegetables, herbs and edible flowers	0.03*–1.5	0.002	0.005–0.143	8	0.027
0260000	Legume vegetables	0.03*	0.002	<LOQ	0	<LOQ
0402010	Olives for oil production ^{d)}	0.15*	0.01	<LOQ	0	<LOQ
0500000	Cereals	0.07*–2	0.005	0.014–0.26	13	0.024
0700000	Hops (dried)	400	0.05	<LOQ	0	<LOQ
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of folpet is not expected)						
0110000	Citrus fruits	0.03*	0.002	0.014	1	0.014
0120000	Tree nuts	0.07*	0.01	<LOQ	0	<LOQ
0140000	Stone fruits	0.03*	0.002	0.01–0.052	9	0.02
0270000	Stem vegetables	0.03*	0.002	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.03*	0.002	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.03*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.07*	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits ^{d)}	0.07*–0.15*	0.005	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*	0.01	0.034–0.093	13	0.054
0800000	Spices (dried)	0.1*	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.03*	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.005	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) 2023/1042 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Olives for oil production appear in both higher and lower parts of the table to indicate the use of the substance for commodities '0402010' and non-use of the substance for all other commodities '04N0000' that are reported under the 'broader' category 0600000 on the table. This creates an inconsistency where the results indicating non-uses are overestimated.

Table 3.7.3.2-2b: Occurrence of folpet from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Folpet (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. Analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
<i>Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities</i>						
<i>Food</i>						
0130000	Pome fruits	0.03*-0.3	0.002	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.03*-20	0.002	0.01-6	171	0.18



Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Folpet (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. Analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0160000	Miscellaneous fruits	0.03*–0.15*	0.01	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.03*–0.06*	0.01	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.03*	0.03	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.03*–5	0.01	0.063–0.086	2	0.075
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.03*	0.03	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.03*–1.5	0.005	0.12–0.13	2	0.125
0260000	Legume vegetables	0.03*	0.01	<LOQ	0	<LOQ
0402010	Olives for oil production ^{d)}	0.15*	0.01	0.015–0.02	3	0.018
0500000	Cereals	0.07*–2	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	400	0.01	<LOQ	0	<LOQ
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of folpet is not expected)						
Food						
0110000	Citrus fruits	0.03*	0.01	<LOQ	0	<LOQ
0120000	Tree nuts	0.07*	0.01	<LOQ	0	<LOQ
0140000	Stone fruits	0.03*	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.03*	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.03*	0.01	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.03*	ND	ND	ND	ND
0300000	Pulses (dried)	0.07*	0.01	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits ^{d)}	0.07*–0.15*	0.01	0.015–0.02	3	0.018
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*	0.05	<LOQ	0	<LOQ
0800000	Spices (dried)	0.1*	0.05	<LOQ	0	<LOQ
0900000	Sugar plants	0.03*	0.024	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.020	<LOQ	0	<LOQ

* Limit of quantification for unprocessed commodities in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available. a) Maximum Residue Level in Reg. (EU) 2023/1042 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Olives for oil production appear in both higher and lower parts of the table to indicate the use of the substance for commodities '0402010' and non-use of the substance for all other commodities '04N0000' that are reported under the 'broader' category 0600000 on the table. This creates an inconsistency where the results indicating non-uses are overestimated.

Occurrence of folpet in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 6,120 samples were collected and analysed for folpet from plant commodities, honey and other apiculture products labelled as organic under a monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 5,031 (82.21%) were unprocessed and 1,089 (17.79%) processed commodities. No residues were

quantified in 6,106 samples out of the 6,120 samples (99.77%). In 13 samples out of the 6,120 samples (0.21%) folpet was found at or above the analytical LOQ but below or at the MRL. MRL was exceeded in one sample out of the 6,120 samples (0.02%) with the quantified level of 0.302 mg/kg in berries and small fruits (wine grapes). These findings are summarised in Appendix B, Table B-7.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.7.3.2-3a for unprocessed and in Table 3.7.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on folpet in feed labelled as organic were submitted to EFSA.

Table 3.7.3.2-3a: Occurrence of folpet from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Folpet (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. Analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.03*	0.005	<LOQ	0	<LOQ
0120000	Tree nuts	0.07*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.03*-0.3	0.002	<LOQ	0	<LOQ
0140000	Stone fruits	0.03*	0.002	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.03*-20	0.002	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.03*-0.15*	0.002	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.03*-0.06*	0.002	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.03*	0.002	0.006	1	0.006
0230000	Fruiting vegetables	0.03*-5	0.002	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.03*	0.002	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.03*-1.5	0.002	0.0355	1	0.036
0260000	Legume vegetables	0.03*	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.03*	0.002	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.03*	0.002	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.03*	0.005	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.07*	0.01	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.07*-0.15*	0.01	<LOQ	0	<LOQ
0500000	Cereals	0.07*-2	0.005	0.028	1	0.028
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	400	0.05	<LOQ	0	<LOQ
0800000	Spices (dried)	0.1*	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.03*	0.05	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.01	<LOQ	0	<LOQ

*Limit of quantification in Reg. (EC) No 396/2005.

Findings of not authorised substances in organic products

a) Maximum Residue Level in Reg. (EU) No 2023/1042 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.7.3.2-3b: Occurrence of folpet from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Folpet (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. Analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.03*	0.01	<LOQ	0	<LOQ
0120000	Tree nuts	0.07*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.03*–0.3	0.01	<LOQ	0	<LOQ
0140000	Stone fruits	0.03*	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.03*–20	0.002	0.031–0.302	10	0.073
0160000	Miscellaneous fruits	0.03*–0.15*	0.01	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.03*–0.06*	0.01	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.03*	ND	ND	ND	ND
0230000	Fruiting vegetables	0.03*–5	0.01	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.03*	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.03*–1.5	0.01	<LOQ	0	<LOQ
0260000	Legume vegetables	0.03*	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.03*	0.05	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.03*	ND	ND	ND	ND
0290000	Algae and prokaryotes organisms	0.03*	ND	ND	ND	ND
0300000	Pulses (dried)	0.07*	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.07*–0.15*	0.01	<LOQ	0	<LOQ
0500000	Cereals	0.07*–2	0.005	0.017 ^{c)}	1	0.017 ^{d)}
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	400	ND	ND	ND	ND
0800000	Spices (dried)	0.1*	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.03*	0.05	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	ND	ND	ND	ND

*Limit of quantification for unprocessed commodities in Reg. (EC) No 396/2005; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2023/1042 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Quantified result in processed cereal-based foods for infants and young children. No quantified results in cereals.

Occurrence of folpet in the EU Organic Farming Information System

The EU OFIS reported 18 quantified results for the folpet (RD) in 2021 and 2022. Five of the samples collected and analysed had EU origin and 13 were of non-EU origin. Residues were found in one sample of miscellaneous fruits (jambuls/jambolans), one sample of bulb vegetables (garlic), four samples of leaf vegetables, herbs and edible flowers (thyme), 1 sample of algae and prokaryotes organisms (*Chlorella* – green algae of the division Chlorophyta), one sample of cereal (wheat), eight samples of teas, coffee, herbal infusions, cocoa and carobs (teas, herbal infusions, cocoa beans and carobs), one sample of spices (fenugreek) and one sample of products or part of products exclusively used for animal feed production (apple pomace). The concentrations of folpet residues were above LOQ but below MRL in 12 samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005. MRL exceeded in five samples. For the sample of products or part of products exclusively used for animal feed production (apple pomace), no MRL is applicable according to Reg. (EC) No 396/2005. The highest concentration was reported for a sample of roasted spelt (*Triticum spelta*), with the quantified level of 0.74 mg/kg. These findings are summarised in Table 3.14.3.2-4.

Table 3.7.3.2-4: Occurrence of folpet from the EU OFIS in the years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
0220010	Garlic	0.03*	0.023 – Garlic	ND
0500090	Wheat	0.4	ND	0.74 – Wheat (spelt) (roasted)
0630000	Herbal infusions	0.1*	0.42 – Herbal infusion (drying)	ND
0810080	Fenugreek	0.1*	0.01 – Fenugreek (drying)	ND
1200000	Products or part of products exclusively used for animal feed production	NA		0.05 – Apple (pomace)
Samples of non-EU origin				
0161070	Jambuls/jambolans	0.03*	ND	0.02 – Acerola (juice)
0256070	Thyme	0.06*	ND	0.13; <0.01; 0.13 – Oregano (rubbed)
0290000	Algae and prokaryotes organisms	0.03*	ND	0.02 – <i>Chlorella</i> (powder)
0610000	Teas	0.1*	0.06; 0.056; 0.062 – Tea (drying)	ND
0630000	Herbal infusions	0.1*	0.065 – Elderflowers (drying)	ND
0640000	Cocoa beans	0.1*	0.033; 0.033 – Cocoa beans (drying)	ND
0650000	Carobs/Saint John's breads	0.1*	-	0.05 – Carob (powder)

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2023/1042 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b)

Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of folpet and phthalimide in untreated samples (control samples) from residue trials

In the evaluation report on the MRLs for folpet in table grapes, blueberries and several stone fruits (Austria, 2013a), residues of folpet and phthalimide were observed in control (untreated) samples of table grapes from two residue trials carried out in Germany. The reason for the



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contamination, as reported by the study director, was likely attributed to the application of folpet-containing fungicide, which was sprayed from a helicopter approximately 200–300 metres away from the test plots.

Quantified findings in control (untreated) samples of folpet were observed in tomato samples from Italy and Spain (Austria, 2010), and in wine grape samples from Hungary and Germany (Austria, 2023a). Three out of four findings in the control samples from wine grapes were exceeding the MRLs for this commodity (0.05* mg/kg).

Regarding feed commodities, residues of folpet in control (untreated) samples were measured in four barley straw samples from southern France and one from Spain (Austria, 2023a). Residues of phthalimide were found in control (untreated) samples of barley straw from two residue trials from northern and southern France.

Apart from table grapes from Germany, where occurrence in untreated samples was explained by helicopter applications (see above), no evidence-based explanations on the causes for these occurrences in control (untreated) samples were provided in the above Member State ERs and RARs.

The summary of the quantified findings of folpet and phthalimide in control (untreated) samples from residue trials carried out for the critical GAP⁴ per crop is given below in Table 3.7.3.2-5.

Table 3.7.3.2-5: Summary of the quantified findings of folpet and phthalimide in control (untreated) samples from residue trials carried out for the critical GAP per crop.

Crop	Country/Area	Results	
		Folpet concentration (mg/kg)	Phthalimide concentration (mg/kg)
Wine grapes	Hungary	0.10; 0.062	ND
	Germany	0.013; 0.067	ND
Tomatoes	Italy	0.08	ND
	Spain	<0.03–0.26 ^{a)}	ND
Table grapes ^{b)}	Germany	0.17; 0.39	0.15; 0.32
Barley straw	Northern France	ND	0.05
	Southern France	0.01; 0.02; 0.025; 0.05	0.04
	Spain	0.03	ND

ND – no data available.

a) The number of quantified findings in the control samples is not specified.

b) An application of folpet-containing fungicide was done from a helicopter approximately 200–300 metres away from the test plots.

- Could the presence of folpet and/or its residues be due to biocide use?

Folpet products are applied as preservatives of plastic materials in end products used indoors or in swimming pools, extruders and injection moulders and sealant products. Mitigation measures are proposed to prevent environmental exposure to folpet (Netherlands, 2021c). These include proposals to restrict plastic materials used in swimming pools only that drain to the municipal sewer, used as liners for above-ground small pools/ponds or used for preservation of plastics intended for uses which involve contact with food, feed or livestock.

PEC calculations in water and soil carried out by the Evaluation Member State for different scenarios (e.g. water discharge of public and private pools via sewage treatment plants or the direct emission to soil on the leaching from roof membranes), gave the highest values of 1.29 µg/L (PEC_w) and 0.918 mg/kg (PEC_{soil}) for folpet, and 44 µg/L (PEC_w) and 28.7 mg/kg (PEC_{soil})



for phthalimide. These PECs, which correspond to a non-agriculture worst-case scenario are very localised and, with a direct application, are covered by those estimated for agricultural uses of the substance (see Section 3.7.3.6).

Based on the above, it can be concluded that the release of residues of folpet and its transformation products in the water and/or soil after biocidal use cannot be excluded.

3.7.3.3 Behaviour in food and feed products

- What key physico-chemical properties of folpet are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of **folpet** are reported in Table 3.7.3.3.

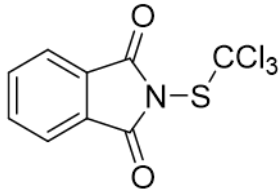
Folpet shows very low to moderate or low persistence in soil (see Section 3.7.3.5). Regarding sorption to soil, the geometric mean of K_{Foc} in Table 3.7.3.3a indicates that the substance has low mobility in soil (EFSA, 2023g).

The maximum calculated PECw for folpet for the representative uses was 28.37 µg/L (late application to vines; 1 × 1.6 kg a.s./ha). The maximum PECw of phthalimide was 41.59 µg/L (late application to vines, 10 × 1.6 kg a.s./ha). This would result in a total folpet equivalents PECw of 112.23 µg/L.

Folpet is not hydrolytically stable at any of the pH values tested at room temperature. There is evidence that folpet is completely degraded during common food processing practices, like pasteurisation (20 minutes at 90°C, pH 4), boiling, brewing, baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). Phthalimide is the major transformation product formed during pasteurisation (92% TRR), whilst levels of phthalic acid increase under conditions simulating boiling, brewing, baking and sterilisation (EFSA, 2014e). Considering that folpet may degrade under food/feed processing, the derived degradation products may not be completely captured by the analytical methods because some of these products are not included in the residue definition for monitoring and, therefore, are not analysed. This would be expected to result in a decrease in the measured residues in the processed commodity when compared with the raw commodity. On the other hand, some processes such as drying may result in higher concentrations of residues in the processed commodities. Therefore, both possibilities (decrease or increase of folpet residues) are plausible in this case, depending on the process.

Folpet has a low vapour pressure (7.6×10^{-6} Pa at 20°C) (EFSA, 2023g).

Table 3.7.3.3a: Physico-chemical properties of folpet

Structural formula	
Appearance (state purity)	White solid crystals (98.8%) White solid (96.5%) Off-white solid (95.7%)
Melting point (state purity)	179–180°C (99.6%)



Boiling point	Not determinable: the test substance decomposes below the boiling point
Temperature of decomposition	The test substance decomposes above its melting point starting at 184°C (99.4%)
Vapour pressure (state temperature, state purity)	1.7×10^{-5} Pa at 20°C (98.1%) 3.6×10^{-5} Pa at 25°C (98.1%) 1.2×10^{-3} Pa at 50°C (98.1%) 7.6×10^{-6} Pa at 20°C (98.3%) 1.5×10^{-5} Pa at 25°C (98.3%) 3.8×10^{-4} Pa at 50°C (98.3%)
Henry's law constant (state temperature)	1.3×10^{-2} Pa m ³ mol ⁻¹ at 25°C 5.6×10^{-3} Pa m ³ mol ⁻¹ at 25°C
Solubility in water (state temperature, state purity and pH)	0.80 mg/L (max) at 25°C (98.8%) 0.50 mg/L (mean) at 15°C (98.8%)
Partition coefficient (state temperature, pH and purity)	log P _{OW} = 3.107 at 25°C (pH not specified) (98.8% purity)
Partition coefficient (octanol/air)	Log P _{oa} = 8.4 (EPISuite KOAWIN v1.10) (Debler et al. 2024)
Atmospheric half-life	DT ₅₀ of 8.15 hours derived by the Atkinson model (AopWin 1.92). OH (12 h) concentration assumed = 1.5×10^6 OH radicals per cm ³
Dissociation constant (state purity)	Folpet does not dissociate at the pH ranges encountered in aqueous solution
Soil adsorption (geometric mean)	K _{Foc} = 865 mL/g
Hydrolytic degradation (>10%)	pH 5: 2.9 h at 25°C (1st order, χ^2 = 1.7 %) pH 7: 1.3 h at 25°C (1st order, χ^2 = 10.9 %) pH 9: 59 s at 25°C (1st order, χ^2 = 11.5 %) degradation compounds at pH 5 Phthalimide: 91.5 % AR (24 h) Phthalamic acid: 0.9 % AR (5 h) Phthalic acid: 8.5 % AR (24 h) degradation compounds at pH 7 Phthalimide: 44.4 % AR (8 h) Phthalamic acid: 2.5 % AR (8 h) Phthalic acid 46.2 % AR (8 h) degradation compounds at pH 9 Phthalimide: 15.7 % AR (~370 s) Phthalamic acid: 2.0 % AR (~20 s) Phthalic acid 78.4 % AR (~612 s)

DT₅₀ – Disappearance time of 50% of the substance in field studies; pH – Potential of Hydrogen; P_{ow} – Octanol/water Partition Coefficient; P_{oa} – Octanol/air Partition Coefficient

Phthalimide is a plant metabolite and breakdown product of folpet but also a breakdown product of other pesticides like ditalimfos and phosmet. Phthalimide can also be produced from phthalic acid and phthalic anhydride in the presence of substances containing primary amino groups (i.e. amino acids), and under dry conditions (EURL-SRM, 2019).

The physico-chemical properties of phthalimide are reported in Table 3.7.3.4.

Phthalimide is very low or low persistent in soil (EFSA, 2023g). Regarding sorption to soil, the geometric mean of K_{F, OC} in Table 3.7.3.3b indicates that the substance has high mobility in soil (EFSA, 2023g).

Phthalimide is hydrolytically stable at 25°C and pH range 4–7, but not at pH 9 where a half-life of 2 h was calculated. As already stated, it degrades to phthalic acid under conditions simulating boiling, brewing, baking and sterilisation (EFSA, 2009c). Considering that phthalimide may degrade under food/feed processing, the derived degradation products may not be completely captured by the analytical methods because they are not included in the residue definition for monitoring and, therefore, are not analysed. This would be expected to result in a decrease in the measured residues in the processed commodity when compared with the raw commodity. On the other hand, some processes such as drying may result in higher concentrations of

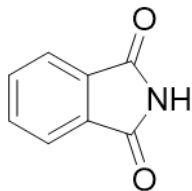


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residues in the processed commodities. Therefore, both possibilities (decrease or increase of phthalimide residues) are plausible in this case, depending on the process.

Phthalimide has a low vapour pressure (1.4×10^{-6} Pa at 20°C) (EFSA, 2023g).

Table 3.7.3.3b: Physico-chemical properties of phthalimide

Structural formula	
Appearance (state purity)	white crystalline solid at 20°C (ECHA)
Melting point (state purity)	238°C is the most frequently reported (ECHA)
Boiling point	No boiling takes place up to 300°C (ECHA)
Temperature of decomposition	No info available
Vapour pressure (state temperature, state purity)	5.6×10^{-6} hPa at 25°C (ECHA)
Henry's law constant (state temperature)	1.03×10^{-3} Pa m ³ mol ⁻¹ at 25°C (Bayer Industry Services, 2004) (ECHA)
Solubility in water (state temperature, state purity and pH)	370 mg/L at 25°C (ECHA)
Partition coefficient (state temperature, pH and purity)	log Pow = 1.15 (no information on temperature and pH) (ECHA)
Partition coefficient (octanol/air)	NA
Atmospheric half-life	DT ₅₀ of 2.6 days derived by the Atkinson model (AopWin 1.91). OH (24 h) concentration assumed = 5×10^5 OH radicals per cm ³ (ECHA)
Dissociation constant (state purity)	8.3 (ECHA)
Soil adsorption (geometric mean)	K _{Foc} = 127 mL/g
Hydrolytic degradation (>10%)	pH 4: 125 d at 25°C (1st order, $\chi^2 = 0.3$ %) pH 4: 141 d at 25°C (1st order, $\chi^2 = 0.6$ %) pH 7: 2.3 d at 25°C (1st order, $\chi^2 = 0.4$ %) pH 9: 0.05 d at 25°C (1st order, $\chi^2 = 4.4$ %)

DT₅₀ – Disappearance time of 50% of the substance in field studies; NA – not applicable; pH – Potential of Hydrogen; Pow – Octanol/water Partition Coefficient

3.7.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from the soil surface at which it is applied).

The highest drift of folpet to neighbouring fields may occur during its applications to fruit crops (up to 29.2%), hops (19.33%), vineyards and vegetables (up to 8.02%) and field crops (up to 2.77%). Drift values should be considered the rate received by neighbouring fields, expressed as a percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field,



the number of applications and potential managerial measures in place (e.g. buffer zones or spray drift-reducing nozzles).

If organic crops are present adjacent to the conventional crops treated, measurable residues of folpet in the untreated crop cannot be excluded (above all if the treated crops are fruit trees). However, since the nature of the potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

As authorised products are to be applied in liquid form, dust drift is not expected to occur.

3.7.3.5 Accumulated/historical residue levels in soil

- What is the persistence of folpet and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

Since, according to available data (EFSA, 2023g), DT_{90} of folpet in soil (in nine laboratory dark aerobic experiments) is <1 year (worst case 20°C laboratory DT_{90} = 99.8 days), folpet is not expected to accumulate in soil over successive seasons. Phthalimide is the main transformation product of folpet in soil (up to 50.6% on a molar basis, worst case 20°C laboratory DT_{90} = 24 days). Therefore, residues of folpet and phthalimide are not expected to accumulate nor to be found in rotational crops (EFSA, 2014e).

Based on the above, uptake of residues of folpet or phthalimide from plants planted or sown in soil previously treated with folpet are considered unlikely. This is also valid for organic crops, when planted in fields that previously used folpet for conventional agriculture, considering that it requires at least 2 years after the last chemical treatment in order for organic crops to be planted in such areas.²

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Accumulation of folpet or its transformation product phthalimide in soil is not expected.

3.7.3.6 Residues from water used for irrigation

- Is there evidence that residues of folpet present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for folpet in water samples were considered.

- The EEA-WATERQUALITY³⁹ database (data retrieved on 9 April 2024) reports 13 analytical results from water samples collected for folpet in Italy in 2019;
- The EMPODAT database (data retrieved on 21 March 2024) reports 14 analytical results from surface water samples collected for folpet in the Netherlands between 2017 and 2019;
- The NAIADES database (data retrieved on 2 April 2024) reports 42,736 analytical results from surface water samples collected in France from 2020 to 2022.



Among the 42,763 analytical results for folpet, 63 were disregarded as found to report quantitative values below the analytical LOQ. Therefore, the number of water samples considered is 42,700.

Based on the screening process described in section 'Data and methodologies', for 100% of water samples analysed and reported in EEA-WATERQUALITY, EMPODAT and NAIADES (42,700 samples), the residue concentrations were below the screening Cw of 0.85 µg/L for folpet.

Therefore, it can be concluded that the transfer of folpet residues from EU water sources to plant commodities when this water is used to irrigate the plants, is unlikely.

Residues of phthalimide in surface water (originated either from the use of folpet or from other phthalimide-containing chemicals) can also contribute to the apparent residues of folpet.

On the EC's IPCHEM¹² the following databases providing occurrence data for phthalimide in water samples were considered:

- The EMPODAT database reports 1013 analytical results from surface water samples collected for phthalimide in the Netherlands between 2017 and 2019;
- The NAIADES database reports 1137 analytical results from surface water samples collected in France from 2019 to 2021.

Based on the screening process described in section 'Data and methodologies', for 100% of surface water samples analysed and reported in EMPODAT and NAIADES (2,150 samples), the residue concentrations were below the screening Cw of 16.9 µg/L for phthalimide. Only one out of the 2,150 samples exceeded the screening Cw.

Therefore, it can be concluded that the transfer of phthalimide residues from water sources to plant commodities when this water is used to irrigate the plants, is unlikely.

3.7.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *folpet*, *industry/industrial*, and *air/atmosphere*) identified only one European study, which was considered irrelevant for this section.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water. Based on conservative estimations of the possible transfer of residues from water used for irrigation to plant commodities, the transfer of residues of folpet from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

A literature review was carried out to gather relevant information. A search in the Scopus database (conducted on March 4, 2025, using the keywords *folpet*, *industry/industrial*, and *water*) did not identify any potential articles with potentially relevant information.



Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Based on information on the possible plant uptake of folpet from EU soil, the transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on March 5, 2025, using the keywords *folpet*, *industry/industrial*, and *soil/sediment*) did not identify any potential articles with potentially relevant information.

3.7.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Medium and long-range aerial transport of residues

In a study by Zaller et al. (2022) the authors employed passive air samplers across 15 regions in Austria with varying land uses over a period of up to 8 months (March to November 2020). The samples were analysed for 566 substances, and relationships between the detected concentrations, land use types, substance properties, and meteorological conditions were examined. Folpet was quantified in 87% of targeted samples in concentrations ranging from 35.5 ng/sample to 1665.2 ng/sample. The authors suggest that folpet, present in 26 commonly used fungicides applied in vineyards, cereal crops, and horticulture in Austria, was likely sourced from these agricultural applications.

Silva et al. (2023) investigated the presence of folpet in 20 outdoor air samples collected during the 2021 growing season across 10 study sites in Europe of organic and conventional agriculture (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). The study was carried out under the framework of the EU SPRINT project. Organic fields had not been treated for 5 consecutive years. Folpet was quantified in 55% of the targeted samples at concentrations ranging from 77.5 to 8088 ng m⁻³ in Portugal. Four out of the nine samples with quantified residues were collected from organic field surrounding areas in Czechia (1239 ng m⁻³), Croatia (87.2 ng m⁻³), Portugal (448.5 ng m⁻³) and Slovenia (189 ng m⁻³).

Residues of folpet have been quantified in air samples collected from April 2021 and June 2022 from two agricultural areas of conventional farming in Portugal (vineyard) and the Netherlands (potatoes, onions and sugar beet) in a study that was carried out in the framework of the EU SPRINT project (Debler et al., 2024). In both countries, folpet's atmospheric presence is qualitative (no quantitative findings are reported) but consistent with folpet's physical properties (e.g. moderate vapour pressure) and prone to particle-phase deposition. Samples from Portugal showed significantly higher detection rates (76%) compared to the Netherlands (2%), likely due to vineyard application in Portugal. The reason is that Portuguese fields had undergone folpet treatment before the collection of the samples from the surrounding area whereas the Dutch fields had not undergone such treatment.

Overall, the results of these studies suggest that folpet transfer via aerial transport outside the treated areas cannot be excluded.

Uptake from organic fertilisers



In a study investigating pesticide residues in organic fertilisers, residues of folpet and other pesticides were quantified (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). The authors attributed the origin of the residues to the presence of plant protection products in the composted crop or in composted manure due to transfer from animal feed after digestion, or in straw used in stables. Analysis of solid organic fertilisers gave an average concentration of 0.14 mg/kg for folpet in one out of 147 samples. Considering that (according to the authors) the use of completely free from residues organic fertilisers is currently unsustainable, transfer of folpet residues from fertilisers used in organic production to organic products cannot be excluded. On the other hand, no residues of folpet were found in any of the products of the crops discussed in the study (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). As assessed above (see Section 3.7.3.5), available information from rotational crop studies indicates that the uptake of folpet from soil by plants is very limited. It may be expected that the same would hold true for the uptake of the folpet residues from soil compost.

3.7.4 Conclusions on folpet

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use. Some of the residues quantified in the residue trials are higher than the implemented MRLs for the respective commodities. This is because these trials were evaluated in the more recent peer review and have not been considered yet by the risk managers (see Section 3.7.3.2).
- Residue trials carried out to support the critical GAP⁴ for folpet, gave residue concentrations of up to 9 mg/kg in berries and small fruits, 192 mg/kg in hops (dried), and up to 19.6 mg/kg in cereal straw for the sum of folpet and phthalimide, expressed as folpet. For folpet only, residue concentrations were up to 6.3 mg/kg in berries and small fruits, 74 mg/kg in hops (dried), and up to 11.3 mg/kg in cereal straw. Concentrations in the ranges reported in Table 3.7.3.2-1 might be associated with active use of folpet according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.
- Concentrations of phthalimide after applications of folpet according to the critical GAP per crop, ranged up to 2.45 mg/kg in berries and small fruits and up to 6.9 mg/kg in cereal straw.
- Phthalimide is a transformation product of folpet and its presence in commodities where folpet is not quantified does not rule out the potential active use of folpet. On the other hand, phthalimide is a common transformation product of folpet and two other non-approved active substances (phosmet and ditalimfos). Thus, its presence in commodities of plant origin in the absence of the parent compound requires investigation and cannot be directly associated with the use of folpet.
- Folpet and/or phthalimide were quantified in the context of residue trials in several European countries in untreated (control) samples with the highest concentrations observed for folpet (0.39 mg/kg) and phthalimide (0.32 mg/kg) in one sample of table grapes from Germany. It is noted that a folpet-containing fungicide was applied by helicopter approximately 200–300 metres from the test plots.
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings



per commodity group, the median concentrations for the sum of folpet and phthalimide (expressed as folpet) in unprocessed commodities with authorised uses of folpet, ranged from 0.017 mg/kg in root and tuber vegetables up to 0.032 mg/kg in brassica vegetables (excluding brassica roots and brassica baby leaf crops).

- None of the unprocessed organic commodities that were analysed under the pesticide residues monitoring programme between 2020 and 2022 had more than five quantified findings per commodity group.
- In organic and not labelled as organic processed commodities, residues of folpet with five or more quantified findings were found only in processed berries and small fruits with a median concentration of 0.073 mg/kg in organic and 0.18 mg/kg in not labelled as organic processed commodities. Considering that folpet and phthalimide may degrade under food/feed processing, the derived degradation products may not be completely captured by the analytical methods because some of these products are not included in the residue definition for monitoring and, therefore, are not analysed. This would be expected to result in a decrease in the measured residues in the processed commodity when compared with the raw commodity. On the other hand, some processes such as drying may result in higher concentrations of residues in the processed commodities. Therefore, both possibilities (decrease or increase of folpet and phthalimide residues) are plausible in this case, depending on the process.
- Without additional information on the individual samples' history and context, it cannot be discerned whether unexpected findings of folpet in organic production may relate to active use or unintentional presence.
- Overall, in commodities labelled as organic, folpet was quantified in 0.2% of samples (14 out of 6,120 samples). This percentage is around three times lower than the percentage reflecting the number of findings in samples not labelled as organic (0.7%) (see Appendix B, Tables B-7.1 and B-7.2). These results suggest that the occurrence of residues of folpet in organic products is less likely when compared with the conventional commodities.
- Potential source of the unintentional presence of residues of folpet (RD) in commodities of plant origin, is drift from conventional crops grown in the vicinity. Aerial transfer of residues to plants cannot be excluded. Presence of phthalimide alone is not necessarily linked to the use of folpet (see previous bullet).
- Folpet is not persistent in soil. The potential plant uptake from soil or from organic fertilisers that contain residues is unlikely.
- The transfer of residues of folpet and phthalimide from EU water sources used for irrigation to plant commodities is unlikely.
- Although phthalimide can occur naturally in burning coal heaps, such occurrence is insufficient to explain its intentional or unintentional presence in plants. REACH registration data do not confirm the use of products that contain phthalimide in the EU Member States¹¹, Iceland, Liechtenstein and Norway; conversely, registration data indicate the use of the substance as an intermediate in the synthesis of other compounds.
- Folpet is used in biocidal products and biocidal products containing folpet may result in the release of residues of folpet into the environment.

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- Conservative estimates of the possible transfer of residues of folpet and phthalimide from water used for irrigation to plant commodities and information on the possible plant uptake of residues of folpet and phthalimide from EU soil suggest that the transfer of residues of these substances from biocidal use and other non-pesticide uses as well as the transfer from industrial emissions to the environment and from the environment to plants and plant commodities is less likely.

The pathways of residues of folpet and phthalimide to plants and plant commodities are summarised in Figures 7.1 and 7.2.

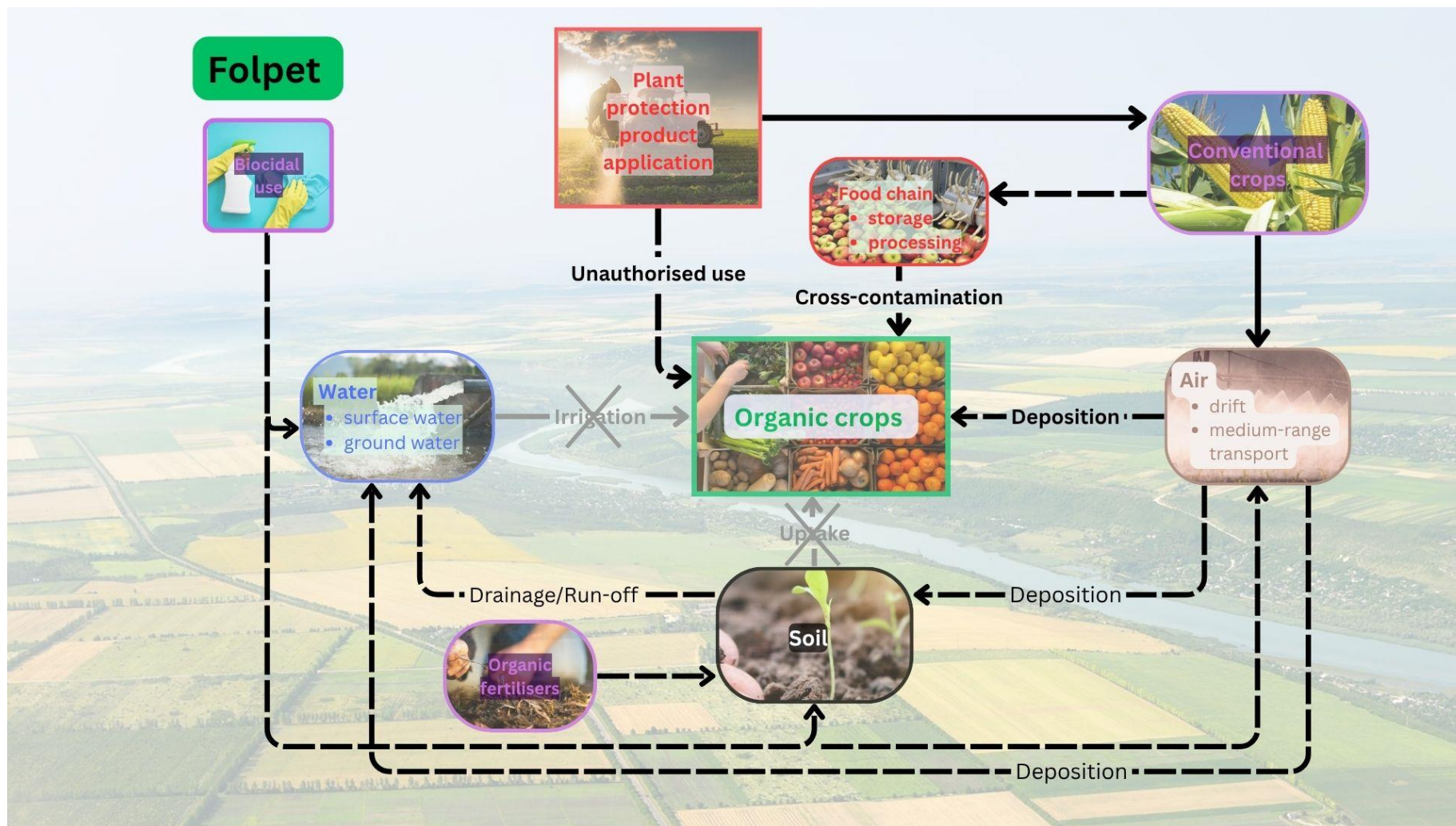
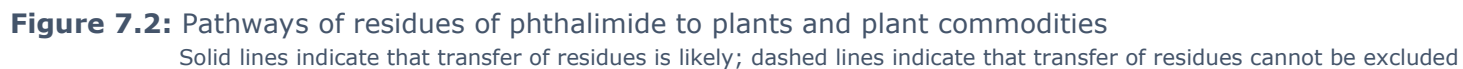


Figure 7.1: Pathways of residues of folpet to plants and plant commodities

Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded



3.8 Pirimiphos-methyl

3.8.1 Method(s)

- What is/are the residues to be monitored for active substance pirimiphos-methyl according to the residue definition for monitoring set in Regulation (EC) No 396/2005?

For the active substance pirimiphos-methyl, the residue definition for enforcement in Regulation (EC) No 396/2005³ for food and feed of plant origin has been set as 'pirimiphos-methyl (F)'⁵⁴. This residue definition was restricted to post-harvest storage only (EC, 2011) and is applicable to both primary and processed commodities (EFSA, 2015f).

In the 2015 EFSA MRL review, the residue definition for enforcement was proposed on a tentative basis to cover the indoor direct or structural treatment of cereals, fruits and fruiting vegetables, pulses and oilseeds considering the lack of metabolism studies for fruits and fruiting vegetables, pulses and oilseeds and the lack of valid methods of analysis of pirimiphos-methyl in dry commodities (EFSA, 2015f). However, only uses in cereals were supported by data (see Section 3.8.3.2 'Active use (all legitimate uses of the substance)').

The residue definition set for plant commodities is also applicable to honey and other apiculture products.

Based on the above, residues of pirimiphos-methyl are to be monitored only in foods of plant origin, honey and other apicultural products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

A multi-residue analytical method using GC-MS is available for the determination of pirimiphos-methyl in high water, high acid, high oil content, and dry commodities of plant origin with an LOQ of 0.05 mg/kg (EFSA, 2005). No independent laboratory validation (ILV) method was available, and this was reported as a data gap in the context of the MRL review for pirimiphos-methyl (EFSA, 2015f).

Another multi-residue QuEChERS method based on GC-MS/MS has also been developed for the analysis of pirimiphos-methyl in high oil content commodities and has been validated at an LOQ of 0.01 mg/kg (EFSA, 2015f).

In the revised assessment report for pirimiphos-methyl, a QuEChERS multi-residue method based on LC-MS/MS and its ILV have been validated in dry and high oil commodities with an LOQ of 0.01 mg/kg. Since the peer review for the reapproval of pirimiphos-methyl is currently ongoing, information on this method is taken by the Rapporteur Member State RAR (United Kingdom³⁵, 2018).

According to the EURL for Residues of Pesticides (EURL, 2024, under 'Documentation as provided to EFSA'), a multi-residue citrate-buffered QuEChERS method based on GC-MS/MS is validated for monitoring pirimiphos-methyl residues in honey and other apiculture products at an LOQ of 0.002 mg/kg.

⁵⁴ (F) indicates that the residue definition is fat soluble.

Overall, there are multi-residue methods available for the monitoring of residues of pirimiphos-methyl in high water, high acid, high oil content and dry commodities of plant origin as well as in honey and other apiculture products with LOQs ranging from 0.002 to 0.05 mg/kg.

3.8.2 Authorisation status and use

- Is pirimiphos-methyl currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has pirimiphos-methyl ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

a) Authorisations for plant protection use in conventional agriculture

Pirimiphos-methyl has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. Its use has been approved for post-harvest storage only (EC, 2011). The expiry date of approval of the active substance is on 15 June 2025, as indicated by the EU Pesticides Database⁵ (accessed 9 January 2024). The application for the renewal of the approval of pirimiphos-methyl is under assessment.

According to the EU Pesticides Database⁵, at national level the substance has been authorised for use in Belgium, Bulgaria, Cyprus, Czechia, Estonia, Greece, Spain, France, Croatia, Hungary, Ireland, Italy, Lithuania, Latvia, the Netherlands, Poland, Portugal, Romania, Slovenia, and Slovakia.

b) Authorisations for purposes other than plant protection

Biocidal use

Based on information from the ECHA website⁶ (accessed 6 June 2024), pirimiphos-methyl has not been approved for biocidal use in the EU.

Other uses

A search carried out on the ECHA website⁹ on 6 June 2024 showed that pirimiphos-methyl has had one active registration under REACH since 2022. Information from this registration indicates the use of the substance in the formulation of mixtures with the relevant product categories (PC) being PC 8: Biocidal products and PC 27: Plant protection products. Industrial, professional or consumer use of the substance in the EU Member States¹¹, Iceland, Liechtenstein and Norway is not confirmed by available registration data.

- What is/was the actual use of pirimiphos-methyl? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of pirimiphos-methyl

According to the EFSA MRL review (EFSA, 2015f), pirimiphos-methyl is a broad-spectrum insecticide and acaricide that belongs to the group of organothiophosphate compounds. It is used for the structural treatment of empty grain stores. The treatment can also be done after harvest directly on the grain.

Pirimiphos-methyl has contact and respiratory actions on target organisms. The substance's biochemical mode of action is via inhibition of the acetylcholinesterase enzyme.

Conditions of use and applicable crops

The uses reported in the EFSA MRL review include (i) direct indoor treatment of stored cereal grains, pulses, oilseeds and palm nuts at 4 g active substance per tonne by fogging and (ii) structural treatment of empty storehouses for storage of cereal grains, tree nuts, sunflower seeds and soya beans at application rates up to 500 g active substance per 1000 m² (EFSA, 2015f). Note was taken that only uses in cereals were supported by data (see Section 3.8.3.2 'Active use (all legitimate uses of the substance)').

b) Uses for purposes other than plant protection

Biocidal use

Pirimiphos-methyl is not approved for biocidal use, therefore, use of the substance in biocidal products is not expected (see also 'authorisations for purposes other than plant protection/biocidal use').

Other uses

There is currently one active registration under REACH for pirimiphos-methyl which indicates use in the formulation of biocidal and plant protection products (see also 'authorisations for purposes other than plant protection/other uses').

3.8.3 Sources of residues in plants

3.8.3.1 Natural occurrence

- Is there evidence that pirimiphos-methyl occurs naturally? What is known about the natural origin of this substance?

Pirimiphos-methyl is a synthetic chemical produced industrially through chemical processes (Snell et al., 1978; Lewis et al., 2016). No information on the potential natural presence of pirimiphos-methyl was found in the literature²².

3.8.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of pirimiphos-methyl per food/feed product would be consistent with active use of pirimiphos-methyl?

Results from analysis of residues of pirimiphos-methyl in the context of residue trials carried out for the critical GAP⁴ for cereals and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.8.3.2-1 to 3.8.3.2-4. The possible presence of residues in control (untreated) samples is also discussed in this section.

For both residue trials and results from monitoring, residue concentrations refer to the residue definition for enforcement (i.e. pirimiphos-methyl).

Occurrence of pirimiphos-methyl from residue trials carried out for the critical GAP per crop

Although EU GAPs were reported for all uses indicated under 3.8.2 'Conditions of use and applicable crops', only data on residue trials for indoor treatment of cereal grains were submitted and evaluated in the EFSA MRL review (EFSA, 2015f).

When applied at the critical GAPs⁴ reported to EFSA, residue levels of pirimiphos-methyl occurred above the LOQ in cereal grain.

These findings are summarised in Table 3.8.3.2-1 'Occurrence of pirimiphos-methyl from residue trials carried out for the critical GAP per crop'.

Table 3.8.3.2-1: Occurrence of pirimiphos-methyl from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pirimiphos-methyl (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
Food				
0120000	Tree nuts ^{c)}	0.01*	NR	-
0300000	Pulses (dried) ^{c)}	0.01*	NR	-
0400000	Oilseeds and oil fruits ^{c), d)}	0.01*–0.5	NR	-
0500000	Cereals: buckwheat and other pseudocereals, maize/corn, rice, rye, others	0.5	1.1–3.6 ^{e)}	2.5 ^{e)}
	Cereals: barley, common millet/proso millet, oat, sorghum and wheat	5		

* Limit of quantification in Reg. (EC) No 396/2005; NR: no residue trials are available '-': not estimated due to lack of data.

a) Maximum Residue Level in Reg. (EU) No 2016/53 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA, 2015f; c) For uses not supported by data, the MRLs were lowered to the LOQ. d) For uses not supported by data, the MRLs were lowered to the LOQ, except for oilseeds where a higher MRL of 0.5 mg/kg was set to cover cross-contamination. e) Results from a combined dataset of trials on barley (3), wheat (2), oats (2), rye (1) and maize (1) covering structural and direct treatments (EFSA, 2005; Germany, 2014c).

Occurrence of pirimiphos-methyl under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to pirimiphos-methyl are given by Regulation (EU) 2016/53⁵⁵ for the years 2020–2022.

Regarding commodities not labelled as organic, 116,041 samples were collected and analysed for pirimiphos-methyl in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 106,819 (92.05%) were unprocessed and 9,222 (7.95%) processed commodities. No residues were quantified in 115,286 samples out of the 116,041 samples (99.35%). In 728 samples out of the 116,041 samples (0.63%) pirimiphos-methyl was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-8.1. MRLs were exceeded in 27 samples out of the 116,041 samples (0.02%). The highest concentrations for samples exceeding the MRLs were 5.96 mg/kg in pulses (dried) (beans) and 12 mg/kg in cereals (barley).

⁵⁵ Commission Regulation (EU) 2016/53 of 19 January 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for diethofencarb, mesotrione, metosulam and pirimiphos-methyl in or on certain products. OJ L 13, 20.1.2016, p. 12–39

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The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of pirimiphos-methyl are summarised in Table 3.8.3.2-2a1 for unprocessed, and in Table 3.8.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on pirimiphos-methyl in feed not labelled as organic were submitted to EFSA.

Table 3.8.3.2-2a1: Occurrence of pirimiphos-methyl from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pirimiphos-methyl (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues ^{b)} only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0120000	Tree nuts	0.01*	0.005	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.01*	0.002	0.005–5.96	11	0.017
0400000	Oilseeds and oil fruits	0.01*–0.5	0.005	0.012–3.1	15	0.021
0500000	Cereals	0.05–5	0.002	0.005–12	400	0.035
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of pirimiphos-methyl is not expected)						
0110000	Citrus fruits	0.01*	0.001	0.016–0.042	3	0.017
0130000	Pome fruits	0.01*	0.001	0.1188	1	0.119
0140000	Stone fruits	0.01*	0.001	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.01*	0.001	0.015	1	0.015
0160000	Miscellaneous fruits	0.01*	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*	0.001	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*	0.001	0.007–0.022	4	0.013
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	0.001	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*–0.02*	0.001	0.01–0.389	2	0.199
0260000	Legume vegetables	0.01*	0.001	0.012–0.11	2	0.061
0270000	Stem vegetables	0.01*	0.001	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	0.01	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*	0.003	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*–3	0.005	0.01–0.093	2	0.052
0900000	Sugar plants	0.01*	0.005	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.01*	0.005	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005.

a) Maximum Residue Level in Reg. (EU) No 2016/53 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the

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table 'Min. analytical LOQ (mg/kg)'; c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

In addition to the pesticide monitoring data collection, an analysis of residues of pirimiphos-methyl in feed samples was carried out in the framework of the VMPR national control activities (not reported in Table 3.8.3.2-2a1). For unprocessed products of conventional agriculture (225 samples), quantified residues were found in 35 samples ranging from 0.00093 to 0.411 mg/kg with a lowest LOQ at 0.00037 mg/kg. Results per feed commodity group are reported in Table 3.8.3.2-2a2.

Table 3.8.3.2-2a2: Occurrence of pirimiphos-methyl from monitoring data submitted in the framework of the VMPR national control activities, from 2020 to 2022 in unprocessed feed commodity groups not labelled as organic.

Feed commodity group	Pirimiphos-methyl (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
	Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues only (mg/kg)	Total no. of quantified results ^{a)}	Median of results from samples with quantified residues only (mg/kg)
Complementary feed for dairy cows	0.002	0.005–0.261	8	0.014
Complementary feed for fattening calves	0.002	0.003–0.012	7	0.006
Complementary feed for fattening cattle	0.003	0.029–0.411	2	0.22
Complete feed for fattening chickens	0.003	0.006–0.012	2	0.009
Complementary feed for growing/fattening pigs	0.003	0.016–0.02	2	0.018
Complete feed for growing/fattening pigs	0.002	0.003–0.246	6	0.006
Complete feed for lactating cows	0.002	0.038	1	0.038
Complete feed for laying hens	0.00037	0.00093–0.037	4	0.008
Complete feed for piglets	0.002	0.009–0.061	2	0.035
Complete feed for rabbits	0.002	0.014	1	0.014

a) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.8.3.2-2b: Occurrence of pirimiphos-methyl from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pirimiphos-methyl (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.01*	0.008	<LOQ	0	<LOQ

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pirimiphos-methyl (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0400000	Oilseeds and oil fruits	0.01*-0.5	0.002	0.011-0.016	4	0.014
0500000	Cereals	0.05-5	0.001	0.002-2.94	307	0.035
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of pirimiphos-methyl is not expected)						
Food						
0110000	Citrus fruits	0.01*	0.001	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*	0.005	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.01*	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*	0.002	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*	0.01	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*	0.001	0.01	1	0.01
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*-0.02*	0.002	0.032-0.11	2	0.071
0260000	Legume vegetables	0.01*	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.005	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	0.05	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*-3	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*	0.008	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.01*	0.005	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2016/53 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of pirimiphos-methyl in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 10,268 samples were collected and analysed for pirimiphos-methyl from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 8,567 (83.43%) were unprocessed and 1701 (16.57%) processed commodities. No residues were quantified in 10,258 samples out of the 10,268 samples (99.9%). In 10 samples out of the 10,268 samples (0.1%) pirimiphos-methyl was found at or above the analytical LOQ but below or at the MRL. No samples labelled as organic were above MRLs. These findings are summarised in Appendix B, Table B-8.2.

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The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.8.3.2-3a for unprocessed and in Table 3.8.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on pirimiphos-methyl in feed labelled as organic were submitted to EFSA.

Table 3.8.3.2-3a: Occurrence of pirimiphos-methyl from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pirimiphos-methyl (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.01*	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*	0.001	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.01*	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*	0.001	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	0.001	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*–0.02*	0.001	<LOQ	0	<LOQ
0260000	Legume vegetables	0.01*	0.001	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*	0.001	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.01*	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–0.5	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.05–5	0.001	0.01–0.21	4	0.013
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*	0.003	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*–3	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.01*	0.005	<LOQ	0	<LOQ

*Limit of quantification in Reg. (EC) No 396/2005.

a) Maximum Residue Level in Reg. (EU) No 2016/53 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.8.3.2-3b: Occurrence of pirimiphos-methyl from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pirimiphos-methyl (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.01*	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.01*	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*	0.005	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*	ND	ND	ND	ND
0230000	Fruiting vegetables	0.01*	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	0.005	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*–0.02*	0.005	<LOQ	0	<LOQ
0260000	Legume vegetables	0.01*	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.005	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0300000	Pulses (dried)	0.01*	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–0.5	0.005	0.029–0.21	2	0.12
0500000	Cereals	0.05–5	0.002	0.015–0.15	4	0.054
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	ND	ND	ND	ND
0800000	Spices (dried)	0.05*–3	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.005	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2016/53 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of pirimiphos-methyl in the EU Organic Farming Information System

The EU OFIS reported 22 findings for pirimiphos-methyl in 2021 and 2022. Six of the products sampled and analysed had EU origin and 16 were of non-EU origin. Residues were found in two samples of tree nuts (cashew nuts), 13 samples of oilseeds and oil fruits (sunflower seeds, soyabeans, mustard seeds, castor beans and oil palms kernels), 5 samples of cereals (buckwheat and other pseudocereals, common millet/proso millet and wheat), 1 sample of spices (dried)

(ginger) and one sample of products or part of products exclusively used for animal feed production (cow feed). The concentrations of pirimiphos-methyl residues were above LOQ but below MRL in 19 samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005³. MRLs exceeded in two samples. For the sample of products or part of products exclusively used for animal feed production (cow feed), no MRL is applicable according to Reg. (EC) No 396/2005³. The highest concentration was reported for a sample of argan oil from non-EU origin, with the quantified level of 0.38 mg/kg. These findings are summarised in Table 3.8.3.2-4.

Table 3.8.3.2-4: Occurrence of pirimiphos-methyl from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
0401050	Sunflower seeds	0.5	0.1; 0.028 – Sunflower seed	ND
0401080	Mustard seeds	0.5	0.021; 0.016 – Mustard seed	ND
0500090	Wheat	5	0.033 – Khorasan wheat	ND
1200000	Products or part of products exclusively used for animal feed production	NA	ND	0.015 Cow feed (feed-related matrix)
Samples of non-EU origin				
0120030	Cashew nuts	0.01*	0.01; 0.02 – Cashew nuts	ND
0401050	Sunflower seeds	0.5	0.002; 0.003; 0.005; 0.002 – Sunflower seeds	ND
0401070	Soyabeans	0.5	ND	0.036 – Soyabean (meal)
0401150	Castor beans	0.5	ND	0.154 – Sea buckthorn (oil)
0402020	Oil palms kernels	0.01*	ND	0.005 – Argan oil (roasted) 0.38; 0.013 – Argan oil
0500020	Buckwheat and other pseudocereals	0.5	0.012 – Chia seed	ND
0500040	Common millet/proso millet	5	0.023; 0.025; 0.017 – Millet	ND
0840020	Ginger	0.05*	0.018 – Ginger	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2016/53 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of pirimiphos-methyl in untreated samples (control samples) from residue trials

No quantified findings of pirimiphos-methyl were observed in control (untreated) samples from residue trials carried out for the critical GAP⁴ per crop (Germany, 2014c; United Kingdom³⁵, 2003).

- Could the presence of pirimiphos-methyl and/or its residues be due to biocide use?

Pirimiphos-methyl is not authorised for use as a biocide, therefore, residues due to biocidal use are not expected for pirimiphos-methyl.

3.8.3.3 Behaviour in food and feed products

- What key physico-chemical properties of pirimiphos-methyl are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

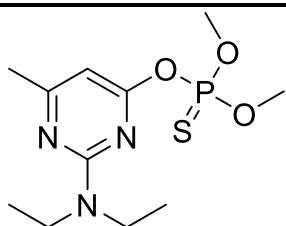
The physico-chemical properties of pirimiphos-methyl are reported in Table 3.8.3.3.

No PECs were calculated in the EFSA peer review for pirimiphos-methyl considering that the substance representative use was post-harvest indoors (EFSA, 2005) for commodities intended for consumption. However, sowing of seeds after treatment cannot be excluded and might result in residues in soil and subsequently in water.

Pirimiphos-methyl has a logP_{ow} around 4 and is classified as fat soluble. Given its short persistence in the atmosphere (1.6 hours), long-range atmospheric transport of pirimiphos-methyl is in principle not expected (Borràs et al. 2017; EFSA, 2005).

Pirimiphos-methyl is hydrolysed in acidic aqueous solutions, but it is relatively stable in neutral or alkaline ones. It was proven hydrolytically stable in hydrolysis studies carried out under baking conditions (white and wholemeal bread, biscuits) but no information is available to EFSA on the behaviour of the substance under conditions of pasteurisation and sterilisation (EFSA, 2015f). Considering that pirimiphos-methyl may degrade under some food/feed processing conditions, a potential formation of degradation products would not be captured by the analytical methods because these products are not included in the residue definition for monitoring and, therefore, are not analysed. This would be expected to result in a decrease in the measured residues in the processed commodity when compared with the raw commodity. On the other hand, some processes such as drying may result in higher concentrations of residues in the processed commodities. Therefore, both possibilities (decrease or increase of residues) are plausible in this case, depending on the process.

Table 3.8.3.3: Physico-chemical properties of pirimiphos-methyl

Structural formula	
Appearance (state purity)	Clear liquid (99.6%) Pale yellow clear liquid (93.5%)
Melting point (state purity)	21°C (99.6%)
Boiling point	Not applicable
Temperature of decomposition	Decomposition occurred at 120°C (93.5%)
Vapour pressure (state temperature, state purity)	2.0×10^{-6} kPa at 20°C
Henry's law constant (state temperature)	6.08×10^{-5} kPa m ³ /mol
Solubility in water (state temperature, state purity and pH)	pH 7: 10 mg/L pH 5: 11 mg/L pH 9: 9.7 mg/L
Partition coefficient (state temperature, pH and purity)	log P _{ow} at 20°C is 3.9 in water buffered at pH 4 and 4.2 in purified water and water buffered at pH 5 and 7
Partition coefficient (octanol/air)	NA
Atmospheric half-life	1.6 h at a theoretical OH concentration of 1.6×10^6 radicals
Dissociation constant (state purity)	4.30 at 20°C

Hydrolytic degradation (>10%)	pH 4: 2 days (DT ₅₀) at 25°C
	pH 5: 7 days (DT ₅₀) at 25°C
	pH 7: 117 days (DT ₅₀) at 25°C
	pH 9: 75 days (DT ₅₀) at 25°C

NA – not applicable; pH – Potential of Hydrogen; P_{ow} – Octanol/water Partition Coefficient

3.8.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

Given the fact that pirimiphos-methyl is only authorised in the structural treatment of empty grain stores and/or post-harvest treatments, spray drift is not expected to occur or be negligible in neighbouring fields. Dust drift to neighbouring fields could occur during drilling of treated grain were it to be used as seed for plant production. Deposition percentile values were considered for neighbouring fields, up to 17% for different crops and techniques (EFSA, 2013b). According to Adriaanse et al. (2022), the use of techniques (deflectors), size of the dust particles and average wind speed were the most important factors determining the amount of dust drift.

3.8.3.5 Accumulated/historical residue levels in soil

- What is the persistence of pirimiphos-methyl and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

Given the fact that the pirimiphos-methyl is only authorised in the structural treatment of empty grain stores and/or post-harvest treatments of commodities, contamination of agricultural soil in principle is not expected to occur. For grains or nuts treated post-harvest and used (sown) as seed afterwards, residues might transfer to soil and, from there, to plants. This, however, is not expected to occur in soil under organic farming systems.

What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Data on the occurrence of pirimiphos-methyl in soil were not available to EFSA.

3.8.3.6 Residues from water used for irrigation

- Is there evidence that residues of pirimiphos-methyl present in water might be transferred to plants following irrigation?

Given the fact that the pirimiphos-methyl is only authorised in the structural treatment of empty grain stores and/or post-harvest treatments of commodities no residue trials with field applications were identified to allow estimation of a screening C_w below which transfer of residues of pirimiphos-methyl to plant commodities from surface waters used for irrigation is not expected.

On the EC's IPCHEM¹² the following databases providing occurrence data for pirimiphos-methyl in water samples were considered:

- The EEA-WATERQUALITY³⁹ database (data retrieved on 10 April 2024) reports 93 analytical results from water samples collected in the Netherlands between 2018 and 2020;

- The EMPODAT database (data retrieved on 21 March 2024) reports 48 analytical results from surface water samples collected in the Netherlands between 2018 and 2020;
- The NAIADES database (data retrieved on 2 April 2024) reports 55,670 analytical results from surface water samples collected in France from 2020 to 2022.

Among the 55,811 analytical results for pirimiphos-methyl, 340 were disregarded as found to report quantitative values below the analytical LOQ. Therefore, the number of water samples considered is 103,108.

All results were below 0.1 µg/L except for three samples that had quantified values at 0.1 µg/L. Although it is not possible to estimate a screening Cw for pirimiphos-methyl, the very low quantified values suggest that transfer of residues of pirimiphos-methyl from water sources to plant commodities when this water is used to irrigate plants, is unlikely.

3.8.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *pirimiphos-methyl*, *industry/industrial*, and *air/atmosphere*) did not identify any relevant European studies.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water. Based on conservative estimations of the possible transfer of residues from water used for irrigation to plant commodities, the transfer of residues of pirimiphos-methyl from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

A literature review was carried out to gather relevant information. A search in the Scopus database (conducted on March 4, 2025, using the keywords *pirimiphos-methyl*, *industry/industrial*, and *water*) identified one European article which was considered irrelevant for this section.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on March 5, 2025, using the keywords *pirimiphos-methyl*, *industry/industrial*, and *soil/sediment*) did not identify any European articles with potentially relevant information.

Considering that pirimiphos-methyl is used in indoor applications, considerable residues of pirimiphos-methyl in soil are not expected. Even if release of residues of pirimiphos-methyl in surrounding soil due to industrial activity, the quantitative uptake of residues from plants growing in this soil and their commodities is less likely.

3.8.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Cross-contamination

Cross-contamination in storage facilities treated with pirimiphos-methyl may result in the unintentional occurrence of residues of pirimiphos-methyl in untreated commodities that were stored in the same facility.

According to the organic agriculture legislation⁵⁶, precautionary measures must be applied in storing organic agricultural products to prevent cross-contamination. This may entail complete separation of conventional from organic commodities or appropriate cleaning measures in facilities in which conventional products have previously been stored. Hence, in principle, cross-contamination of organic products from empty storehouses previously treated with pirimiphos-methyl is not expected.

3.8.4 Conclusions on pirimiphos-methyl

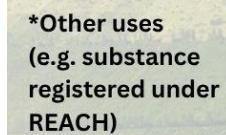
- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use.
- Residue trials carried out to support the critical GAPs⁴ for pirimiphos-methyl in cereal grains (post-harvest), gave residue concentrations from 1.1 to 3.6 mg/kg. Concentrations in the ranges reported in Table 3.8.3.2-1 might be associated with active use of pirimiphos-methyl according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.
- Analysis of untreated commodities (control samples) in the context of residue trials carried out for pirimiphos-methyl did not give quantified results.
- In some dry commodities from conventional agriculture (e.g. oilseeds), concentrations of pirimiphos-methyl up to 0.5 mg/kg may relate to cross-contamination from storage in silos previously treated with the active substance. Cross-contamination was also the reason a higher MRL of 0.5 mg/kg was set for pirimiphos-methyl in oilseeds.
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for pirimiphos-methyl in unprocessed commodities for which EU GAPs were submitted to EFSA ranged from 0.017 mg/kg in pulses (dried) to 0.035 mg/kg in cereals. In unprocessed feed products analysed under the VMPP national control activities, the median concentrations ranged from 0.006 mg/kg in complementary feed for fattening calves and complete feed for growing/fattening pigs to 0.014 mg/kg in complementary feed for dairy cows.

⁵⁶ Regulation (EU) 2018/848, Article 38(1)(a), (b) and (c) on 'Additional rules on official controls and on action to be taken by the competent authorities', and Annex III, point 7 on 'Storage of products'.

- In unprocessed commodities labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022, no commodity group with five or more quantified residues of pirimiphos-methyl was identified.
- In processed commodities labelled as organic, no commodity group with five or more quantified residues of pirimiphos-methyl was identified. In samples from processed products not labelled as organic with five or more quantified findings, residues of pirimiphos-methyl were found in cereal grain with a median concentration of 0.035 mg/kg. Considering that pirimiphos-methyl may degrade under some food/feed processing conditions, a potential formation of degradation products would not be captured by the analytical methods because these products are not included in the residue definition for monitoring and, therefore, are not analysed. This would be expected to result in a decrease in the measured residues in the processed commodity when compared with the raw commodity. On the other hand, some processes such as drying may result in higher concentrations of residues in the processed commodities. Therefore, both possibilities (decrease or increase of residues) are plausible in this case, depending on the process. It should be noted that drying of harvested grain and oilseeds would typically be carried out before and not after any treatment.
- Overall, in commodities labelled as organic, pirimiphos-methyl was quantified in 0.1% of samples (10 out of 10,268 samples). This percentage is around seven times lower than the percentage reflecting the number of findings in samples not labelled as organic (0.65%) (see Appendix B, Tables B-8.1 and B-8.2). These results suggest that the occurrence of residues of pirimiphos-methyl in organic products is less likely when compared with the conventional commodities. A potential source of the unintentional presence of residues of pirimiphos-methyl is the cross-contamination from treated storage facilities. This, however, would not be expected to occur in products from organic agriculture where legal provisions are in place to avoid such incidents.
- Given that pirimiphos-methyl is only authorised in the structural treatment of empty grain stores and/or post-harvest treatments, spray drift from conventional crops grown in the vicinity or short- and/or long-term air transfer of pirimiphos-methyl residues are not expected. However, dust drift during the drilling of treated seeds to adjacent crops cannot be completely excluded. Overall, plant uptake of residues of pirimiphos-methyl from soil is unlikely.
- Conservative estimates of the possible transfer of residues from water used for irrigation to plant commodities indicate that the transfer of residues of pirimiphos-methyl from water sources to plant commodities is unlikely.
- Note was taken that pirimiphos-methyl has been registered under REACH. The available registration data confirm the use of the substance in the formulation of mixtures intended for biocidal and plant protection use but other uses in the EU Member States¹¹, Iceland, Liechtenstein and Norway are not confirmed.
- Considering that pirimiphos-methyl is used indoors, considerable residues of pirimiphos-methyl in the environment are not expected. Even in case of other non-pesticide uses or the release of residues of pirimiphos-methyl into the environment due to industrial activity, the quantitative uptake of residues from plants growing in these areas and their commodities is less likely.

Findings of not authorised substances in organic products

The pathways of residues of pirimiphos-methyl to plants and plant commodities are summarised in Figure 8.



Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded

3.9 Azoxystrobin

3.9.1 Method(s)

- What is/are the residues to be monitored per azoxystrobin according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

For the active substance azoxystrobin, the residue definition for enforcement in food and feed of plant origin has been proposed as 'azoxystrobin' in the EFSA peer review and the EFSA MRL review (EFSA, 2010b, 2013e). This residue definition is applicable to primary, rotational crops, processed products. This residue definition for enforcement is implemented in Regulation (EC) No 396/2005³ and is also applicable to honey and other apiculture products.

Based on the above only residues of azoxystrobin are to be monitored in foods of plant origin, honey and other apiculture products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

A multi-residue QuEChERS analytical method using HPLC-MS/MS is suitable for enforcing azoxystrobin in commodities of plant origin with high water, high acid and high oil content, as well as dry commodities, with an LOQ of 0.01 mg/kg (EFSA, 2013e).

Another multi-residue analytical method (DFG S19) based on GC-MS is validated for the same crops, with the same LOQ of 0.01 mg/kg (EFSA, 2013e).

The HPLC-MS/MS (RAM 305/03) method is validated for high water, high acid, high oil content, and dry commodities, with an LOQ of 0.01 mg/kg. It is also validated for hops at the same LOQ (EFSA, 2013e, 2023h).

According to the EURL for Residues of Pesticides (EURL, 2024, under 'Documentation as provided to EFSA'), a multi-residue citrate-buffered QuEChERS method based on GC-MS/MS is validated to monitor azoxystrobin residues in honey samples at an LOQ of 0.002 mg/kg. Higher sensitivities can be achieved by utilising multi-residue methods based on LC-Q-TOF (LOQ: 0.001 mg/kg). A multi-residue QuEChERS method based on GC-MS/MS is available to monitor azoxystrobin residues in pollen collected by bees with an LOQ of 0.005 mg/kg.

Overall, multi-residue methods are available for the monitoring of azoxystrobin residues in food of plant origin with high water, high acid, high oil content and in dry plant commodities, as well as in honey and other apiculture products. The LOQs for monitoring azoxystrobin residues in products of plant origin and honey and other apiculture products range from 0.001 to 0.01 mg/kg.

3.9.2 Authorisation status and use

- Is azoxystrobin currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has azoxystrobin ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

a) Authorisations for plant protection use in conventional agriculture

Azoxystrobin has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹³¹. The expiry date of its approval is 31 May 2027, as indicated in the EU Pesticides database⁵ (accessed on 26 November 2024).

According to the EU Pesticides database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, France, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, and Slovakia.

b) Authorisations for uses other than plant protection

Biocidal use

Azoxystrobin has been approved for biocidal use in the EU Member States, Iceland and Norway in accordance with Regulation (EU) No 528/2012⁷, since 1 November 2018. The expiry date of approval for the use of the substance as a film preservative, as a fibre, leather, rubber and polymerised materials preservative, and as a construction material preservative is on 31 October 2025 as indicated in the ECHA website⁶ (accessed 12 February 2024) (other updates in progress).

Other uses

According to the search carried out on the ECHA website⁹ on 6 June 2024, azoxystrobin is not currently registered under REACH.

- What is/was the actual use of azoxystrobin? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of azoxystrobin

Azoxystrobin is a synthetic fungicide that belongs to the group of strobilurin compounds. It is a systemic substance used to protect fruits, vegetables, and grains from various diseases by mimicking naturally occurring strobilurins found in fungi (EFSA, 2013e). Azoxystrobin acts by inhibiting the fungal mitochondrial respiration (WHO/FAO, 2008).

Conditions of use and applicable crops

The uses reported in the EFSA MRL review for azoxystrobin include food and feed commodities belonging to the following crop groups: berries and small fruits, miscellaneous fruits (banana), root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds, cereals, herbal infusions from flowers and leaves, hops (dried), seed spices (dried), fruit and berry spices (dried) and sugar plants (EFSA, 2013e). Note was taken that uses in miscellaneous fruits (banana) were not supported by data (see Section 3.9.3.2 'Active use (all legitimate uses of the substance)').

After the MRL review, more applications were submitted to EFSA to support new uses or modify the existing MRLs in berries and small fruits, leaf vegetables, herbs and edible flowers (chervil) and stem vegetables (rhubarb), oil seeds and hops (dried) (EFSA, 2016b,c, 2022f, 2023h). All

these uses involved foliar sprays except root and tuber vegetables. Application rates ranged from 0.16 kg a.s./ha to 0.40 kg a.s./ha for foliar spraying (EFSA, 2013e, 2016b,c, 2022f, 2023h).

Application rates are up to 0.75 g a.s./ha for soil treatment (in furrow spray) in root and tuber vegetables (potato) (EFSA, 2013e).

b) Uses for purposes other than plant protection

Biocidal use

Although azoxystrobin is approved for biocidal use, according to the ECHA website⁶, there are currently no products that contain azoxystrobin authorised for use in biocidal product formulations at national level in the EU.

Other use

A search carried out on the ECHA website⁹ for REACH registrations did not give any results for azoxystrobin.

3.9.3 Sources of residues in plants

3.9.3.1 Natural occurrence

- Is there evidence that azoxystrobin occurs naturally? What is known about the natural origin of this substance?

Azoxystrobin is a synthetic fungicide, produced industrially through chemical processes (Lewis et al., 2016). No information on the potential natural presence of azoxystrobin was found in the literature²².

3.9.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of azoxystrobin per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of azoxystrobin in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.9.3.2-1 to 3.9.3.2-4. Findings relating to residues in control (untreated) samples are also discussed in this section.

In all matrices and for both residue trials and results from monitoring, azoxystrobin residue concentrations refer to the residue definition for enforcement (i.e. azoxystrobin).

Occurrence of azoxystrobin from residue trials carried out for the critical GAP per crop

Following product applications based on the critical GAPs⁴ reported to EFSA, residue levels of azoxystrobin were quantified in berries and small fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oil seeds and oil fruits, cereals, herbal infusions, hops (dried), seed spices, fruit spices and sugar plants (EFSA, 2013e, 2016b,c, 2022f, 2023h).

Regarding feed commodities, residues of azoxystrobin were quantified in cereal straw and sugar beet tops (EFSA, 2013e).

The results from residue trials carried out for the critical GAP per crop for azoxystrobin in commodities for which uses were submitted to EFSA are summarised in Table 3.9.3.2-1 'Occurrence of azoxystrobin from residue trials carried out for the critical GAP per crop'.

Table 3.9.3.2-1: Occurrence of azoxystrobin from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Azoxystrobin (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
Food				
0150000	Berries and small fruits	0.5–10	0.11–2.46	0.41
0210000	Root and tuber vegetables	1–7	<LOQ (0.01)–0.58	0.04
0220000	Bulb vegetables	10	<LOQ (0.01)–0.95	0.01
0230000	Fruiting vegetables	0.01*–3	0.03–1.6	0.28
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	5–6	<LOQ (0.01)–3.5	0.04
0250000	Leaf vegetables, herbs and edible flowers	0.01*–70	<LOQ (0.01)–6.2	0.46
0260000	Legume vegetables	3	0.02–0.57	0.10
0270000	Stem vegetables	0.01*–15	<LOQ (0.05)–5.7	0.24
0300000	Pulses (dried)	0.15	<LOQ (0.01)–0.07	0.01
0401000	Oilseeds	0.01*–0.7	<LOQ (0.01)–0.37	0.01
0500000	Cereals	0.01*–10	<LOQ (0.01)–3.0	0.04
0631000	Herbal infusions from flowers	60	2.1–34	10.2
0632000	Herbal infusions from leaves and herbs	60	2.1–34	10.2
0700000	Hops (dried)	40	0.83–20.8	6.37
0810000	Seed spices	0.3	<LOQ (0.039)–0.21	0.05
0820000	Fruit spices	0.3	<LOQ (0.039)–0.21	0.05
0900000	Sugar plants	0.01*–5	<LOQ (0.01)–0.13	0.01
Feed				
1200000	Cereal straw	NA	0.11- 10.1	2.02
	Sugar beet tops	NA	0.11- 0.38	0.21

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable.

a) Maximum Residue Level in Reg. (EU) No 2024/1078 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA 2013e, 2016b,c, 2022f, 2023h.

Occurrence of azoxystrobin under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to azoxystrobin are given by Regulation (EU) 2019/552³² for the year 2020, Regulation (EU) 2019/552³² and Regulation (EU) 2021/1807³³ for the year 2021 and Regulation (EU) 2021/1807³³, Regulation (EU) 2022/476⁵⁷ and Regulation (EU) 2022/1363⁵⁸ for the year 2022.

Regarding commodities not labelled as organic, 116,396 samples were collected and analysed for azoxystrobin in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 106,960 (91.89%) were unprocessed and 9,436 (8.11%) processed commodities. No residues were quantified in 111,166 samples out of the 116,396 samples (95.51%). In 5,215 samples out of

⁵⁷ Commission Regulation (EU) 2022/476 of 24 March 2022 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetic acid, azoxystrobin, benzovindiflupyr, cyantraniliprole, cyflufenamid, emamectin, flutolanil, lime sulphur, maltodextrin and proquinazid in or on certain products. OJ L 98, 25.3.2022, p. 9–37.

⁵⁸ Commission Regulation (EU) 2022/1363 of 3 August 2022 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2,4-D, azoxystrobin, cyhalofop-butyl, cymoxanil, fenhexamid, flazasulfuron, florasulam, fluroxypyr, iprovalicarb and silthiofam in or on certain products. OJ L 205, 5.8.2022, p. 207–225.

the 116,396 samples (4.48%) azoxystrobin was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-9.1. MRLs were exceeded in 15 samples out of the 116,396 samples (0.1%). The highest concentration for samples exceeding the MRLs was 13.2 mg/kg in brassica vegetables (excluding brassica roots and brassica baby leaf crops) (flowering brassica – broccoli).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of azoxystrobin are summarised in Table 3.9.3.2-2a for unprocessed and in Table 3.9.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on azoxystrobin in feed not labelled as organic were submitted to EFSA.

Table 3.9.3.2-2a: Occurrence of azoxystrobin monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Azoxystrobin (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0150000	Berries and small fruits	0.5–10	0.001	0.001–9.7	688	0.049
0210000	Root and tuber vegetables	1–7	0.001	0.001–1	766	0.013
0220000	Bulb vegetables	10	0.001	0.001–1.829	83	0.017
0230000	Fruiting vegetables	0.01*–3	0.001	0.001–2.05	952	0.024
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	5–6	0.001	0.001–13.2	628	0.022
0250000	Leaf vegetables, herbs and edible flowers	0.01*–70	0.001	0.001–69.8	882	0.05
0260000	Legume vegetables	3	0.001	0.002–0.95	159	0.022
0270000	Stem vegetables	0.01*–15	0.001	0.001–4.9	387	0.02
0300000	Pulses (dried)	0.15	0.002	0.011–0.034	28	0.025
0401000	Oilseeds	0.01*–0.7	0.005	0.011–0.034	5	0.029
0500000	Cereals	0.01*–10	0.001	0.002–0.39	187	0.017
0631000	Herbal infusions from flowers ^{d)}	60	0.01	0.013	1	0.013
0632000	Herbal infusions from leaves and herbs	60	0.005	0.021–12.5	8	0.035
0700000	Hops (dried)	40	0.01	0.02–3.7	12	0.263
0810000	Seed spices ^{d)}	0.3	0.005	0.022–0.074	3	0.041
0820000	Fruit spices ^{d)}	0.3	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*–5	0.005	0.014	1	0.014
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
	Sugar beet tops	NA	ND	ND	ND	ND
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of azoxystrobin is not expected)						
0110000	Citrus fruits	15	0.001	0.002–2.3	66	0.024
0120000	Tree nuts	0.01–1	0.005	0.012–0.04	3	0.027
0130000	Pome fruits	0.01*	0.001	0.001–0.01	12	0.003
0140000	Stone fruits	2	0.001	0.001–0.9	24	0.015

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Azoxystrobin (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0160000	Miscellaneous fruits	0.01*-4	0.001	0.004-2.2	142	0.14
0280000	Fungi, mosses and lichens	0.01*	0.001	0.007-2.05	4	0.009
0290000	Algae and prokaryotes organisms	0.01*	0.01	ND	ND	ND
0400000	Oilseeds and oil fruits	0.01*-0.7	0.002	0.011-0.034	5	0.029
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*-60	0.005	0.012-12.5	11	0.024
0800000	Spices (dried)	0.05*-0.3	0.005	0.014-0.074	4	0.032
1040000	Honey and other apiculture products	0.05*	0.005	0.01-0.035	9	0.014

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2024/1078 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Oilseeds, herbal infusions, seed spices and fruit spices appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0401000, 0630000, 0810000 and 0820000 and non-use of the substance for all other commodities '040N000' '06N0000' or '08N0000' that are reported under the 'broader' category 0400000, 0600000 or 0800000 on the table. This creates an inconsistency in the results indicating non-uses which are overestimated.

Table 3.9.3.2-2b: Occurrence of azoxystrobin from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Azoxystrobin (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0150000	Berries and small fruits	0.5–10	0.001	0.005–0.17	58	0.022
0210000	Root and tuber vegetables	1–7	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	10	0.01	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*–3	0.001	0.001–0.36	42	0.036
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	5–6	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*–70	0.002	0.01–7.6	38	0.13
0260000	Legume vegetables	3	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*–15	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.15	0.002	0.005–0.027	2	0.016
0401000	Oilseeds	0.01*–0.7	0.002	0.002–0.09	13	0.007
0500000	Cereals	0.01*–10	0.001	0.01–0.023	16	0.018

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Azoxystrobin (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0631000	Herbal infusions from flowers ^{d)}	60	0.01	<LOQ	0	<LOQ
0632000	Herbal infusions from leaves and herbs	60	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	40	0.01	1.1–2.8	3	2.5
0810000	Seed spices ^{d)}	0.3	0.01	0.32	1	0.32
0820000	Fruit spices ^{d)}	0.3	0.005	<LOQ	<LOQ	<LOQ
0900000	Sugar plants	0.01*–5	0.002	<LOQ	0	<LOQ
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
	Sugar beet tops	NA	ND	ND	ND	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of azoxystrobin is not expected)						
0110000	Citrus fruits	15	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.01–1	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	2	0.002	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*–4	0.002	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.005	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0400000	Oilseeds and oil fruits	0.01*–0.7	0.002	0.002–2.05	15	0.012
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*–60	0.005	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*–0.3	0.005	0.32	1	0.32
1040000	Processed apiculture products	0.05*	0.002	0.012	2	0.012

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2024/1078 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Oilseeds, herbal infusions, seed spices and fruit spices appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0401000, 0630000, 0810000 and 0820000 and non-use of the substance for all other commodities '040N000', '06N0000' or '08N0000' that are reported under the 'broader' category 0400000, 0600000 or 0800000 on the table. This creates an inconsistency in the results indicating non-uses which are overestimated.

Occurrence of azoxystrobin in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 10,099 samples were collected and analysed for azoxystrobin from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 8,408 (83.26%) were unprocessed and 1691 (16.74%) processed commodities. No residues were quantified in 10,077 samples out of the 10,099 samples (99.78%). In 22 samples out of the 10,099 samples (0.22%) azoxystrobin was found at or above the analytical LOQ but below or at the MRL. No MRLs exceeded in samples from organic production. These findings are summarised in Appendix B, Table B-9.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.9.3.2-3a for unprocessed and in Table 3.9.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on azoxystrobin in feed labelled as organic were submitted to EFSA.

Table 3.9.3.2-3a: Occurrence of azoxystrobin from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Azoxystrobin (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	15	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.01–1	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	2	0.001	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.5–10	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*–4	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	1–7	0.001	0.01–0.012	2	0.011
0220000	Bulb vegetables	10	0.001	0.003–0.04	4	0.022
0230000	Fruiting vegetables	0.01*–3	0.001	0.001	2	0.001
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	5–6	0.001	0.001–0.76	6	0.026
0250000	Leaf vegetables, herbs and edible flowers	0.01*–70	0.001	0.003–0.22	2	0.013
0260000	Legume vegetables	3	0.001	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*–15	0.001	0.5	1	0.5
0280000	Fungi, mosses and lichens	0.01*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.15	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–0.7	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.01*–10	0.001	0.01–2.05	3	0.019
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*–60	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	40	0.01	0.023	1	0.023
0800000	Spices (dried)	0.05*–0.3	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*–5	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.005	<LOQ	0	<LOQ

*Limit of quantification in Reg. (EC) No 396/2005.

a) Maximum Residue Level in Reg. (EU) No 2024/1078 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.9.3.2-3b: Occurrence of azoxystrobin from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Azoxystrobin (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	15	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.01–1	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	2	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.5–10	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*–4	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	1–7	0.005	<LOQ	0	<LOQ
0220000	Bulb vegetables	10	ND	ND	ND	ND
0230000	Fruiting vegetables	0.01*–3	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	5–6	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*–70	0.005	<LOQ	0	<LOQ
0260000	Legume vegetables	3	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*–15	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.01	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0300000	Pulses (dried)	0.15	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–0.7	0.002	<LOQ	0	<LOQ
0500000	Cereals	0.01*–10	0.0001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*–60	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	40	ND	ND	ND	ND
0800000	Spices (dried)	0.05*–0.3	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*–5	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.01	0.013	1	0.013

*Limit of quantification in Reg. (EC) No 396/2005; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2024/1078 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of azoxystrobin in the EU Organic Farming Information System

The EU OFIS reported 19 findings for azoxystrobin in 2021 and 2022. Nine of the products sampled and analysed had EU origin and 10 were of non-EU origin. Residues were found in two samples of berries and small fruits (strawberries), one sample of miscellaneous fruits with inedible peel, large (bananas), one sample of root and tuber vegetables (carrots), one sample of fruiting vegetables (sweet peppers/bell peppers – chilli), one sample of brassica vegetables (excluding brassica roots and brassica baby leaf crops) (broccoli), six samples of leaf vegetables, herbs and edible flowers (sage, thyme and basil and edible flowers), one sample of legume vegetables (peas (without pods)), one sample of cocoa beans (cocoa beans), one sample of hops (hops), one sample of seed spices (fenugreek) and two samples of products or part of products

exclusively used for animal feed production (hop pellets). The concentrations of azoxystrobin residues were above LOQ but below MRL in all 19 samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005³. No samples labelled as organic were above MRLs. The highest concentration was reported for a sample of brassica vegetables (excluding brassica roots and brassica baby leaf crops) – broccoli of EU origin, with the quantified level of 0.71 mg/kg. These findings are summarised in Table 3.9.3.2-4.

Table 3.9.3.2-4: Occurrence of azoxystrobin from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
0213020	Carrots	1	ND	0.026 – Carrots (dehydrated)
0220010	Garlic	10	0.038 – Garlic (Violet Spring)	ND
0231020	Sweet peppers/bell peppers	3	0.018 – Chilli	ND
0241010	Broccoli	5	0.71 – Broccoli	ND
0256070	Thyme	70	ND	0.195 – Thyme (dried)
0700000	Hops	40	0.023 – Hops	ND
0810080	Fenugreek	0.3	0.012 – Fenugreek (blue)	ND
1200000	Products or part of products exclusively used for animal feed production	NA	ND	0.023; 0.1 – Hop pellets
Samples of non-EU origin				
0152000	Strawberries	10	0.014 – Strawberries	0.014 – Strawberries (frozen)
0163020	Bananas	2	0.43 – Bananas	ND
0256050	Sage	70	0.015 – Sage	ND
0256070	Thyme	70	0.051; 0.015 – Oregano	0.007 – Oregano (rubbed)
0256080	Basil and edible flowers	70	0.031 – Basil	ND
0260040	Peas (without pods)	3	0.015 – Peas (without pods)	ND
0640000	Cocoa beans	0.05*	ND	0.022 – Cocoa nibs

*Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2024/1078 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of azoxystrobin in untreated samples (control samples) from residue trials

Quantified findings for azoxystrobin were observed in control (untreated) samples from eight residue trials on hops carried out in Germany. The residue concentrations in fresh hop cones were 0.02, 2×0.04 and 0.06 mg/kg whilst in dried hop cones, the concentrations were 2×0.04, 0.14 and 0.23 mg/kg, respectively (Germany, 2023b). Additionally, a residue trial from Germany found 0.64 mg/kg of azoxystrobin on control samples in wild chamomile (Germany, 2009).

No evidence-based explanations on the causes for these occurrences in control (untreated) samples were provided in the above-mentioned evaluation reports.

- Could the presence of azoxystrobin and/or its residues be due to biocide use?

According to the ECHA website⁶, there are currently no products that contain azoxystrobin and are authorised for use in biocidal product formulations at national level in the EU. Therefore, the transfer of residues of azoxystrobin due to its use as a biocide is unlikely.



3.9.3.3 Behaviour in food and feed products

- What key physico-chemical properties of azoxystrobin are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of azoxystrobin are shown in Table 3.9.3.3.

Azoxystrobin exhibits moderate to high persistence in soil (see Section 3.9.3.5). Regarding sorption to soil, the geometric mean of K_{Foc} in Table 3.9.3.3 indicates that the substance has medium mobility in soil (EFSA, 2010b).

The maximum calculated PECw for azoxystrobin for the representative uses was 7.58 µg/L (spray application to brassicas; 2 × 250 g a.s./ha) (EFSA, 2010b).

Azoxystrobin was shown to be stable during standard conditions of pasteurisation, cooking, boiling, brewing, baking and sterilisation (EFSA, 2010b). Considering azoxystrobin is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Azoxystrobin has a very low vapour pressure (10^{-10} Pa at 20°C) and atmospheric half-life (2.7 hours) (EFSA, 2010b).

Table 3.9.3.3: Physico-chemical properties of azoxystrobin (EFSA, 2010b)

Structural formula	
Appearance (state purity)	White crystalline powder (99%), technical (96%) as a pale brown crystalline powder.
Melting point (state purity)	116°C (99%)
Boiling point	Above 360°C
Temperature of decomposition	Approximately 345°C at atmospheric pressure
Vapour pressure (state temperature, state purity)	1.1×10^{-10} Pa at 20°C (99%)
Henry's law constant (state temperature)	7.4×10^{-9} Pa m ³ mol ⁻¹
Solubility in water (state temperature, state purity and pH)	pH 5.2: 6.7 mg/L at 20°C (96%) pH 7.0: 6.7 mg/L at 20°C (96%) pH 9.2: 5.9 mg/L at 20°C (96%)
Partition coefficient (state temperature, pH and purity)	log Pow = 2.5 at 20°C (without pH dependence)
Partition coefficient (octanol/air)	Log P _{oa} = 14.0 (EPISuite KOAWIN v1.10) (Debler et al. 2024)
Atmospheric half-life	DT ₅₀ of 2.7 hours derived by the Atkinson model (AOPWIN version 1.8). OH (12h) radical concentration assumed = 1.5×10^6 cm ⁻³
Dissociation constant (state purity)	No dissociation within environmentally relevant pH range



Soil adsorption (geometric mean)	$K_{Foc} = 392 \text{ mL/g}$
Hydrolytic degradation (>10%)	Hydrolytically stable (pH 5–9 at 25°C)

DT₅₀ – Disappearance time of 50% of the substance in field studies; pH – Potential of Hydrogen; P_{ow} – Octanol/water Partition Coefficient; P_{oa} – Octanol/air Partition Coefficient

3.9.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from soil surface at which it is applied).

The highest drift of azoxystrobin to neighbouring fields may occur during its applications to fruit crops (applicability limited to bananas in Spain, France and Cyprus up to 29.2%), hops (19.33%), vineyards and vegetables (up to 8.02%) and field crops (up to 2.77%). Drift values should be considered the rate received by neighbouring fields, expressed as a percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. buffer zones or spray drift-reducing nozzles).

If organic crops are present adjacent to the conventional crops treated, measurable residues of azoxystrobin in the untreated crop cannot be excluded. However, since the nature of the potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

3.9.3.5 Accumulated/historical residue levels in soil

- What is the persistence of azoxystrobin and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

According to available data (EFSA, 2010b), the DT₉₀ of azoxystrobin in soil estimated from three field soil studies has a worst-case value of 870 days, indicating a potential for accumulation in soil after discontinued use of the substance.

Considering the persistence of azoxystrobin in soil, confined and field rotational crop studies were carried out with bare soil to investigate the potential soil uptake of the substance by the plants (EFSA, 2013e). These studies suggest that significant plant uptake of residues from soil is not expected if the substance is used according to the representative GAPs⁴.

The above information is also valid for organic crops, when planted in fields that were previously used for conventional agriculture, considering that it requires at least 2 years after the last chemical treatment in order for organic crops to be planted in such area².



- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

The estimated plateau concentrations in soil for azoxystrobin were 0.646 mg/kg after 7 years of application (EFSA, 2010b). The DT₉₀ of azoxystrobin ranging up to 870 days, suggests that azoxystrobin can still be found in soil more than 2 years after its last application. On the other hand, data on the magnitude of residues in rotational crops indicate that, even if present, their uptake from soil is unlikely (see previous section).

Monitoring data for azoxystrobin in soil are available from the LUCAS pesticides 2018 (JRC, 2023) on IPCHEM¹². The data show background levels of the substance in soil samples from 21 EU countries: Austria (2 samples), Belgium (1 sample), Bulgaria (6 samples), Cyprus (1 sample), Czechia (28 samples), Denmark (12 samples), Estonia (1 sample), Finland (9 samples), France (141 samples), Germany (21 samples), Greece (3 samples), Hungary (12 samples), Italy (16 samples), Latvia (7 samples), Lithuania (17 samples), the Netherlands (10 samples), Poland (24 samples), Romania (3 samples), Slovakia (5 samples), Spain (50 samples) and Sweden (8 samples) at concentrations ranging from 0.001 mg/kg to 0.21 mg/kg. The highest concentration was reported for a soil sample from Lithuania. In LUCAS soil, the lack of information on the agricultural use history of the sites where soil was sampled precluded knowing whether the reported quantified findings were related to recent active use or historical levels in soil for azoxystrobin.

Evidence on the occurrence of azoxystrobin residues in soil is provided by Chiaia-Hernandez et al. (2017), who analysed 29 archived agricultural soil samples collected from 14 monitoring sites from 1995 to 2008 in Switzerland. The sites were selected from locations where crops had been regularly treated with pesticides. Selection was based on land use characteristics and long-term patterns of pesticide application. Azoxystrobin was detected in nine samples (31%) from cropland, vegetable and viticulture land use sites, with levels ranging from 0.002 to 0.086 mg/kg. Azoxystrobin was applied and detected in 31% of cases. Additionally, a major transformation product of azoxystrobin was detected in eight samples (28%) from all land use sites, including cropland, orchard, vegetable and viticulture.

In a study by Riedo et al. (2021) the presence of azoxystrobin was analysed in soil samples from 60 agricultural sites with different management systems (conventional tillage, conventional without soil tillage, and organic) sampled in May 2016 for an on-farm study throughout Switzerland. Results showed the presence of azoxystrobin in 51% of the samples at concentrations ranging from 0.00039 to 0.81 mg/kg in all types of soil, with higher levels in soil samples from conventional vegetable farming. The concentrations in soil samples under organic farming systems are reported to be <0.01 mg/kg in a total of six out of 40 samples (15%).

Additional evidence on the occurrence of azoxystrobin in soil is provided by Silva et al. (2023) in a study carried out in the framework of the EU SPRINT project. The study assessed the presence of 209 pesticide residues in 100 soil samples from conventional agriculture and 63 soil samples from organic agriculture collected during the 2021 growing season across 10 study sites in Europe: Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark. Azoxystrobin was quantified in 30 conventional soil samples (30%) at concentrations ranging from 0.002 to 0.340 mg/kg from Czechia, Denmark, Italy, The Netherlands, Portugal and Spain, and in two soil samples under organic farming systems (3%)



at concentrations of 0.0021 and 0.0023 mg/kg in Denmark and Czechia, respectively. The highest concentrations were found in conventional soil from Spain.

Considering the available evidence, plant uptake of azoxystrobin from soil containing azoxystrobin is not expected even if the crop is grown in soil that contain residues at the levels quantified in these studies.

3.9.3.6 Residues from water used for irrigation

- Is there evidence that residues of azoxystrobin present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for azoxystrobin in water samples were considered:

- The EEA-WATERQUALITY³⁹ database (data retrieved on 10 April 2024) reports 1755 analytical results from water samples collected in France (69 samples), Italy (977 samples), the Netherlands (693 samples), Slovenia (4 samples) and Sweden (12 samples) between 2018 and 2020.
- The EMPODAT database (data retrieved on 2 April 2024) reports 19,992 analytical results from surface water samples collected in Austria (15 samples), Bulgaria (28 samples), Croatia (8 samples), Czechia (8 samples), Germany (24 samples), Hungary (40 samples), the Netherlands (19,992 samples), Romania (5 samples) and Slovakia (36 samples) between 2017 and 2019;
- The NAIADES database (data retrieved on 2 April 2024) reports 54,014 analytical results from surface water samples collected in France from 2020 to 2022.

Among the 75,761 analytical results for azoxystrobin, 676 were disregarded as found to report quantitative values below the LOQ. Therefore, the total number of results considered for azoxystrobin is 75,085.

Based on the screening process described in section 'Data and methodologies', for 98.1% of water samples analysed and reported in the above-mentioned databases (73,692 samples), the residue concentrations in these waters were or below the screening Cw of 0.13 µg/L and, therefore, transfer of residues from water sources to plant commodities is unlikely.

For 1.9% of samples (1393 out of 75,085 samples), the residue concentrations were found to be at or above the screening Cw of 0.13 µg/L and the potential transfer of residues to plant commodities if water containing residues at these levels is used for irrigation cannot be excluded. Since Cw is a screening value derived from worst-case calculations it requires experimental evidence in order to confirm or rule out the potential transfer of residues from the specific water sources. Therefore, if azoxystrobin is quantified in organic commodities, analysis of the water source used to irrigate the plants is recommended.

In a study by Silva et al. (2023) carried out under the framework of the EU SPRINT project the authors assessed the presence of 209 pesticide residues in 58 water samples collected during the 2021 growing season across 10 study sites in Europe: Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark. Azoxystrobin was detected in 15 samples (26% detection frequency) at concentrations ranging from 0.0045 to 0.160 µg/L, with only one sample from the Netherlands found to contain residues above 0.1 µg/L.



Overall, the available evidence suggests that the transfer of azoxystrobin residues from water sources to plant commodities when this water is used to irrigate plants cannot be excluded.

3.9.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *azoxystrobin*, *industry/industrial*, and *air/atmosphere*) identified only one European study, which was considered irrelevant for this section.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water.

A mapping exercise was conducted by overlaying georeferenced water sampling data from IPCHEM (2020–2022) with georeferenced data on chemical industry facilities from the European Industrial Emissions Portal. Of the 1393 relevant water samples (exceeding the screening value, as reported in Table 2.1), 384 were collected between 2020–2022. For the conducted spatial analysis, it is important to note that these numbers reflect the total number of sampling events rather than distinct sampling locations, as some sites were monitored multiple times during the study period. Of these 384 samples, only one was located within a 1 km radius of a chemical facility, whilst 32 fell within a 5 km radius. No clear spatial association was identified. Additionally, some sampling locations corresponded to groundwater and others to surface water, an important factor when considering emission and transport pathways. However, due to the limited spatial relevance of available data, this distinction was not explored in detail in this study.

A literature review was also carried out to gather relevant information. A search in the Scopus database (conducted on March 4, 2025, using the keywords *azoxystrobin*, *industry/industrial*, and *water*) identified one European articles with potentially relevant information.

In a study by Sayed et al. (2021), the authors assessed the presence of 111 pesticides in wastewater samples at three vegetable and two potato processing companies located in Flanders (Belgium). Washed, peeled and/or cut, and frozen fries and vegetables were the main end products of the companies. Samples were collected over 1 year (2019–2020), resulting in a total of 52 water samples (26 untreated influent water samples and 26 treated water samples). All treatment plants consisted of a primary, secondary and potentially tertiary treatment unit before discharging the treated water. Azoxystrobin was found to be predominant in the vegetable industry, found in both influent and treated water. For the treated water, azoxystrobin was above 0.1 µg/L 30 times out of all 52 samples. The maximum detected concentration was 4.54 µg/L. According to the authors, pesticide residues in wastewater from the vegetable industry could originate from a mix of different crops. Also, a possible accumulation of pesticide residues could take place when reusing treated water within the same production processes.

Overall, a mapping of the locations of water samples on IPCHEM that were analysed for azoxystrobin with georeferenced data from the EEA's industrial emissions portal did not show



associations between environmental occurrence and industrial activity in the surrounding areas. The one study from the literature showing a transfer of residues from industrial activity to environmental water sources does not provide insight into the potential transfer of residues from water to plants.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Based on information on the possible plant uptake of azoxystrobin from EU soil, the transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on March 5, 2025, using the keywords *azoxystrobin*, *industry/industrial*, and *soil/sediment*) did not identify any European articles with potentially relevant information.

3.9.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Medium and long-range aerial transport of residues

In a study by López et al. (2022), the authors developed a comprehensive strategy to identify (unknown) pollutants in the particulate matter of ambient air (PM₁₀) and to characterise the pollutant profiles in different areas in Spain. PM₁₀ samples were collected in May 2021 from three different areas: one industrial (Onda), one urban (Valencia-Viveros), and one rural (Burriana). A total of 15 samples (5 samples in each area) were collected. The presence of azoxystrobin was confirmed in urban areas, with the maximum estimated concentration of 36.25 pg m⁻³. No additional details on possible sources were provided.

Silva et al. (2023) investigated the presence of azoxystrobin in 20 outdoor air samples collected during the 2021 growing season across 10 study sites in Europe of organic and conventional agriculture (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). The study was carried out under the framework of the EU SPRINT project. Organic fields had not been treated for 5 consecutive years. Azoxystrobin was quantified in one sample from the surrounding area of conventional farming from Portugal at a concentration of 515 ng m⁻³.

In a study investigating the potential transport of pesticide residues from apple-growing fields in South Tyrol (Vinschgau Valley, where grapevines are also present) to higher altitudes, an analysis of the soil showed the presence of azoxystrobin at levels between the LOD and the LOQ in three out of 53 samples in the study. In vegetation outside the treated areas, azoxystrobin was detected but not quantified in one out of 53 samples (Brühl et al. 2024).

In a study published under the SPRINT project and investigating the presence of pesticides in air samples collected between April 2021 and June 2022 from two agricultural areas of conventional farming in Portugal (vineyard) and the Netherlands (potatoes, onions and sugar beet), azoxystrobin was quantified in samples from both countries with detection frequencies of 16% and 17%, respectively (Debler et al., 2024). Concentrations in Portugal ranged from 10 to 968 pg/m³ (particle phase: 10–914 pg/m³; gas phase: 54 pg/m³) and in the Netherlands from



13 to 62 pg/m³ (particle phase). It was noted that both sites had undergone azoxystrobin treatment before the collection of the samples from the surrounding areas and measurement.

Overall, the results of these studies indicate that medium-range aerial transport (through aerosols) of azoxystrobin outside the treated areas cannot be excluded.

Uptake from organic fertilisers

In a study investigating pesticide residues in organic fertilisers, residues of azoxystrobin and other pesticides were quantified (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). The authors attributed the origin of the residues to the presence of plant protection products in the composted crop or in composted manure due to transfer from animal feed after digestion, or in straw used in stables. Analysis of solid organic fertilisers gave an average concentration of 0.376 mg/kg for azoxystrobin in four out of 147 samples. Considering that (according to the authors) the use of completely free from residues organic fertilisers is currently unsustainable, transfer of azoxystrobin residues from fertilisers used in organic production to organic products cannot be excluded. On the other hand, no residues of azoxystrobin were found in any of the products of the crops discussed in the study (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). This outcome is supported by studies in rotational crops indicating that plant uptake from soil that contains residues is unlikely (see Section 3.9.3.5).

3.9.4 Conclusions on azoxystrobin

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use.
- Residue trials carried out to support the critical GAPs⁴ for azoxystrobin, gave residue concentrations of up to 34 mg/kg in herbal infusions and up to 10.1 mg/kg in cereal straw. Concentrations in the ranges reported in Table 3.9.3.2-1 might be associated with active use of azoxystrobin according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.
- Azoxystrobin was quantified in the context of residue trials in untreated (control) samples with the highest concentrations observed for one sample of wild chamomile from Germany (0.64 mg/kg).
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for azoxystrobin in unprocessed commodities with authorised uses ranged from 0.013 mg/kg in root and tuber vegetables to 0.263 mg/kg in hops (dried).
- In organic commodities that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings, the median concentrations for azoxystrobin in unprocessed commodities were 0.026 mg/kg in brassica vegetables (excluding brassica roots and brassica baby leaf crops). In all other commodities residues were not quantified or were quantified in fewer than five samples per commodity.



- Without additional information on the individual samples' history and context, it is not possible to conclude if quantified results in organic commodities are associated with active use or unintentional presence of azoxystrobin.
- In organic processed commodities, residues of azoxystrobin were quantified in one sample only. In samples from processed products not labelled as organic with five or more quantified findings, the median concentrations of residues of azoxystrobin ranged from 0.007 mg/kg in oilseeds to 0.13 mg/kg in leaf vegetables, herbs and edible flowers. Considering that azoxystrobin is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.
- Overall, in commodities labelled as organic, azoxystrobin was quantified in 0.22% of samples (22 out of 10,099 samples). This percentage is 20 times lower than the percentage reflecting the number of findings in samples not labelled as organic (4.49%) (see Appendix B, Tables B-9.1 and B-9.2). These results suggest that the occurrence of residues of azoxystrobin in organic products is less likely when compared with the conventional commodities.
- Potential sources of the unintentional presence of residues of azoxystrobin in commodities of plant origin are drift from conventional crops grown in the vicinity and medium-range aerosol transport.
- Azoxystrobin is persistent in soil, however, not all substances accumulating in soil are taken up by plants. Studies assessed by EFSA on crops grown in rotation showed that plant uptake of residues of azoxystrobin from soil containing residues or organic fertilisers is considered a less likely explanation for residues found in crops where azoxystrobin has not been actively used.
- Transfer of residues from azoxystrobin-containing water to plant commodities via irrigation cannot be excluded. If azoxystrobin is quantified in organic commodities, analysis of the water source used to irrigate the plants is recommended.
- Release of residues of azoxystrobin in the water and/or soil after biocidal use cannot be excluded. Considering, however, that currently products that contain azoxystrobin are not authorised for use in biocidal product formulations at national level in the EU, transfer of residues of azoxystrobin due to its use as a biocide is unlikely.
- A mapping of the locations of samples analysed for azoxystrobin on IPCHEM with georeferenced data from the EEA's industrial emissions portal did not show associations between environmental occurrence and industrial activity in the surrounding areas. The one study from the literature showing a transfer of residues from industrial activity to environmental water sources does not provide insight into the potential transfer of residues of azoxystrobin from water to plants.

The pathways of residues of azoxystrobin to plants and plant commodities are summarised in Figure 9.

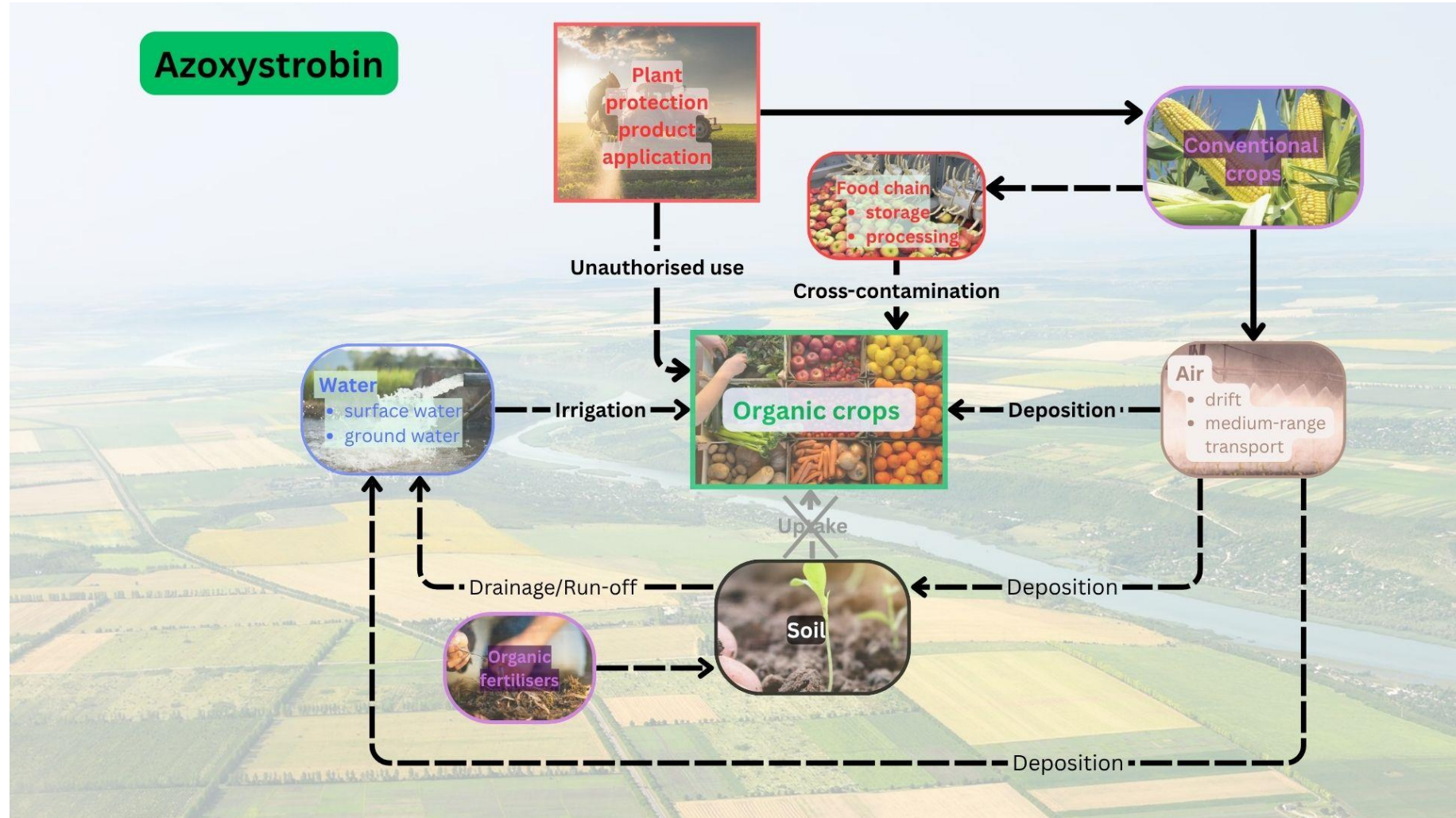


Figure 9: Pathways of residues of azoxystrobin to plants and plant commodities

Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded



3.10 Fluopyram

3.10.1 Method(s)

- What is/are the residues to be monitored for the active substance fluopyram according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

For the active substance fluopyram, the residue definition for enforcement in food and feed of plant origin has been proposed as 'fluopyram' in the EFSA peer review conclusion and the EFSA MRL review (EFSA, 2013f, 2020b). This residue definition for enforcement is implemented in Regulation (EC) No 396/2005³ and is applicable to primary, rotational crops and processed products. In the absence of specific metabolism studies on honey and other apiculture products, the same residue definition is also proposed for honey (EFSA, 2023i).

Based on the above only residues of fluopyram are to be monitored in foods of plant origin, honey and other apiculture products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

A multi-residue QuEChERS method is available for the determination of residues of fluopyram in high water and high acid content commodities with an LOQ of 0.002 mg/kg and in high oil content and dry commodities with an LOQ of 0.01 mg/kg (EFSA, 2020b).

Another multi-residue QuEChERS method utilising HPLC-MS/MS is validated for the determination of fluopyram in difficult matrices (hops, coffee, black tea, cocoa and coriander seeds) with an LOQ of 0.01 mg/kg (EFSA, 2023i).

The multi-residue DFG S19 method utilising GC-MS detection is validated for monitoring fluopyram in plant matrices. The method allows quantification of residues of fluopyram at the LOQ of 0.01 mg/kg in high water, high acid, high oil content, and dry matrices (EFSA, 2014f, 2023i).

In honey, an HPLC-MS/MS method is validated for the determination of residues of fluopyram with an LOQ of 0.01 mg/kg (EFSA, 2023i).

According to the EURL for Residues of Pesticides (EURL, 2024 under 'Documentation as provided to EFSA'), fluopyram residues in honey can be monitored with a multi-residue citrate-buffered QuEChERS method based on GC-Orbitrap at an LOQ of 0.002 mg/kg. Higher sensitivities can be achieved by utilising a multi-residue method based on LC-Q-TOF (LOQ: 0.001 mg/kg).

Overall, there are multi-residue methods available for the monitoring of residues of fluopyram in high water, high acid, high oil content, dry and complex matrices of plant commodities, as well as in honey and other apiculture products with LOQs ranging from 0.001 to 0.01 mg/kg.

3.10.2 Authorisation status and use

- Is fluopyram currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has fluopyram ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?



a) Authorisations for plant protection use in conventional agriculture

Fluopyram has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of approval of the active substance is on 30 June 2026, as indicated by the EU Pesticides Database⁵ (accessed on 8 February 2024). The application for the renewal of the approval of fluopyram is under assessment.

According to the EU Pesticides Database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, France, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, the Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, and Slovakia.

b) Authorisations for uses other than plant protection

Biocidal use

Fluopyram has not been approved for biocidal use in the EU Member States¹¹, Iceland, Liechtenstein and Norway, according to information from the ECHA website⁶ (accessed 12 February 2024).

Other uses

According to the search carried out on the ECHA website⁹ on 6 June 2024, fluopyram is not currently registered under REACH.

- What is/was the actual use of fluopyram? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of fluopyram

Fluopyram is a fungicide that belongs to the compound group of pyridinyl ethyl-benzamides (EFSA, 2013f). It acts by inhibiting the enzyme succinate dehydrogenase (SDH), blocking the electron transport in the fungal mitochondrial respiratory chain (Rathod et al., 2022).

Conditions of use and applicable crops

The uses reported in the EFSA MRL review for fluopyram included applications from the northern and southern EU in food and feed commodities belonging to the following crop groups: tree nuts, pome fruits, stone fruits, berries and small fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds, cereals, hops (dried), and sugar plants (EFSA, 2020b).

After the EFSA MRL review in 2020, applications were submitted to EFSA to modify the existing MRLs for pome fruits, miscellaneous fruits, stem vegetables, seed spices (except dill), herbal infusions from flowers, leaves and herbs (dried) and honey and other apiculture products (EFSA, 2023i).

Note was taken that uses in tree nuts, pulses (dried) and sugar plants were not supported by data (see Section 3.10.3.2 'Active use (all legitimate uses of the substance)').

Fluopyram treatment included outdoor and indoor foliar applications, outdoor soil treatments and indoor local treatments:

- Foliar applications were reported for food and feed commodities belonging to the following crop groups: tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds, cereals, herbal infusions (dried), hops (dried), seed spices (dried) and sugar plants (EFSA, 2020b, 2023i). Application rates range from 75 g a.s./ha to 250 g a.s./ha for outdoor use and from 100 g a.s./ha to 300 g a.s./ha for indoor use (EFSA, 2020b, 2023i).
- Soil treatments of fluopyram were reported for root and tuber vegetables and fruiting vegetables (tomatoes). Application rates range from 250 to 500 g a.s./ha (EFSA, 2020b).
- Local treatment was reported only for indoor witloofs crops at an application rate of 0.05 kg a.s./ton (EFSA, 2020b).

b) Uses for purposes other than plant protection

Biocidal use

Fluopyram is not approved for biocidal use, therefore, use of the substance in biocidal products is not expected (see also 'authorisations for purposes other than plant protection/biocidal use').

Other use

A search carried out on the ECHA website⁹ for REACH registrations did not give any results for fluopyram.

3.10.3 Sources of residues in plants

3.10.3.1 Natural occurrence

- Is there evidence that fluopyram occurs naturally? What is known about the natural origin of this substance?

Fluopyram is a synthetic fungicide, produced industrially through chemical processes (Lewis et al., 2016). No information on the potential natural presence of fluopyram was found in the literature²².

3.10.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of fluopyram per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of fluopyram in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.10.3.2-1 to 3.10.3.2-4. Findings relating to residues in control (untreated) samples are also discussed in this section.

In all matrices and for both residue trials and results from monitoring, fluopyram residue concentrations refer to the applicable residue definition for enforcement (i.e. fluopyram).

Occurrence of fluopyram from residue trials carried out for the critical GAP per crop

Following product applications based on the critical GAPs⁴ reported to EFSA, residue levels of fluopyram were below the LOQ in honey and other apiculture products (EFSA, 2023i).

Residues of fluopyram were quantified in pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, oilseeds, cereals, herbal infusions, hops and seed spices (EFSA, 2020b, 2023i). Regarding feed commodities, residues were quantified in cereal straw and maize stover. Residue trials were not available for tree nuts and pulses (dried).

Although EU GAPs were reported for all uses indicated under 3.10.2 'Conditions of use and applicable crops', data on residue trials for tree nuts, pulses (dried) and sugar plants were not submitted and evaluated in the EFSA MRL review (EFSA, 2020b).

The results from residue trials carried out for the critical GAP per crop for fluopyram in commodities for which uses were submitted to EFSA are summarised in Table 3.10.3.2-1 'Occurrence of fluopyram from residue trials carried out for the critical GAP per crop'.

Table 3.10.3.2-1: Occurrence of fluopyram from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fluopyram (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
Food				
0120000	Tree nuts ^{c)}	0.03	NR	-
0130000	Pome fruits	0.8	0.01–0.4	0.11
0140000	Stone fruits	0.01*–2	0.05–1.1	0.265
0150000	Berries and small fruits	0.01*–7	0.07–2.1	0.42
0160000	Miscellaneous fruits	0.01*–0.8	0.02–0.53	0.26
0210000	Root and tuber vegetables	0.01*–0.4	<LOQ (0.01)–0.2	0.03
0220000	Bulb vegetables	0.07–3	<LOQ (0.01)–1.2	0.01
0230000	Fruiting vegetables	0.01*–2	<LOQ (0.01)–1.4	0.1
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.15–2	<LOQ (0.01)–0.84	0.04
0250000	Leaf vegetables, herbs and edible flowers	0.01*–60	0.02–10	0.575
0260000	Legume vegetables	0.01*–3	<LOQ (0.01)–1.5	0.08
0270000	Stem vegetables	0.01*–20	<LOQ (0.01)–5.6	0.092
0300000	Pulses (dried) ^{c)}	0.5	NR	-
0401000	Oilseeds	0.01*–1	<LOQ (0.01)–0.61	0.1
0500000	Cereals	0.01*–4	<LOQ (0.01)–0.11	0.012
0630000	Herbal infusions	0.05*–40	0.083–25.2	0.705
0700000	Hops (dried)	60	0.27–1.3	0.93
0810000	Seed spices	0.05*–70	1.8–13.2	6.8
0900000	Sugar plants ^{c)}	0.01*–0.1	NR	-
1040000	Honey and other apiculture products	0.05*	<LOQ (0.01)	<LOQ (0.01)
Feed				
1200000	Cereal straw and maize stover	NA	0.03–1.7	0.14
	Turnip tops	NA	NR	-

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; NR – no residue trials are available; '-': not estimated due to lack of data.

a) Maximum Residue Level in Reg. (EU) No 2021/1807 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA, 2020b, 2023i; c) For uses not supported by data, the MRLs were lowered to the LOQ, except for tree nuts and pulses (dried) where higher MRLs of 0.03 mg/kg and 0.5 mg/kg, respectively were set based on US residue trials and sugar plants where a higher MRL of 0.1 mg/kg was derived from rotational crops.

Occurrence of fluopyram under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to fluopyram are given in Regulation (EU) 2019/1791⁵⁹ for the year 2020, Regulations (EU) 2019/1791⁵⁹, (EU) 2021/618⁶⁰ and (EU) 2021/1807³³ for the year 2021 and Regulation (EU) 2021/1807³³ for the year 2022.

Regarding commodities not labelled as organic, 108,442 samples were collected and analysed for fluopyram in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 100,859 (93.01%) were unprocessed and 7,583 (6.99%) processed commodities. No residues were quantified in 99,850 samples out of the 108,442 samples (92.08%). In 8,568 samples out of the 108,442 samples (7.90%) fluopyram was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-10.1. MRLs were exceeded in 24 samples out of the 116,396 samples (0.02%). The highest concentration for samples exceeding the MRLs was 3.15 mg/kg in leaf vegetables, herbs and edible flowers (grape leaves and similar species).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of fluopyram are summarised in Table 3.10.3.2-2a for unprocessed and in Table 3.10.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on fluopyram in feed not labelled as organic were submitted to EFSA.

Table 3.10.3.2-2a: Occurrence of fluopyram monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fluopyram (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b), c)} only (mg/kg)	Total no. of quantified results ^{d)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0120000	Tree nuts	0.03	0.005	0.012–0.03	8	0.021
0130000	Pome fruits	0.8	0.001	0.001–0.27	847	0.025
0140000	Stone fruits	0.01*–2	0.001	0.001–0.805	2010	0.045
0150000	Berries and small fruits	0.01*–7	0.001	0.001–7	2037	0.054
0160000	Miscellaneous fruits	0.01*–0.8	0.001	0.005–0.09	5	0.043
0210000	Root and tuber vegetables	0.01*–0.4	0.001	0.001–0.17	292	0.014
0220000	Bulb vegetables	0.07–3	0.001	0.001–0.21	97	0.008
0230000	Fruiting vegetables	0.01*–2	0.001	0.001–0.96	1997	0.024
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.15–2	0.001	0.001–1.6	196	0.013
0250000	Leaf vegetables, herbs and edible flowers	0.01*–60	0.001	0.001–3.2	627	0.016
0260000	Legume vegetables	0.01*–3	0.001	0.004–0.74	123	0.02
0270000	Stem vegetables	0.01*–20	0.001	0.001–0.082	114	0.014

⁵⁹ Commission Regulation (EU) 2019/1791 of 17 October 2019 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1-decanol, 2,4-D, ABE-IT 56, cyprodinil, dimethenamid, fatty alcohols, floupyrauxifen-benzyl, fludioxonil, fluopyram, mepiquat, pendimethalin, picolinafen, pyraflufen-ethyl, pyridaben, S-abciscic acid and trifloxystrobin in or on certain products. OJ L 277, 29.10.2019, p. 1–65.

⁶⁰ Commission Regulation (EU) 2021/618 of 15 April 2021 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for diclofop, fluopyram, ipconazole and terbuthylazine in or on certain products. OJ L 131, 16.4.2021, p. 55–71.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fluopyram (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b), c)} only (mg/kg)	Total no. of quantified results ^{d)}	Median of results from samples with quantified residues only (mg/kg)
0300000	Pulses (dried)	0.5	0.002	0.006–0.038	5	0.021
0401000	Oilseeds ^{e)}	0.01*–1	0.005	0.01–0.2	31	0.033
0500000	Cereals	0.01*–4	0.002	0.006–0.058	38	0.014
0630000	Herbal infusions ^{e)}	0.05*–40	0.005	0.012	1	0.012
0700000	Hops (dried)	60	0.01	<LOQ	0	<LOQ
0810000	Seed spices ^{e)}	0.05*–70	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*–0.1	0.005	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.004	0.013–0.022	3	0.014
Feed						
1200000	Cereal straw and maize stover	NA	ND	ND	ND	ND
	Turnip tops	NA	ND	ND	ND	ND
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of fluopyram is not expected)						
0110000	Citrus fruits	0.01*–0.9	0.001	0.001	1	0.001
0280000	Fungi, mosses and lichens	0.01*	0.001	0.001–0.14	2	0.071
0290000	Algae and prokaryotes organisms	0.01*	0.002	ND	ND	ND
0400000	Oilseeds and oil fruits	0.01*–1	0.005	0.01–0.2	31	0.033
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*–40	0.005	0.012	1	0.012
0800000	Spices (dried)	0.05*–70	0.005	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2021/1807 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) The measured residues are not only related to direct use but can also be taken up from rotational crops; d) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); e) Oilseeds, herbal infusions and seed spices appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0401000, 0630000 and 0810000 and non-use of the substance for all other commodities '040N000', '06N0000' or '08N0000' that are reported under the 'broader' category 0400000, 0600000 or 0800000 on the table. This creates an inconsistency in the results indicating non-uses which are overestimated.

Table 3.10.3.2-2b: Occurrence of fluopyram from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fluopyram (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b), c)} only (mg/kg)	Total no. of quantified results ^{d)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0120000	Tree nuts	0.03	0.01	0.015	1	0.015
0130000	Pome fruits	0.8	0.001	0.007	1	0.007
0140000	Stone fruits	0.01*-2	0.002	0.007-0.072	5	0.031
0150000	Berries and small fruits	0.01*-7	0.001	0.001-0.48	93	0.016
0160000	Miscellaneous fruits	0.01*-0.8	0.005	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*-0.4	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.07-3	0.01	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*-2	0.001	0.01-0.21	16	0.068
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.15-2	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*-60	0.002	0.012-0.019	4	0.018
0260000	Legume vegetables	0.01*-3	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*-20	0.002	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.5	0.002	<LOQ	0	<LOQ
0401000	Oilseeds ^{e)}	0.01*-1	0.002	0.002-0.51	21	0.014



Findings of not authorised substances in organic products

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fluopyram (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b), c)} only (mg/kg)	Total no. of quantified results ^{d)}	Median of results from samples with quantified residues only (mg/kg)
0500000	Cereals	0.01*-4	0.0007	0.011-0.016	2	0.014
0630000	Herbal infusions ^{e)}	0.05*-40	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	60	0.005	0.42-1.9	3	1.3
0810000	Seed spices ^{e)}	0.05*-70	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*-0.1	0.002	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.01	0.011-0.016	3	0.013
Feed						
1200000	Cereal straw and maize stover	NA	ND	ND	ND	ND
	Turnip tops	NA	ND	ND	ND	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of fluopyram is not expected)						
0110000	Citrus fruits	0.01*-0.9	0.001	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.005	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0400000	Oilseeds and oil fruits	0.01*-1	0.002	0.002-0.51	27	0.015
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*-40	0.005	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*-70	0.005	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available; NA – not applicable.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2021/1807 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) residues are not only related to direct use but can also be taken up from rotational crops; d) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); e) oilseeds, herbal infusions and seed spices appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0401000, 0630000 and 0810000 and non-use of the substance for all other commodities '040N000', '06N0000' or '08N0000' that are reported under the 'broader' category 0400000, 0600000 or 0800000 on the table. This creates an inconsistency in the results indicating non-uses which are overestimated.

Occurrence of fluopyram in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 9,836 samples were collected and analysed for fluopyram from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 8,218 (83.55%) were unprocessed and 1,618 (16.45%) processed commodities. No residues were quantified in 9,815 samples out of the 9,836 samples (99.79%). In 21 samples out of the 9,836 samples (0.21%) fluopyram was found at or above the analytical LOQ but below or at the MRL. No samples labelled as organic were above MRLs. These findings are summarised in Appendix B, Table B-10-2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.10.3.2-3a for unprocessed and in Table 3.10.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on fluopyram in feed labelled as organic were submitted to EFSA.

Table 3.10.3.2-3a: Occurrence of fluopyram from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fluopyram (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b), c)} only (mg/kg)	Total no. of quantified results ^{d)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.01*-0.9	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.03	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.8	0.001	0.006-0.047	2	0.027
0140000	Stone fruits	0.01*-2	0.001	0.047	1	0.047
0150000	Berries and small fruits	0.01*-7	0.001	0.001-0.37	4	0.1
0160000	Miscellaneous fruits	0.01*-0.8	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*-0.4	0.001	0.001-0.01	3	0.003
0220000	Bulb vegetables	0.07-3	0.001	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*-2	0.001	0.002-0.11	7	0.006
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.15-2	0.001	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*-60	0.001	0.002-0.011	2	0.007
0260000	Legume vegetables	0.01*-3	0.001	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*-20	0.001	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.5	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*-1	0.005	0.035	1	0.035
0500000	Cereals	0.01*-4	0.001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*-40	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	60	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*-70	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*-0.1	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.005	<LOQ	0	<LOQ

*Limit of quantification in Reg. (EC) No 396/2005.

a) Maximum Residue Level in Reg. (EU) No 2021/1807 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) residues are not only related to direct use but can also be taken up from rotational crops; d) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.10.3.2-3b: Occurrence of fluopyram from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fluopyram (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b), c)} only (mg/kg)	Total no. of quantified results ^{d)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.01*-0.9	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.03	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.8	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*-2	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.01*-7	0.001	0.004	1	0.004
0160000	Miscellaneous fruits	0.01*-0.8	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*-0.4	0.002	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.07-3	ND	ND	ND	ND
0230000	Fruiting vegetables	0.01*-2	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.15-2	0.01	<LOQ	0	<LOQ

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fluopyram (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b), c)} only (mg/kg)	Total no. of quantified results ^{d)}	Median of results from samples with quantified residues only (mg/kg)
0250000	Leaf vegetables, herbs and edible flowers	0.01*-60	0.005	<LOQ	0	<LOQ
0260000	Legume vegetables	0.01*-3	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*-20	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.005	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0300000	Pulses (dried)	0.5	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*-1	0.002	<LOQ	0	<LOQ
0500000	Cereals	0.01*-4	0.00004	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*-40	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	60	ND	ND	ND	ND
0800000	Spices (dried)	0.05*-70	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*-0.1	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.01	<LOQ	0	<LOQ

*Limit of quantification in Reg. (EC) No 396/2005; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2021/1807 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) residues are not only related to direct use but can also be taken up from rotational crops; d) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of fluopyram in the EU Organic Farming Information System

The EU OFIS reported 18 findings for fluopyram in 2021 and 2022. Fifteen of the products sampled and analysed had EU origin and three were of non-EU origin. Residues were found in two samples of tree nuts (almonds), six samples of berries and small fruits (strawberries and raspberries), one sample of miscellaneous fruits with inedible peel, small (prickly pears/cactus fruits – pitaya), four samples of root and tuber vegetables (carrots), three samples of bulb vegetables (garlic and onions), one sample of herbal infusions from leaves and herbs (strawberries – *Equisetum arvense*/horsetail herb) and one sample of products or part of products exclusively used for animal feed production (hop pallets). The concentrations of fluopyram residues were above LOQ but below MRL in all 19 samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005³. No samples labelled as organic were above MRLs. The highest concentration was reported in two samples of berries and small fruits (strawberries purée) of EU origin, with the quantified level of 0.1 mg/kg. These findings are summarised in Table 3.10.3.2-4.

Table 3.10.3.2-4: Occurrence of fluopyram from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
0120010	Almonds	0.03	ND	0.08; 0.017 – Almond (flour)
0152000	Strawberries	2	ND	0.04; 0.1; 0.1; 0.04 – Strawberries (purée)
0153030	Raspberries (red and yellow)	5	ND	0.009 – Raspberries (purée)
0162040	Prickly pears/cactus fruits	0.01*	0.029 – White pitaya	ND
0213020	Carrots	0.4	0.014; 0.024; 0.053 – Carrots	0.023 – Carrots (dehydrated)
0220010	Garlic	0.07	0.012 – Garlic; 0.009 – Garlic (Violet Spring)	ND

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
0220020	Onions	0.07	0.016 – Onions	ND
Samples of non-EU origin				
0152000	Strawberries	2	0.013 – Strawberries	ND
0632010	Strawberry	40	0.022 – <i>Equisetum arvense</i> /horsetail herb	ND
1200000	Products or part of products exclusively used for animal feed production	NA	ND	0.064 – Hops (pellets)

*Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2021/1807 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of fluopyram in untreated samples (control samples) from residue trials

In the evaluation report of fluopyram, quantified findings in control (untreated) samples were detected in two residue trials of fennel from Southern France (Germany, 2022a).

Residues were also quantified in parsley and savory from Germany (Germany, 2019d). Residues of fluopyram were measured in three trials on pea from the United Kingdom³⁵ and Germany (Belgium, 2018a; Greece, 2018; Italy, 2018a).

No evidence-based explanations on the causes for these occurrences in control (untreated) samples were provided in the above-mentioned evaluation reports.

The summary of the quantified findings of residues of fluopyram in control (untreated) samples from residue trials carried out for the critical GAP⁴ per crop is given below in Table 3.10.3.2-5.

Table 3.10.3.2-5: Summary of the quantified findings of fluopyram in control (untreated) samples from residue trials carried out for the critical GAP per crop.

Crop	Country/Area	Residues (mg/kg)
Fennel	France (South)	0.013, 0.018
Parsley	Germany	0.034
Pea	Germany	0.029
	United Kingdom ³⁵	0.01, 0.011
Savory	Germany	0.017

- Could the presence of fluopyram and/or its residues be due to biocide use?

Fluopyram is not approved for biocidal use, therefore, residues due to biocidal use are not expected for fluopyram.

3.10.3.3 Behaviour in food and feed products

- What key physico-chemical properties of fluopyram currently not authorised for EU organic farming are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of fluopyram are reported in Table 3.10.3.3.

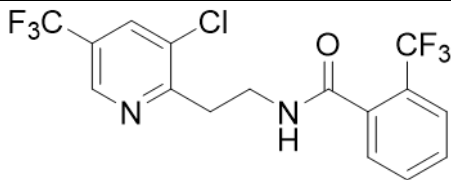
Fluopyram shows very high persistence in soil (see Section 3.10.3.5). Regarding sorption to soil, the geometric mean of K_{Foc} in Table 3.10.3.3 indicates that the substance has medium mobility in soil (EFSA, 2013f).

The maximum calculated PEC_w for fluopyram for the representative uses was 9.09 µg/L (spray application to tomatoes or strawberries; 2 × 250 g a.s./ha) (EFSA, 2013f).

Fluopyram is hydrolytically stable under standard conditions of pasteurisation, baking, brewing, boiling and sterilisation (EFSA, 2013f). Considering that fluopyram is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Fluopyram has a low vapour pressure (10^{-6} Pa) and low Henry constant (10^{-5} Pa m³ mol⁻¹) (EFSA, 2013f).

Table 3.10.3.3: Physico-chemical properties of fluopyram (EFSA, 2013f)

Structural formula	
Chemical name IUPAC	N-{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl}-α,α,α-trifluoro-o-toluidide
Appearance (state purity)	White odourless powder (99.8% and 97.5%)
Melting point (state purity)	117.5°C (99.8%)
Boiling point	318–321°C (correlated range) under decomposition (99.8%)
Temperature of decomposition	300–395°C (99.8%)
Vapour pressure (state temperature, state purity)	1.2×10^{-6} Pa at 20°C (99.8%)
Henry's law constant (state temperature)	2.98×10^{-5} Pa m ³ mol ⁻¹
Solubility in water (state temperature, state purity and pH)	16 mg/L at 20°C (pH 7, no pH dependency) (99.8%)
Partition coefficient (state temperature, pH and purity)	log P _{ow} : 3.3 at 20°C (99.4%)
Partition coefficient (octanol/air)	Log P _{oa} = 13.6 (EPISuite KOAWIN v1.10) (Debler et al. 2024)
Atmospheric half-life	DT ₅₀ of 21 hours derived by the Atkinson model (AOPWIN version 1.91). OH (12 h) radical concentration assumed = 1.5×10^6 OH/cm ³
Dissociation constant (state purity)	No dissociation in the environmental pH range
Soil adsorption (geometric mean)	K_{Foc} = 273 mL/g
Hydrolytic degradation (>10%)	Hydrolytically stable (pH 5–9 up to 50°C)

DT₅₀ – Disappearance time of 50% of the substance in field studies; pH – Potential of Hydrogen; P_{ow} – Octanol/water Partition Coefficient; P_{oa} – Octanol/air Partition Coefficient



3.10.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from the soil surface at which it is applied).

The highest drift of fluopyram to neighbouring fields may occur during its applications to fruit crops (up to 29.2%), hops (19.33%), vineyards and vegetables (up to 8.02%) and field crops (up to 2.77%). Drift values should be considered the rate received by neighbouring fields, expressed as a percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. buffer zones or spray drift-reducing nozzles).

If organic crops are present adjacent to the conventional crops treated, measurable residues of fluopyram in the untreated crop cannot be excluded (above all if the treated crops are fruit trees). However, since the nature of the potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

3.10.3.5 Accumulated/historical residue levels in soil

- What is the persistence of fluopyram and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

According to available data (EFSA, 2013f), the DT₉₀ of fluopyram in soil is > 1 year (worst-case field DT₉₀ = 1370 days), indicating a potential for accumulation in soil and its continued presence after discontinued use of the substance.

The potential plant uptake of residues of fluopyram from soil previously treated with fluopyram, was investigated based on results from field rotational crop studies available to EFSA (EFSA, 2020b). The studies were carried out in turnips/carrot, head lettuce, potato, spinach and wheat with PBIs of 28 to 49 days, 90 to 240 days or 286 to 320 days. Samples were taken 100 to 425 days after the last treatment and fluopyram was found in all analysed commodities: carrots (0.05 and 0.03 mg/kg), lettuce (0.03 and 0.01 mg/kg), potato (0.02 mg/kg), spinach (0.02 to 0.09 mg/kg), wheat grains (0.01 mg/kg), straw (up to 0.28 mg/kg) and green material (surrogate for forage) (0.12 mg/kg), for PBIs up to 240 days. For longer PBIs, no residues were quantified. For fruits and fruiting vegetables data from tomatoes, sweet peppers and cucurbits (used as surrogate) showed that significant residues from rotational crops are not expected in the edible parts of these crop groups. Based on the above, EFSA suggested mitigation measures to limit the uptake of fluopyram from rotational crops. EFSA also made MRL proposals for fluopyram in rotational crops (EFSA, 2020b) acknowledging that the latter ones are characterised by considerable uncertainties.



Overall, transfer of fluopyram in plants planted or sown in soil previously treated with fluopyram cannot be excluded in organic crops, even if they are planted 2 years after the last chemical treatment, as required by the regulatory provisions for organic agriculture².

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Monitoring data for fluopyram in soil are available from the LUCAS pesticides 2018 (JRC, 2023) on IPCHEM¹². The data show background levels of the substance in soil samples from 18 EU countries: Austria (1 sample), Belgium (3 samples), Bulgaria (2 samples), Czechia (11 samples), Denmark (9 samples), Estonia (6 samples), France (118 samples), Germany (15 samples), Greece (6 samples), Hungary (2 samples), Italy (9 samples), Latvia (6 samples), Lithuania (6 samples), the Netherlands (1 sample), Poland (9 samples), Portugal (1 sample), Spain (17 samples) and Sweden (5 samples). The reported residue levels range from 0.0011 mg/kg to 0.33 mg/kg. The highest concentration was found in a sample from France. In LUCAS soil, the lack of information on the agricultural use history of the sites where soil was sampled precluded knowing whether the reported quantified findings were related to recent active use or historical levels in soil for fluopyram.

In a study by Riedo et al. (2021) the presence of fluopyram was analysed in soil samples from 60 agricultural sites with different management systems (conventional tillage, conventional without soil tillage, and organic) sampled in May 2016 for an on-farm study throughout Switzerland. Results showed the presence of fluopyram in 1% of the samples at a concentration of 0.0013 mg/kg in soil from no-till arable farming. Fluopyram was not found in any of the sampled organic farming system soil.

Further evidence of fluopyram in soil was carried out by Silva et al. (2023) carried out in the framework of the EU SPRINT project. The study assessed the presence of 209 pesticide residues in 100 soil samples from conventional agriculture and 63 soil samples from organic agriculture collected during the 2021 growing season across 10 study sites in Europe: Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark. Fluopyram was quantified in 23 conventional soil samples (23%) at concentrations ranging from 0.0023 to 0.0317 mg/kg and three soil samples under organic farming systems (5%) at concentrations ranging from 0.0024 to 0.0079 mg/kg. The highest concentrations were found in conventional soil samples from France and soil under organic farming systems from Italy.

Considering that fluopyram is persistent in the soil, that plant uptake of fluopyram from soil containing residues is plausible and that fluopyram was found in soil samples of organic agriculture, it can be concluded that the uptake of residues of fluopyram by organic crops planted in such soil cannot be excluded. If fluopyram is quantified in organic crops, an analysis of the soil the plant was grown in is recommended.

3.10.3.6 Residues from water used for irrigation

- Is there evidence that residues of fluopyram present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for fluopyram in water samples were considered:



- The EMPODAT database (data retrieved on 25 March 2024) reports 4,771 analytical results from surface water samples collected in the Netherlands between 2017 and 2019;
- The NAIADES database (data retrieved on 25 March 2024) reports 2017 analytical results from surface water samples collected in France from 2020 to 2022.

Based on the screening process described in section 'Data and methodologies', for 43% of surface water samples analysed and reported in the above-mentioned databases (2,910 samples), the residue concentrations in these waters were below the screening Cw of 0.07 µg/L and, therefore, transfer of residues from surface water sources to plant commodities is unlikely.

For 57% of samples (3,878 out of 6,788 results), the residue concentrations were found to be equal to or more than the screening Cw of 0.07 µg/L and the potential transfer of residues to plant commodities if water containing residues at these levels is used for irrigation cannot be excluded. Since Cw is a screening value derived from worst-case calculations it requires experimental evidence in order to confirm or rule out the potential transfer of residues from the specific water sources. Therefore, if fluopyram is quantified in organic commodities, analysis of the water source used to irrigate the plant is recommended.

The high number of samples exceeding the screening Cw for fluopyram was investigated. It was noticed that 17.4% of samples reported in NAIADES (351 out of 2017 samples) and 73.9% of samples reported in EMPODAT (3,527 out of 4,771 samples) were exceeding the screening Cw. Although the sampling strategy is unknown, when these results are considered in conjunction with the results for boscalid, where 100% of samples were reported to exceed the screening Cw in NAIADES, and 100% of samples in EMPODAT and only 9% of samples in EEA-WATERQUALITY, this suggests that samples reported in NAIADES and EMPODAT were collected based on more risk-based strategies, aiming for positive findings.

In a study by Silva et al. (2023) carried out under the framework of the EU SPRINT project the authors assessed the presence of 209 pesticide residues in 58 water samples collected during the 2021 growing season across 10 study sites in Europe (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). Fluopyram was detected in 23 samples (40% detection frequency) at concentrations ranging from 0.002 to 0.032 µg/L, with the highest concentration found in the Netherlands. No sample was found to contain residues above 0.1 µg/L.

Overall, the available evidence suggests that the transfer of fluopyram residues from water sources to plant commodities when this water is used to irrigate plants cannot be excluded.

3.10.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *fluopyram*, *industry/industrial*, and *air/atmosphere*) did not identify any relevant European studies.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water.

A mapping exercise was conducted by overlaying georeferenced water sampling data from IPCHEM (2020–2022) with georeferenced data on chemical industry facilities from the European Industrial Emissions Portal. Of the 3,878 relevant water samples (exceeding the screening value, as reported in Table 2.1), 351 were collected between 2020–2022. For the conducted spatial analysis, it is important to note that these numbers reflect the total number of sampling events rather than distinct sampling locations, as some sites were monitored multiple times during the study period. Of these 351 samples, none was located within a 1 km radius of a chemical facility, whilst 58 fell within a 5 km radius. No clear spatial association was identified.

A literature review was also conducted to gather relevant information. A search in the Scopus database (conducted on February 7, 2025, using the keywords *fluopyram*, *industry/industrial*, and *water*) did not identify any relevant European study.

Overall, a mapping of the locations of water samples on IPCHEM that were analysed for fluopyram with georeferenced data from the EEA's industrial emissions portal did not show associations between environmental occurrence and industrial activity in the surrounding areas. No study was identified on the transfer of residues of fluopyram from industrial activity to environmental water sources and from water to plants.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Although plant uptake of fluopyram from soil containing fluopyram cannot be excluded, there is no evidence showing that residues from industrial emissions are transferred to soil at levels that might be taken up by plants and their products.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 17, 2025, using the keywords *fluopyram*, *industry/industrial*, and *soil/sediment*) did not identify any relevant European study.

3.10.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Medium and long-range aerial transport of residues

Figueiredo et al. (2021) investigated pesticide presence in air samples indoors and outdoors during periods of use and non-use of fluopyram in the surrounding area (up to 500 m distance) from the agricultural field (bulb field) in the Netherlands between May 2016 and December 2017. Aerial concentrations of fluopyram appeared to decrease between use and non-use periods. Comparable aerial concentrations were reported for locations close to the agricultural areas and at a 500 m distance during the use period. Lowest concentrations during the non-use period were recorded at the control homes, with most of values below the limit of detection. No consistent temporal pattern in outdoor air concentrations during the use period was observed for fluopyram. According to the authors, wind direction and nearby agricultural fields, including other crops being sprayed, affect air pesticide concentrations.



Silva et al. (2023) investigated the presence of fluopyram in 20 outdoor air samples collected during the 2021 growing season across 10 study sites in Europe of organic and conventional agriculture (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). The study was carried out under the framework of the EU SPRINT project. Organic fields had not been treated for 5 consecutive years. Fluopyram was detected in seven out of 20 targeted samples (35%) at concentrations up to 472 ng m⁻³ in France. Three out of the seven samples with quantified results were collected from the surrounding areas of organic fields in the Czechia (47.8 ng m⁻³), Denmark (14.5 ng m⁻³) and the Netherlands (12.5 ng m⁻³).

In a study investigating the potential transport of pesticide residues from apple-growing fields in South Tyrol (Vinschgau Valley) to higher altitudes, an analysis of the soil showed the presence of fluopyram in one out of 53 samples. Residues of fluopyram in soil were above the LOD but below the LOQ of 0.03 mg/kg in the study and, therefore, were not quantified. In vegetation outside the treated areas, fluopyram was detected but not quantified in one out of 53 samples.

In another study published by Debler et al. (2024) under the EU SPRINT project, fluopyram was quantified in air samples collected between April 2021 and June 2022 from two agricultural areas of conventional farming in Portugal (vineyard) and the Netherlands (potatoes, onions and sugar beet). In both countries, the detection frequencies were 53% and 11%, respectively. Concentrations in the Netherlands ranged from 7 to 4,689 pg/m³ (with particle-phase concentrations up to 4,467 pg/m³ and gas-phase concentrations up to 222 pg/m³). In Portugal, concentrations ranged between 4 and 27 pg/m³ in the particle phase. It was noted that the Dutch fields had undergone fluopyram treatment before the collection of the samples from the surrounding areas, whereas the Portuguese fields had not undergone such treatment.

Overall, the results of these studies indicate that aerial transport (through aerosols) of fluopyram outside the treated areas cannot be excluded.

Uptake from organic fertilisers

In a study investigating pesticide residues in organic fertilisers, residues of fluopyram and other pesticides were quantified (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). The authors attributed the origin of the residues to the presence of plant protection products in the composted crop or in composted manure due to transfer from animal feed after digestion, or in straw used in stables. Analysis of solid organic fertilisers gave an average concentration of 1.496 mg/kg for fluopyram in 12 out of 147 samples. Considering that (according to the authors) the use of completely free from residues organic fertilisers is currently unsustainable, transfer of fluopyram residues from fertilisers used in organic production to organic products cannot be excluded. On the other hand, no residues of fluopyram were found in any of the products of the crops discussed in the study (van der Blom et al., 2022, under 'Documentation as provided to EFSA').

3.10.4 Conclusions on fluopyram

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use.
- Residue trials carried out to support the critical GAPs⁴ for fluopyram, gave residue concentrations of up to 25.2 mg/kg in herbal infusions and up to 1.7 mg/kg in cereal straw.

Concentrations in the ranges reported in Table 3.10.3.2-1 might be associated with active use of fluopyram according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.

- Fluopyram was quantified in the context of residue trials in several European countries in untreated (control) samples with the highest concentrations observed for one sample of parsley from Germany (0.034 mg/kg).
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for fluopyram in unprocessed commodities with authorised uses ranged from 0.008 mg/kg in bulb vegetables to 0.054 mg/kg in berries and small fruits.
- In organic commodities that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings, the median concentrations for fluopyram in unprocessed commodities were 0.006 mg/kg in fruiting vegetables. In all other commodities residues were not quantified or were quantified in fewer than five samples per commodity.
- Without additional information on the individual samples' history and context, it is not possible to conclude if quantified results in organic commodities are associated with active use or unintentional presence of fluopyram.
- In organic processed commodities, residues of fluopyram were not quantified in most of the commodities analysed. In samples from processed products not labelled as organic with five or more quantified findings, the median concentrations of residues of fluopyram ranged from 0.014 mg/kg in oilseeds to 0.068 mg/kg in fruiting vegetables. Considering that fluopyram is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.
- Overall, in commodities labelled as organic, fluopyram was quantified in 0.21% of samples (21 out of 9,836 samples). This percentage is more than 37 times lower than the percentage reflecting the number of findings in samples not labelled as organic (7.9%) (see Appendix B, Tables B-10.1 and B-10.2). These results suggest that the occurrence of residues of fluopyram in organic products is less likely when compared with the conventional commodities.
- Potential sources of residues are drift from conventional crops grown in the vicinity or from transfer of residues in the medium range through aerosol transport.
- Fluopyram is persistent in soil. Studies assessed by EFSA on crops growing in rotation showed that plant uptake of fluopyram from soil containing residues cannot be excluded. Therefore, a potential source of the unintentional presence of residues of fluopyram in commodities of plant origin is plant uptake from soil that had been treated with fluopyram in the past. If fluopyram is quantified in organic crops, analysis of the soil the plants were grown is recommended.

- Plant uptake of residues of fluopyram from organic fertilisers is considered a less likely explanation for residues found in crops where fluopyram has not been actively used.
- Transfer of residues from fluopyram-containing water to plant commodities via irrigation cannot be excluded. If fluopyram is quantified in organic commodities, analysis of the water source used to irrigate the plants is recommended.
- A mapping of the locations of samples analysed for fluopyram on IPCHEM with georeferenced data from the EEA's industrial emissions portal did not show associations between environmental occurrence and industrial activity in the surrounding areas. No study was identified on the transfer of residues of fluopyram from industrial activity to environmental water sources and from water sources to plants and, although plant uptake of fluopyram from soil containing fluopyram cannot be excluded, there is no evidence showing that residues from industrial emissions are transferred to the soil at levels that might be taken up by plants and their products.

The pathways of residues of fluopyram to plants and plant commodities are summarised in Figure 10.

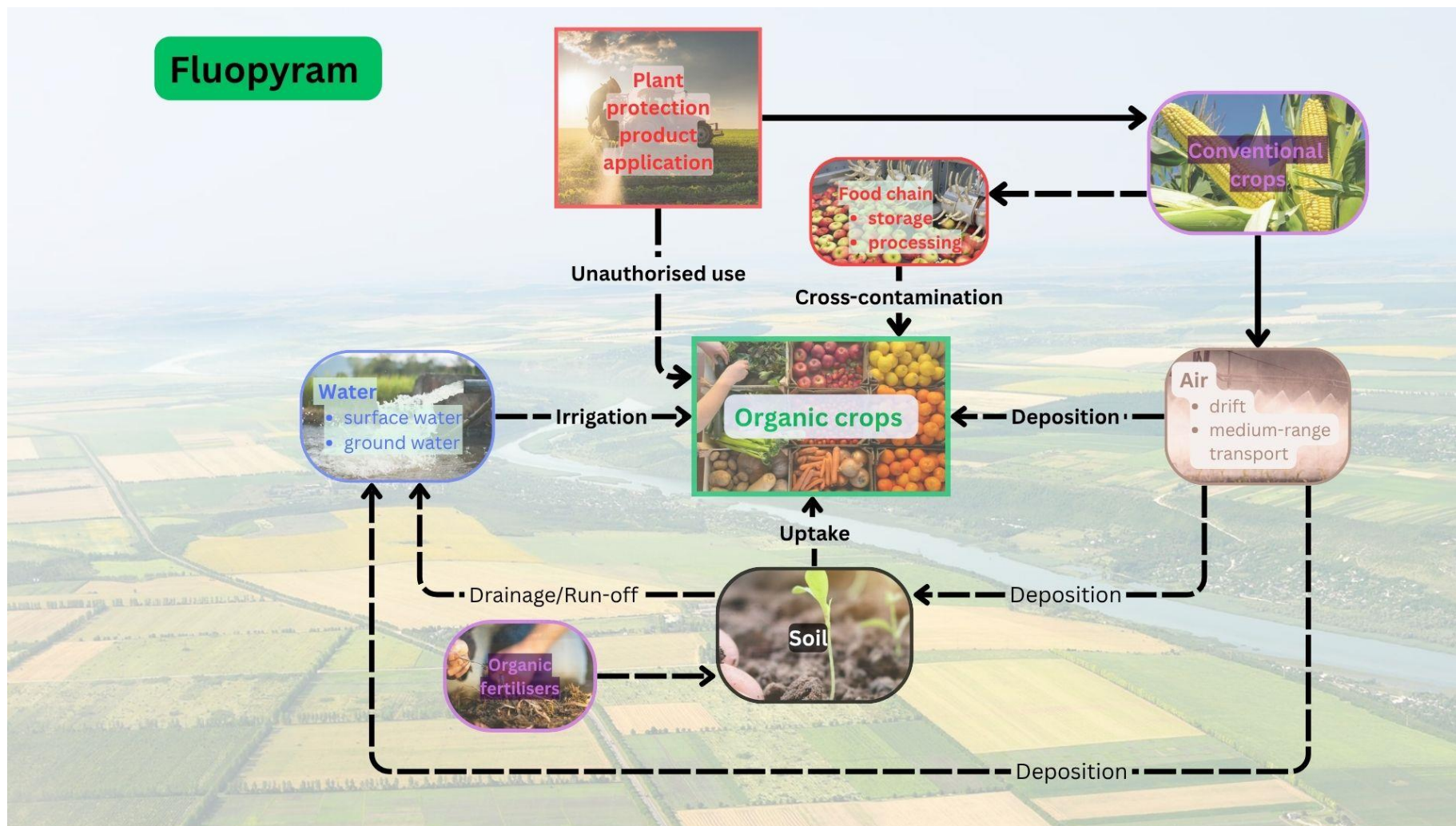


Figure 10: Pathways of residues of fluopyram to plants and plant commodities

Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded

3.11 Lambda-cyhalothrin

3.11.1 Method(s)

- What is/are the residues to be monitored for the active substance lambda-cyhalothrin according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

For the active substance lambda-cyhalothrin, the residue definition for enforcement in food and feed of plant origin has been proposed as 'lambda-cyhalothrin' in the EFSA peer review conclusion, the EFSA MRL review and revision of the MRL review (EFSA, 2014g,h, 2015g). This residue definition includes the sum of lambda-cyhalothrin isomers (includes gamma-cyhalothrin)⁶¹ and is applicable to primary and rotational crops; it is also tentatively applicable in processed products considering the parent was found to significantly degrade under conditions simulating sterilisation (EFSA, 2015g). This residue definition for enforcement is implemented in Regulation (EC) No 396/2005³ as 'lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S- and S,R isomers)'. The same residue definition is also proposed for honey.

Based on the above only residues of lambda-cyhalothrin are to be monitored in foods of plant origin, honey and other apiculture products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

The analytical methods available for the monitoring of residues of lambda-cyhalothrin do not allow for the separate measurement of lambda- and gamma-cyhalothrin (EFSA, 2015g). Therefore, methods of analysis that analyse lambda-cyhalothrin as a sum of isomers will be discussed in this section.

Multi-residue QuEChERS method based on GC-MS, and a multi-residue LC-MS/MS method have been reported for the monitoring of residues of lambda-cyhalothrin in high water, high acid, high oil, and dry commodities of plant origin at or above the LOQ of 0.01 mg/kg (EFSA, 2014g,h, 2015g). Additionally, the multi-residue QuEChERS method has been validated for analysis in complex matrices, achieving an LOQ of 0.1 mg/kg for lambda-cyhalothrin residues (EFSA, 2020c).

A multi-residue analytical method, DFG S19, employing GC-ECD and GC-MS or GC-MS/MS, has been validated for the monitoring of residues of lambda-cyhalothrin in high water, high acid, high oil content and dry plant commodities, with an LOQ of 0.01 mg/kg (EFSA, 2017c).

A single residue method based on GC-ECD was sufficiently validated for the analysis of lambda-cyhalothrin residues in hops, with an LOQ of 0.1 mg/kg (EFSA, 2013g).

According to the EURL for Residues of Pesticides (EURL, 2024, under 'Documentation as provided to EFSA'), a multi-residue citrate-buffered QuEChERS method based on GC-MS/MS is validated for monitoring lambda-cyhalothrin in honey samples at an LOQ of 0.002 mg/kg.

⁶¹ Lambda-cyhalothrin is a 1:1 mixture of two of the four components of cyhalothrin, the R,S- and the S,R- isomers; isomer S,R alone constitutes the substance gamma-cyhalothrin (EFSA, 2014g). According to the EU Pesticides database, gamma-cyhalothrin is an approved active substance for plant protection purposes (https://food.ec.europa.eu/plants/pesticides/eu-pesticides-database_en).

Overall, multi-residue methods of analysis are available for the monitoring of lambda-cyhalothrin residues in high water, high acid, high oil content, dry and complex matrices of plant commodities, as well as in honey and other apiculture products, according to the residue definition for enforcement currently in place. However, these methods do not differentiate between the isomers of lambda-cyhalothrin or between lambda- and gamma-cyhalothrin. The LOQs of the methods of analysis intended for enforcement purposes of lambda-cyhalothrin range from 0.002 to 0.1 mg/kg, depending on the food/feed matrix.

3.11.2 Authorisation status and use

- Is lambda-cyhalothrin currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has lambda-cyhalothrin ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

a) Authorisations for plant protection use

Lambda-cyhalothrin has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of approval of the active substance is 31 August 2026, as indicated in the EU Pesticides Database⁵ (accessed 10 January 2024). The application for the renewal of the approval of lambda-cyhalothrin is under assessment. According to Regulation (EU) 2021/1165⁶², lambda-cyhalothrin is authorised in organic products for plant protection purposes providing that it will be used only in traps with specific attractants against *Bactrocera oleae* and *Ceratitis capitata*.

According to the EU Pesticides database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, France, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Poland, Portugal, Romania, Slovenia, and Slovakia.

b) Authorisations for uses other than plant protection

Biocidal use

Lambda-cyhalothrin has been approved for biocidal use in the EU Member States, Iceland, Liechtenstein and Norway in accordance with Regulation (EU) No 528/2012⁷ since 10 October 2013. The expiry date of approval of the active substance is on 31 March 2026 as indicated by the ECHA website⁶ (accessed 12 February 2024). The application for the renewal of the approval of lambda-cyhalothrin is under assessment.

According to the ECHA website⁶, at national level, lambda-cyhalothrin has received authorisation in biocidal product formulations in Austria, Belgium, Czechia, Cyprus, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

⁶² Commission Implementing Regulation (EU) 2021/1165 of 15 July 2021 authorising certain products and substances for use in organic production and establishing their lists. OJ L 253, p. 13–48.

Other uses

A search carried out on the ECHA website⁹ on 6 June 2024 indicated one registration for lambda-cyhalothrin under REACH. This registration has been inactive since 1 January 2021 due to the UK's withdrawal from the EU.

- What is/was the actual use of lambda-cyhalothrin? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes

Mode of action of lambda-cyhalothrin

Lambda-cyhalothrin is an insecticide that belongs to the pyrethroid compounds group. It has a broad spectrum of applications to control a large number of harmful insects across various crops, including those in agriculture, horticulture, viticulture, hops, forestry, and stored grains. It is effective against multiple species of *Lepidoptera*, *Hemiptera*, *Diptera*, and *Coleoptera*, exhibiting adulticidal, ovicidal, and larvicidal properties. As a non-systemic active ingredient, lambda-cyhalothrin targets the nervous system of insects, disrupting neuron function through interaction with sodium channels (EFSA, 2015g).

Conditions of use and applicable crops

The uses reported in the revision of the EFSA MRL review from 2015 for lambda-cyhalothrin include northern and southern Europe applications in food and feed commodities belonging to the following crop groups: citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, wild fungi, pulses (dried), oilseeds and oil fruits, cereals, hops (dried), sugar plants and alfalfa forage (EFSA, 2015g). Note was taken that uses in alfalfa forage were not supported by data (see Section 3.11.3.2 'Active use (all legitimate uses of the substance)') (EFSA, 2015g).

After the revision of the EFSA MRL review, applications were submitted to EFSA to modify the existing MRLs and to support new uses for stem vegetables, cereals, seed spices (dried) and fruit spices (dried) (EFSA, 2019d, 2020c).

Lambda-cyhalothrin applications include outdoor and indoor foliar applications as well as outdoor soil treatment (EFSA, 2015g, 2017c, 2019d, 2020c).

- Indoor and outdoor foliar treatments were reported for all above-mentioned crop groups and the application rates range from 5.00 g a.s./ha up to 125 g a.s./ha or from 1.00 g a.s./hL to 2.00 g a.s./hL for outdoor uses and from 5.00 g a.s./ha up to 20.00 g a.s./ha for indoor uses (EFSA, 2015g, 2017c, 2019d, 2020c).
- Outdoor soil treatments were reported for escarole (broad-leaf endive) and cotton seed only at an application rate of 40–60 g a.s./ha (EFSA, 2015g).

Use of lambda-cyhalothrin in traps containing specific attractants against *Bactrocera oleae* and *Ceratitis capitata* is not expected to result in residues in plant commodities (EC, 2022).

b) Uses for purposes other than plant protection

Biocidal use

Products containing lambda-cyhalothrin are reported to be used as insecticides in livestock installations, buildings and structures (indoor and/or outdoor). Biocidal products containing lambda-cyhalothrin can be applied by both professional and non-professional users. Product application rates range from 10 mg a.s./m² to 25 mg a.s./m² (Sweden, 2011a) (see also 'authorisations for purposes other than plant protection/biocidal use').

Other uses

According to the ECHA website⁹, there is 1 REACH registration dossier available for lambda-cyhalothrin, which was active until 2021 but is presently inactive (see 'authorisations for purposes other than plant protection/other uses').

3.11.3 Sources of residues in plants

3.11.3.1 Natural occurrence

- Is there evidence that lambda-cyhalothrin occurs naturally? What is known about the natural origin of this substance?

Lambda-cyhalothrin is a synthetic insecticide produced industrially through chemical processes (Fetoui et al., 2015; Lewis et al., 2016; Malhat et al., 2016). No information on the potential natural presence of lambda-cyhalothrin was found in the literature²².

3.11.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of lambda-cyhalothrin per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of lambda-cyhalothrin in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.11.3.2-1 to 3.11.3.2-4. Findings relating to residues in control (untreated) samples are also discussed in this section.

In all matrices and for both residue trials and results from monitoring, lambda-cyhalothrin residue concentrations refer to the residue definition for enforcement (i.e. lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)).

Occurrence of lambda-cyhalothrin from residue trials carried out for the critical GAP per crop

When applied at the critical GAPs⁴ reported to EFSA, residue levels of lambda-cyhalothrin were below the LOQ in tree nuts, pulses (dried), and sugar plants (EFSA, 2015g).

Quantified residues of lambda-cyhalothrin were found in citrus fruits, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, wild fungi, oilseeds and oil fruits, cereals, hops (dried), seed spices (dried) and fruit spices (dried) (EFSA, 2015g, 2017c, 2019d, 2020c).

Findings of not authorised substances in organic products

Regarding feed commodities, residues of lambda-cyhalothrin were quantified in cereal straw and fodder beet (EFSA, 2015g).

Although EU GAPs were reported for all uses indicated under 3.11.2 'Conditions of use and applicable crops', no data on residue trials for alfalfa forage were submitted and evaluated in the EFSA MRL review and its revision (EFSA, 2014h, 2015g).

The results from residue trials carried out for the critical GAP per crop for lambda-cyhalothrin in commodities for which uses were submitted to EFSA are summarised in Table 3.11.3.2-1 'Occurrence of lambda-cyhalothrin from residue trials carried out for the critical GAP per crop'.

Table 3.11.3.2-1: Occurrence of lambda-cyhalothrin from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Lambda-cyhalothrin (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA				
Food				
0110000	Citrus fruits	0.2	0.02–0.16	0.05
0120000	Tree nuts	0.01*	<LOQ (0.01)	<LOQ (0.01)
0130000	Pome fruits	0.01*–0.2	<LOQ (0.01)–0.13	0.03
0140000	Stone fruits	0.01*–0.3	<LOQ (0.01)–0.2	0.03
0150000	Berries and small fruits	0.01*–0.2	<LOQ (0.01)–0.12	0.02
0160000	Miscellaneous fruits	0.01*–1	<LOQ (0.01)–0.3	0.03
0210000	Root and tuber vegetables	0.01*–0.15	<LOQ (0.01)–0.05	0.01
0220000	Bulb vegetables	0.2	<LOQ (0.01)–0.04	0.01
0230000	Fruiting vegetables	0.01*–0.3	<LOQ (0.01)–0.09	0.01
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*–0.3	<LOQ (0.01)–0.15	0.02
0250000	Leaf vegetables, herbs and edible flowers	0.01*–1.5	<LOQ (0.01)–0.63	0.05
0260000	Legume vegetables	0.01*–0.4	<LOQ (0.01)–0.17	0.01
0270000	Stem vegetables	0.01*–0.3	<LOQ (0.01)–0.14	0.03
0280020	Wild fungi	0.5	0.09–0.23	0.17
0300000	Pulses (dried)	0.05	<LOQ (0.01)	<LOQ (0.01)
0400000	Oilseeds and oil fruits	0.01*–0.5	<LOQ (0.01)–0.3	0.01
0500000	Cereals	0.01*–0.5	<LOQ (0.01)–0.33	0.01
0700000	Hops (dried)	10	2.6–3.6	3.3
0810000	Seed spices (dried)	0.3	<LOQ (0.01)–0.13	0.02
0820000	Fruit spices (dried)	0.3–2	<LOQ (0.01)–0.13	0.02
0900000	Sugar plants	0.01*–0.05	<LOQ (0.01)	<LOQ (0.01)
Feed				
1200000	Alfalfa forage	NA	NR	-
	Cereal straw	NA	0.1–1.62	0.43
	Fodder beet	NA	<LOQ (0.01)–0.21	0.055

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; NR – no residue trials are available; '-': not estimated due to lack of data.

a) Maximum Residue Level in Reg. (EU) No 2021/590 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA, 2015g, 2017c, 2019d, 2020c.

Occurrence of lambda-cyhalothrin under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to lambda-cyhalothrin are given in Regulation (EU) 2019/1015⁶³ for the year 2020, Regulations (EU) 2019/1015⁶³ and (EU) 2021/590⁴⁹ for the year 2021 and Regulation (EU) 2021/590⁴⁹ for the year 2022.

⁶³ Commission Regulation (EU) 2019/1015 of 20 June 2019 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, captan, cyazofamid, flutianil, kresoxim-methyl, lambda-cyhalothrin, mandipropamid, pyraclostrobin, spiromesifen, spirotetramat, teflubenzuron and tetraconazole in or on certain products. OJ L 165, 21.6.2019, p. 23–64.

Regarding commodities not labelled as organic, 100,019 samples were collected and analysed for lambda-cyhalothrin in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 92,701 (92.68%) were unprocessed and 7,318 (7.32%) processed commodities. No residues were quantified in 97,682 samples out of the 100,019 samples (97.66%). In 2,260 samples out of the 100,019 samples (2.26%) lambda-cyhalothrin was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-11.1. MRLs were exceeded in 77 samples out of the 100,019 samples (0.08%). The highest concentration for samples exceeding the MRLs was 2.33 mg/kg in leaf vegetables, herbs and edible flowers (lettuces and salad plants).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of lambda-cyhalothrin are summarised in Table 3.11.3.2-2a for unprocessed and in Table 3.11.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on lambda-cyhalothrin in feed not labelled as organic were submitted to EFSA.

Table 3.11.3.2-2a: Occurrence of lambda-cyhalothrin monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Lambda-cyhalothrin (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0110000	Citrus fruits	0.2	0.001	0.001–0.58	226	0.018
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*–0.2	0.001	0.001–0.17	111	0.016
0140000	Stone fruits	0.01*–0.3	0.001	0.001–0.25	595	0.017
0150000	Berries and small fruits	0.01*–0.2	0.001	0.001–0.19	192	0.016
0160000	Miscellaneous fruits	0.01*–1	0.001	0.001–0.2	147	0.022
0210000	Root and tuber vegetables	0.01*–0.15	0.001	0.001–0.056	81	0.01
0220000	Bulb vegetables	0.2	0.001	0.006–0.098	10	0.032
0230000	Fruiting vegetables	0.01*–0.3	0.001	0.001–0.104	83	0.017
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*–0.3	0.001	0.001–1.5	165	0.018
0250000	Leaf vegetables, herbs and edible flowers	0.01*–1.5	0.001	0.001–2.3	521	0.034
0260000	Legume vegetables	0.01*–0.4	0.001	0.002–0.14	14	0.02
0270000	Stem vegetables	0.01*–0.3	0.001	0.002–0.55	87	0.018
0280020	Wild fungi	0.5	0.001	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.05	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–0.5	0.001	<LOQ	0	<LOQ
0500000	Cereals	0.01*–0.5	0.001	0.006–0.011	2	0.009
0700000	Hops (dried)	10	0.01	0.5–0.68	2	0.59
0810000	Seed spices (dried) ^{d)}	0.3	0.01	0.054	1	0.054
0820000	Fruit spices (dried) ^{d)}	0.3–2	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*–0.05	0.005	<LOQ	0	<LOQ
Feed						
1200000	Alfalfa forage	NA	ND	ND	ND	ND
	Cereal straw	NA	ND	ND	ND	ND
	Fodder beet	NA	ND	ND	ND	ND
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of lambda-cyhalothrin is not expected)						
0280000	Fungi, mosses and lichens	0.01*–0.5	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	0.005	<LOQ	0	<LOQ

Findings of not authorised substances in organic products

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Lambda-cyhalothrin (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.01*	0.003	<LOQ	0	<LOQ
0800000	Spices (dried)	0.01*-2	0.01	0.054	1	0.054
1040000	Honey and other apiculture products	0.05*	0.001	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2021/590 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Spices (dried) appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0810000 and 0820000 and non-use of the substance for all other commodities '08N0000' that are reported under the 'broader' category 0800000 on the table. This creates an inconsistency where the results indicating non-uses are overestimated.

Table 3.11.3.2-2b: Occurrence of lambda-cyhalothrin from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Lambda-cyhalothrin (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0110000	Citrus fruits	0.2	0.001	0.0075	1	0.008
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*-0.2	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*-0.3	0.001	0.03	1	0.03
0150000	Berries and small fruits	0.01*-0.2	0.001	0.009-0.16	24	0.028
0160000	Miscellaneous fruits	0.01*-1	0.001	0.01-0.017	3	0.016
0210000	Root and tuber vegetables	0.01*-0.15	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.2	0.01	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*-0.3	0.001	0.003-0.15	14	0.032
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*-0.3	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*-1.5	0.002	0.01-0.38	12	0.041
0260000	Legume vegetables	0.01*-0.4	0.001	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*-0.3	0.005	<LOQ	0	<LOQ
0280020	Wild fungi	0.5	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.05	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*-0.5	0.002	0.011-0.15	44	0.02
0500000	Cereals	0.01*-0.5	0.0001	<LOQ	0	<LOQ
0700000	Hops (dried)	10	0.05	<LOQ	0	<LOQ
0810000	Seed spices (dried) ^{d)}	0.3	0.01	<LOQ	0	<LOQ
0820000	Fruit spices (dried) ^{d)}	0.3-2	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*-0.05	0.002	<LOQ	0	<LOQ
Feed						
1200000	Alfalfa forage	NA	ND	ND	ND	ND
	Cereal straw	NA	ND	ND	ND	ND
	Fodder beet	NA	ND	ND	ND	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of lambda-cyhalothrin is not expected)						
0280000	Fungi, mosses and lichens	0.01*-0.5	0.01	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.01*	0.01	<LOQ	0	<LOQ

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Lambda-cyhalothrin (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0800000	Spices (dried)	0.01*-2	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.001	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2021/590 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Spices (dried) appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0810000 and 0820000 and non-use of the substance for all other commodities '08N0000' that are reported under the 'broader' category 0800000 on the table. This creates an inconsistency where the results indicating non-uses are overestimated.

Occurrence of lambda-cyhalothrin in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 9,376 samples were collected and analysed for lambda-cyhalothrin from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 7,838 (83.6%) were unprocessed and 1,538 (16.4%) processed commodities. No residues were quantified in 9,372 samples out of the 9,376 samples (99.96%). In four samples out of the 9,376 samples (0.04%) lambda-cyhalothrin was found at or above the analytical LOQ but below or at the MRL. No samples labelled as organic were above MRLs. These findings are summarised in Appendix B, Table B-11.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.11.3.2-3a for unprocessed and in Table 3.11.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on lambda-cyhalothrin in feed labelled as organic were submitted to EFSA.

Table 3.11.3.2-3a: Occurrence of lambda-cyhalothrin from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Lambda-cyhalothrin (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.2	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*-0.2	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*-0.3	0.001	0.029	1	0.029
0150000	Berries and small fruits	0.01*-0.2	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*-1	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*-0.15	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.2	0.001	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*-0.3	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*-0.3	0.001	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*-1.5	0.001	<LOQ	0	<LOQ

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Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Lambda-cyhalothrin (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0260000	Legume vegetables	0.01*-0.4	0.001	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*-0.3	0.001	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*-0.5	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.05	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*-0.5	0.001	<LOQ	0	<LOQ
0500000	Cereals		0.001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.01*	0.003	<LOQ	0	<LOQ
0700000	Hops (dried)	10	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.01*-2	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*-0.05	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.005	<LOQ	0	<LOQ

*Limit of quantification in Reg. (EC) No 396/2005.

a) Maximum Residue Level in Reg. (EU) No 2021/590 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.11.3.2-3b: Occurrence of lambda-cyhalothrin from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Lambda-cyhalothrin (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.2	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*-0.2	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*-0.3	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.01*-0.2	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*-1	0.001	0.004	1	0.004
0210000	Root and tuber vegetables	0.01*-0.15	0.005	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.2	ND	ND	ND	ND
0230000	Fruiting vegetables	0.01*-0.3	0.003	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*-0.3	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*-1.5	0.01	<LOQ	0	<LOQ
0260000	Legume vegetables	0.01*-0.4	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*-0.3	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*-0.5	0.01	0.038	1	0.038
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0300000	Pulses (dried)	0.05	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*-0.5	0.002	0.021	1	0.021
0500000	Cereals		0.0001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.01*	0.001	<LOQ	0	<LOQ
0700000	Hops (dried)	10	ND	ND	ND	ND
0800000	Spices (dried)	0.01*-2	0.025	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*-0.05	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.001	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2021/590 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative

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findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of lambda-cyhalothrin in the EU Organic Farming Information System

The EU OFIS reported 17 findings for lambda-cyhalothrin in 2021 and 2022. Seven of the products sampled and analysed had EU origin and 10 were of non-EU origin. Residues were found in three samples of citrus fruits (oranges), 1 sample of stone fruits (cherries), 3 samples of berries and small fruits (table grapes), 2 samples of root and tuber vegetables (potatoes and carrots), 5 samples of leaf vegetables, herbs and edible flowers (thyme) and three samples of oilseeds and oil fruits (sunflower seeds). The concentrations of lambda-cyhalothrin residues were above LOQ but below MRL in 16 samples. MRL was exceeded in one sample. The highest concentration was reported for a sample of thyme (marjoram) from non-EU origin, with the quantified level of 0.22 mg/kg. These findings are summarised in Table 3.11.3.2-4.

Table 3.11.3.2-4: Occurrence of lambda-cyhalothrin from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
0110020	Oranges	0.2	0.014; 0.038; 0.011- Oranges	ND
0211000	Potatoes	0.01*	0.1 – Potatoes	ND
0213020	Carrots	0.04	0.027 – Carrots	ND
0256070	Thyme	0.7	ND	0.032; 0.032 – Marjoram (rubbed)
Samples of non-EU origin				
0140020	Cherries (sweet)	0.3	ND	0.016 – Cherries (sour dried)
0151010	Table grapes	0.08	0.029 – Raisins (unprocessed)	0.043 – Raisins paste 0.037 – Raisins (dried)
0256070	Thyme	0.7	0.031; 0.032; 0.22 – Marjoram	ND
0401050	Sunflower seeds	0.2	0.009; 0.009; 0.029 – Sunflowers seeds	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2021/590 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of lambda-cyhalothrin in untreated samples (control samples) from residue trials

Residues of lambda-cyhalothrin were quantified in control (untreated) olive samples at 0.06 mg/kg from a residue trial in Spain (France, 2013a). Peaches from southern France and cherries from southern and northern France also showed quantified residues (France, 2013a). The residue concentrations were not reported.

No evidence-based explanations on the causes for these occurrences in control (untreated) samples were provided in the above-mentioned evaluation report.

- Could the presence of lambda-cyhalothrin and/or its residues be due to biocide use?

Lambda-cyhalothrin is applied as a biocidal insecticide used in livestock installations, buildings and structures. Mitigation measures are proposed to prevent environmental exposure to lambda-cyhalothrin (Sweden, 2011a). These include proposals to restrict uses to prevent emissions to the sewage treatment plant (STP) and applications only in areas that are not liable to submersion or becoming wet.

The product is applied as a capsule suspension formulation at concentrations of 0.5–9.6% (w/w). PEC values have been calculated to predict the potential contamination of water and soil for

different scenarios (e.g. outdoor use in rural areas or indoor use in urban areas connected to STP) carried out by the Evaluation Member State; the highest values were 0.03 µg/L (PEC_w) and 0.01 mg/kg (PEC_{soil}). These PECs are covered by those estimated for agricultural uses of the substance (see Section 3.11.3.6).

Based on the above, it can be concluded that the release of residues of lambda-cyhalothrin in the water and/or the soil after biocidal use cannot be excluded.

3.11.3.3 Behaviour in food and feed products

- What key physico-chemical properties of lambda-cyhalothrin are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

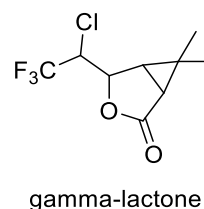
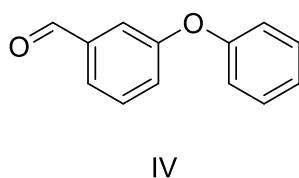
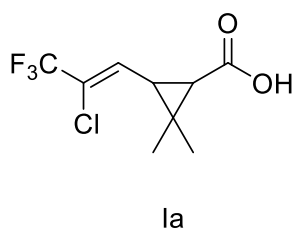
The physico-chemical properties of lambda-cyhalothrin are reported in Table 3.11.3.3.

Lambda-cyhalothrin has a DT₉₀ of 158 days (worst-case field value) and is not expected to accumulate in soil over successive seasons (see Section 3.11.3.5). Regarding sorption to soil, the geometric mean of K_{Foc} in Table 3.11.3.3 indicates that the substance is immobile in soil (EFSA, 2014g).

The maximum calculated PEC_w for lambda-cyhalothrin for the representative uses was 0.387 µg/L (full canopy application to plums; 1 × 10 g a.s./ha) (EFSA, 2014g).

Lambda-cyhalothrin is hydrolytically stable under the standard conditions of pasteurisation, baking, brewing and boiling. However, during sterilisation it showed to degrade into transformation products Ia at 59% TRR, IV at 63% TRR, and gamma-lactone at 15% TRR (structures represented below) (EFSA, 2014h). Considering that lambda-cyhalothrin may degrade under some food/feed processing conditions, a potential formation of degradation products would not be captured by the analytical methods because these products are not included in the residue definition for monitoring and, therefore, are not analysed. This would be expected to result in a decrease in the measured residues in the processed commodity when compared with the raw commodity. On the other hand, some processes such as drying may result in higher concentrations of residues in the processed commodities. Therefore, both possibilities (decrease or increase of residues) are plausible in this case, depending on the process.

Transformation products structures:



Lambda-cyhalothrin has a low vapour pressure (10⁻⁷ Pa) (EFSA, 2014g).

Table 3.11.3.3: Physico-chemical properties of lambda-cyhalothrin (EFSA, 2014g)

Structural formula	
Isomeric composition	Racemic mixture (50:50) of the two enantiomers. The one on top: (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate The one on the bottom: (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate enantiomer is also known as gamma-cyhalothrin (ISO common name)
Appearance (state purity)	Purified grade: white solid with no characteristic odour (99.0 % w/w) Technical grade: light beige solidified melt (94.0 % w/w); white solid (98.8 % w/w); no characteristic odour (96.5 % w/w)
Melting point (state purity)	49°C (99.0% w/w)
Boiling point	No boiling point before decomposition (99.0 % w/w)
Temperature of decomposition	Ca. 275°C at atmospheric pressure (99% w/w)
Vapour pressure (state temperature, state purity)	2×10^{-7} Pa at 20°C (99.0% w/w)
Henry's law constant (state temperature)	0.02 Pa·m ³ /mol at 20°C (calculated using the vapour pressure and water solubility at pH 6.5)
Solubility in water (state temperature, state purity and pH)	pH 5: 4 µg/L at 20°C pH 6.5: 5 µg/L at 20°C pH 9.2: 4 µg/L at 20°C
Partition coefficient (state temperature, pH and purity)	log Pow = 5.5 at 20°C (neutral pH; 97.2 % w/w); no pH effect anticipated
Partition coefficient (octanol/air)	Log Poa = 11.2 (EPISuite KOAWIN v1.10) (Debler et al. 2024)
Atmospheric half-life	DT ₅₀ 12.2 hours (assuming global average OH-conc over 24 hours of 0.5×10^6 mol/cm ³)
Dissociation constant (state purity)	No dissociation within environmentally relevant pH range
Soil adsorption (geometric mean)	K _{Foc} 189959 mL/g
Hydrolytic degradation (>10%)	Hydrolytically stable at pH 4 (25°C) pH 7: DT₅₀ = 167 days (20°C); 87.4 days (25°C) pH 9: DT₅₀ = 17.8 days (20°C); 1.3 days (25°C)

DT₅₀ – Disappearance time of 50% of the substance in field studies; pH – Potential of Hydrogen; P_{ow} – Octanol/water Partition Coefficient; P_{oa} – Octanol/air Partition Coefficient

3.11.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the

substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from the soil surface at which it is applied).

The highest drift of lambda-cyhalothrin to neighbouring fields may occur during its applications to fruit crops (up to 29.2 %), hops (19.33%), vineyards and vegetables (up to 8.02 %) and field crops (up to 2.77 %). Drift values should be considered the rate received by neighbouring fields, expressed as a percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. Buffer zones or spray drift-reducing nozzles).

The use of lambda-cyhalothrin in granular form has been identified (EFSA, 2015g), which necessitates consideration of potential dust drift. Although these granules are relatively large and will not contribute to drift themselves, small dust particles that are small enough to be taken downwind by the wind may break off. Deposition percentile values were considered for neighbouring fields, distinguishing between seed treatments (up to 17%) and granule applications (9.6%) for different crops and techniques (EFSA, 2013b). According to Adriaanse et al. (2022), the use of techniques (deflectors), size of the dust particles and average wind speed were the most important factors determining the amount of dust drift.

If organic crops are present adjacent to the conventional crops treated, measurable residues of lambda-cyhalothrin in the untreated crop cannot be excluded. However, since the nature of the potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

3.11.3.5 Accumulated/historical residue levels in soil

- What is the persistence of lambda-cyhalothrin and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

According to available data (EFSA, 2014g), the DT₉₀ of lambda-cyhalothrin in soil has a worst-case field value of 158 days, indicating that lambda-cyhalothrin is not expected to accumulate in soil when used over successive seasons.

In order to investigate the potential soil uptake of residues of lambda-cyhalothrin by plants, confined rotational crop studies with lambda-cyhalothrin were carried out (EFSA, 2014h). These studies did not show significant residues above the LOQ (0.01 mg/kg) in edible parts of wheat, lettuce and carrots sown as rotational crops after the last application of lambda-cyhalothrin to a primary crop (EFSA, 2014h). Therefore, transfer of residues of lambda-cyhalothrin to plants planted or sown in soil previously treated with the lambda-cyhalothrin is not expected if the substance is applied according to the submitted GAPs⁴.

The above suggests that the presence of lambda-cyhalothrin in untreated crops is less likely to be associated with plant uptake from contaminated soil. This is also valid for organic crops, when planted in fields that were previously used for conventional agriculture, considering that it requires at least 2 years after the last chemical treatment in order for organic crops to be planted in such areas.²

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Lambda-cyhalothrin is not expected to accumulate in soil.

Evidence of lambda-cyhalothrin in soil was provided by Silva et al. (2023) in a study carried out under the EU SPRINT project. The study assessed the presence of 209 pesticide residues in 100 soil samples from conventional agriculture and 63 soil samples from organic agriculture collected during the 2021 growing season across 10 study sites in Europe: Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark. Lambda-cyhalothrin was quantified in 23 conventional soil samples (23%) at concentrations ranging from 0.00005 to 0.1611 mg/kg and one organic soil (2%) at a concentration of 0.003 mg/kg in Italy. The highest concentration was found in a conventional soil from Spain.

Considering the available evidence, plant uptake of lambda-cyhalothrin from soil containing lambda-cyhalothrin is not expected even if the crop is grown in soil that contain residues at the levels quantified in these studies.

3.11.3.6 Residues from water used for irrigation

- Is there evidence that residues of lambda-cyhalothrin present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for lambda-cyhalothrin in surface water samples were considered:

- The EMPODAT database (data retrieved on 25 March 2024) reports 19 analytical results from surface water samples collected in the Netherlands between 2018 and 2020;
- The NAIADES database (data retrieved on 2 April 2024) reports 50,044 analytical results from surface water samples collected in France from 2020 to 2022.

Among the 50,063 analytical results for lambda-cyhalothrin, 896 were disregarded as found to report quantitative values below the analytical LOQ. Therefore, the number of water samples considered is 49,167.

Based on the screening process described in section 'Data and methodologies', for 99.99% of surface water samples analysed and reported in the above-mentioned databases (49,160 samples), the residue concentrations in these waters were below the screening Cw of 0.07 µg/L and, therefore, transfer of residues from surface water sources to plant commodities is unlikely.

For 0.01% of samples (7 out of 49,167 samples), the residue concentrations were found to be at or above the screening Cw of 0.07 µg/L and the potential transfer of residues to plant commodities if water containing residues at these levels is used for irrigation cannot be excluded.

Overall, considering that for 99.99% of water samples analysed and reported for lambda-cyhalothrin in EEA-WATERQUALITY, EMPODAT and NAIADES (49,167 samples), the residue concentrations were below the screening Cw of 0.07 µg/L, it can be concluded that the transfer of lambda-cyhalothrin residues from water sources to plant commodities when this water is used to irrigate plants, is unlikely.

3.11.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *lambda-cyhalothrin*, *industry/industrial*, and *air/atmosphere*) did not identify any relevant European studies.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water. Based on conservative estimations of the possible transfer of residues from water used for irrigation to plant commodities, the transfer of residues of lambda-cyhalothrin from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 7, 2025, using the keywords *lambda-cyhalothrin*, *industry/industrial*, and *water*) did not identify any relevant European study.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Based on information on the possible plant uptake of lambda-cyhalothrin from EU soil, the transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 17, 2025, using the keywords *lambda-cyhalothrin*, *industry/industrial*, and *soil/sediment*) did not identify any relevant European study.

3.11.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Medium and long-range aerial transport of residues

Silva et al. (2023) investigated the presence of lambda-cyhalothrin in 20 outdoor air samples collected during the 2021 growing season across 10 study sites in Europe of organic and conventional agriculture (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). The study was carried out under the framework of the EU SPRINT project. Organic fields had not been treated for 5 consecutive years. Lambda-cyhalothrin was quantified in one sample of conventional agriculture from Spain at a concentration of 56.6 ng m⁻³.

In a study published under the EU SPRINT project investigating the presence of lambda-cyhalothrin in air samples collected between April 2021 and June 2022 from one agricultural area of conventional farming in Portugal (vineyard), lambda-cyhalothrin was quantified in 14% of air samples from Portugal. Particle-phase concentrations ranged from 12 to 20 pg/m³. No

gas-phase detection was reported (Debler et al., 2024). Note was taken that the field had undergone lambda-cyhalothrin treatment before the collection of the samples of the surrounding area and measurement. Overall, the exclusive detection in the particle phase and its minimal volatility reduces the likelihood of lambda-cyhalothrin aerial transfer to plants.

Overall, a possible medium-range aerial transport of residues from treated to untreated areas is less likely to explain the presence of unexpected findings of lambda-cyhalothrin in organic crops and their products.

Use as veterinary medicine

Cyhalothrin, a mixture that contains the two diastereomers of lambda-cyhalothrin (the *R,S*- and the *S,R*- isomers), is a veterinary medicine used in bovine species²³ (EMEA, 2001; EFSA, 2024c). When cyhalothrin is used in veterinary medicine, residues measured as lambda-cyhalothrin are released in the environment and may be taken up by plants. Conservative estimates of the possible transfer of residues of lambda-cyhalothrin from water used for irrigation to plant commodities and information on the possible plant uptake of residues of lambda-cyhalothrin from the EU soil suggest that transfer of residues of lambda-cyhalothrin from veterinary use is less likely. Since cyhalothrin is composed of two of the four lambda-cyhalothrin isomers, the same conclusion is applicable to cyhalothrin.

3.11.4 Conclusions on lambda-cyhalothrin

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use.
- Residue trials carried out to support the critical GAPs⁴ for lambda-cyhalothrin, gave residue concentrations of up to 3.6 mg/kg in food commodities (highest value for leaf hops (dried)) and of up to 1.62 mg/kg in feed commodities (cereal straw). Concentrations in the ranges reported in Table 3.11.3.2-1 might be associated with active use of lambda-cyhalothrin according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.
- Lambda-cyhalothrin was quantified in the context of residue trials in untreated (control) olive samples from Spain (0.06 mg/kg) and control peach and cherry samples from France (residue concentrations not available).
- Findings of lambda-cyhalothrin may also relate to applications of gamma-cyhalothrin that is an approved active substance, considering that lambda-cyhalothrin contains the gamma isomer and that the available methods of analysis do not differentiate between lambda- and gamma-cyhalothrin.
- Use of lambda-cyhalothrin in traps containing specific attractants against *Bactrocera oleae* and *Ceratitis capitata* is not expected to result in residues in plant commodities.
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for lambda-cyhalothrin in unprocessed commodities with authorised uses ranged from 0.01 mg/kg in root and tuber vegetables to 0.034 mg/kg in leaf vegetables, herbs and edible flowers.

- In unprocessed products labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 there were no commodity groups with five or more quantified findings.
- In processed commodities, residues of lambda-cyhalothrin were quantified in three products labelled as organic and sampled under the EU monitoring programmes from 2020 to 2022. In samples from processed products not labelled as organic with five or more quantified findings, the median concentrations of residues of lambda-cyhalothrin ranged from 0.02 mg/kg in oilseeds and oil fruits to 0.041 mg/kg in leaf vegetables, herbs and edible flowers. Considering that lambda-cyhalothrin may degrade under some food/feed processing conditions, a potential formation of degradation products would not be captured by the analytical methods because these products are not included in the residue definition for monitoring and, therefore, are not analysed. This would be expected to result in a decrease in the measured residues in the processed commodity when compared with the raw commodity. On the other hand, some processes such as drying may result in higher concentrations of residues in the processed commodities. Therefore, both possibilities (decrease or increase of residues) are plausible in this case, depending on the process.
- Overall, in commodities labelled as organic, lambda-cyhalothrin was quantified in 0.04% of samples (4 out of 9,376 samples). This percentage is 58 times lower than the percentage reflecting the number of findings in samples not labelled as organic (2.34%) (see Appendix B, Tables B-11.1 and B-11.2). These results suggest that the occurrence of residues of lambda-cyhalothrin in organic products is less likely when compared with conventional commodities.
- A potential source of the unintentional presence of residues of lambda-cyhalothrin in commodities of plant origin is drift from conventional crops grown in the vicinity.
- A possible medium-range aerial transport of residues (as aerosols) from treated to untreated areas is less likely to explain the presence of unexpected findings of lambda-cyhalothrin in organic crops and their products.
- Lambda-cyhalothrin is not persistent in soil. Plant uptake of residues of lambda-cyhalothrin from contaminated soil is considered a less likely explanation for residues found in crops where lambda-cyhalothrin has not been actively used.
- Transfer of lambda-cyhalothrin residues from EU water sources used for irrigation to plant commodities is unlikely.
- Lambda-cyhalothrin is used in biocidal products and cyhalothrin as veterinary medicine²³. These applications may result in the release of residues of lambda-cyhalothrin into the environment.
- Note was taken that lambda-cyhalothrin had been registered under REACH⁹ between 2020 and 2022; the registration at the time included industrial uses the description of which is not available. As of 6 June 2024, uses of the substance in the EU Member States¹¹, Iceland, Liechtenstein and Norway cannot be confirmed in REACH registration data.
- Conservative estimates of the possible transfer of residues of lambda-cyhalothrin from water used for irrigation to plant commodities and information on the possible plant uptake of residues of lambda-cyhalothrin from EU soil suggest that the transfer of residues of

lambda-cyhalothrin from biocidal, veterinary medicine uses and other non-pesticide uses as well as the transfer from industrial emissions to the environment and from the environment to plants and plant commodities is less likely.

The pathways of residues of lambda-cyhalothrin to plants and plant commodities are summarised in Figure 11.

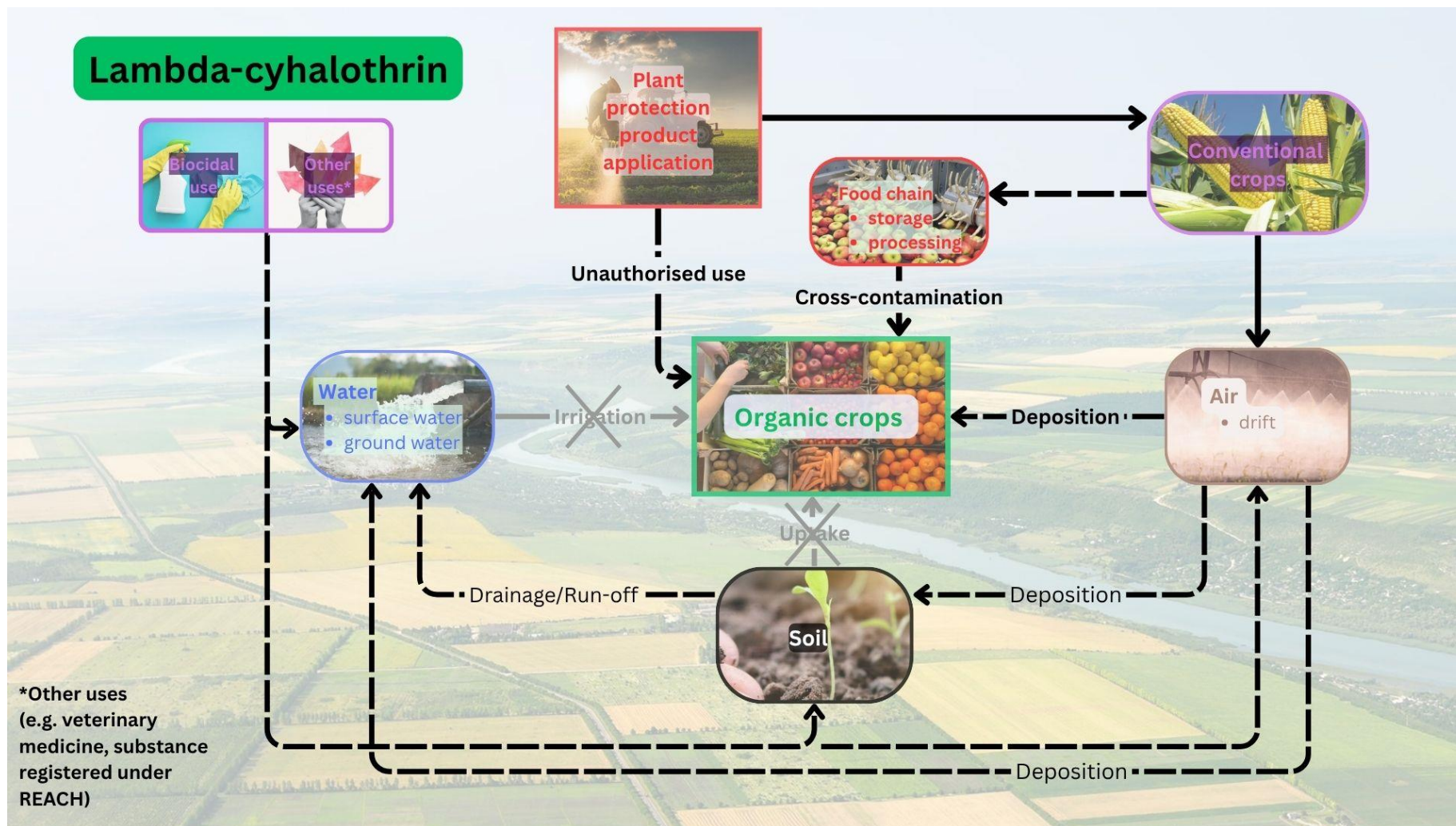


Figure 11: Pathways of residues of lambda-cyhalothrin to plants and plant commodities

Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded

3.12 Acetamiprid

3.12.1 Method(s)

- What is/are the residues to be monitored for the active substance acetamiprid according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

For the active substance acetamiprid, the residue definition for enforcement in food and feed of plant origin has been proposed as 'acetamiprid' in the EFSA peer review conclusion (EFSA, 2016d). This residue definition is applicable to primary, rotational crops, processed products. The same residue definition is also proposed for honey (EFSA, 2021). This residue definition for enforcement is implemented in Regulation (EC) No 396/2005³.

Based on the above only residues of acetamiprid are to be monitored in foods of plant origin, honey and other apiculture products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

The multi-residue QuEChERS method described in the European Standard EN 15662:2008 is validated for determining acetamiprid residues in high water, acidic, high oil content and dry commodities and difficult matrices (e.g. straw), as well as for honey. The method utilises HPLC-MS/MS with an LOQ of 0.01 mg/kg (EFSA, 2016d, 2018f, 2021c).

Another multi-residue method based on GC-ECD (DFG-S19) has been validated for the analysis of acetamiprid in high water content commodities with LOQs ranging from 0.01 mg/kg (apples) to 0.05 mg/kg (tomatoes) (EFSA, 2011d).

A GC-ECD method (confirmed by HPLC-MS/MS) has also been validated in the EFSA peer review for high water (LOQ of 0.01 mg/kg), high oil (LOQ of 0.01 mg/kg) and high acid content commodities (LOQ of 0.05 mg/kg). An ILV was submitted and validated for high oil matrices only (EFSA, 2011d). It is unclear whether it is a single or a multi-residue method.

A fully validated single residue method (RD-11285), as presented in the evaluation report submitted by the Netherlands, is available for determining acetamiprid residues in honey, with an LOQ of 0.05 mg/kg (EFSA, 2021c).

In summary, multi-residue methods are available for monitoring acetamiprid residues in high water, high acid, high oil content, dry and difficult matrices of plant commodities, as well as in honey and other apiculture products. LOQs for the methods of analysis of acetamiprid residues in products of plant origin and honey range from 0.01 to 0.05 mg/kg.

3.12.2 Authorisation status and use

- Is acetamiprid currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has acetamiprid ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

a) Authorisations for plant protection use in conventional agriculture

Acetamiprid has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of approval of the active substance is 28 February 2033, as indicated by the EU Pesticides Database⁵ (accessed 10 January 2024).

According to the EU Pesticides database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, and Slovakia.

b) Authorisations for purposes other than plant protection

Biocidal use

Acetamiprid has been approved for biocidal use in the EU Member States, Iceland, Liechtenstein and Norway in accordance with Regulation (EU) No 528/2012⁷ since 1 February 2020. The expiry date of approval of the active substance is on 31 January 2027 as indicated by the ECHA website⁶ (accessed 12 February 2024).

According to the ECHA website⁶, at national level, acetamiprid has received authorisation in biocidal product formulations in France from 30 November 2022 to 29 November 2027.

Other uses

A search carried out on the ECHA website⁹ on 6 June 2024 indicated that acetamiprid is not currently registered under REACH.

- What is/was the actual use of acetamiprid? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of acetamiprid

Acetamiprid belongs to the group of neonicotinoid compounds. In plants, it is used to control insects of the *Hemiptera*, *Lepidoptera*, *Thysanoptera*, and *Coleoptera* families. Acetamiprid is systemically active in plants and exhibits translaminar activity. It functions as an agonist of the nicotinic acetylcholine receptor, disrupting synaptic transmission in the central nervous system of the insect (EFSA, 2011d).

Conditions of use and applicable crops

The uses reported in the EFSA MRL review include indoor and outdoor foliar treatments to control various pests in both northern and/or southern Europe in food and feed commodities belonging to the following crop groups: citrus fruits, pome fruits, stone fruits, miscellaneous fruits, root and tuber vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds, cereals and alfalfa (EFSA, 2011d).

After the EFSA MRL review, applications were submitted to EFSA to support new uses or modify the existing MRLs for pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops),

leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds and oil fruits, cereals and honey and other apiculture products (EFSA, 2012g, 2014i, 2015h, 2016e, 2018f, 2021c, 2022g, 2024d, 2025a). These additional applications also involved foliar spraying. Application rates range from 0.03 kg a.s./ha to 0.17 kg a.s./ha for food commodities and 0.02 kg a.s./ha in feed commodity alfalfa (EFSA, 2012g, 2014i, 2015h, 2016d,e, 2018f, 2021c, 2022g, 2024d, 2025a).

b) Uses for purposes other than plant protection

Biocidal use

One product containing acetamiprid was identified for use as a physico-chemical barrier against termites (*Reticulitermes* sp.) in France, to protect buildings under construction underground. The product is used by professionals during the construction of the building and is applied as a liquid formulation at concentrations of 0.2% w/w. (France, 2022a). There is no information for product authorisation in other EU countries (see also 'authorisations for purposes other than plant protection/biocidal use').

Other use

According to the ECHA website⁹, acetamiprid is not registered under REACH (see 'authorisations for purposes other than plant protection/other uses').

3.12.3 Sources of residues in plants

3.12.3.1 Natural occurrence

- Is there evidence that acetamiprid occurs naturally? What is known about the natural origin of this substance?

Acetamiprid is a synthetic compound produced industrially through chemical processes (MacBean 2012; Lewis et al., 2016). No information on the potential natural presence of acetamiprid was found in the literature²².

3.12.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of acetamiprid per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of acetamiprid in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.12.3.2-1 to 3.12.3.2-4. The possible presence of residues in control (untreated) samples is also discussed in this section.

In all matrices and for both residue trials and results from monitoring, acetamiprid residue concentrations refer to the residue definition for enforcement (i.e. acetamiprid).

Occurrence of acetamiprid from residue trials carried out for the critical GAP per crop

Following product applications based on the critical GAPs⁴ reported to EFSA, residues of acetamiprid were quantified in citrus fruits, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem

vegetables, pulses (dried), oilseeds and oil fruits, cereals and honey (EFSA, 2011d, 2012g, 2014i, 2015h, 2016d,e, 2018f, 2021c, 2022g, 2024d, 2025a). Residue levels of acetamiprid were below the LOQ in root and tuber vegetables (EFSA, 2011d, 2016d). Regarding feed commodities, residues of acetamiprid were quantified in cereal straw and alfalfa (EFSA, 2011d, 2016e, 2018f).

The results from residue trials carried out for the critical GAP per crop for acetamiprid in commodities for which uses were submitted to EFSA are summarised in Table 3.12.3.2-1 'Occurrence of acetamiprid from residue trials carried out for the critical GAP per crop'.

Table 3.12.3.2-1: Occurrence of acetamiprid from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Acetamiprid (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
Food				
0110000	Citrus fruits	0.9	0.02–0.83	0.19
0130000	Pome fruits	0.4–0.8	<LOQ (0.01)–0.21	0.04
0140000	Stone fruits	0.01*–1.5	<LOQ (0.01)–0.33	0.04
0150000	Berries and small fruits	0.01*–2	<LOQ (0.01)–0.34	0.13
0160000	Miscellaneous fruits	0.01*–3	<LOQ (0.01)–0.48	0.095
0210000	Root and tuber vegetables	0.01*	<LOQ (0.01)	<LOQ (0.01)
0230000	Fruiting vegetables	0.01*–0.6	<LOQ (0.01)–0.37	0.04
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*–0.4	<LOQ (0.01)–0.25	0.01
0250000	Leaf vegetables, herbs and edible flowers	0.01*–3	0.02–1.9	0.19
0260000	Legume vegetables	0.01*–0.6	<LOQ (0.01)–0.32	0.01
0270000	Stem vegetables	0.01*–0.8	<LOQ (0.01)–0.25	0.01
0300000	Pulses (dried)	0.15	<LOQ (0.003)–0.08	0.01
0400000	Oilseeds and oil fruits	0.01*–3	<LOQ (0.01)–0.2	0.02
0500000	Cereals	0.01*–0.1	<LOQ (0.01)–0.06	0.01
1040000	Honey and other apiculture products	0.05*	<LOQ (0.05)–0.55 ^{c)}	0.05
Feed				
1200000	Cereal straw	NA	0.01–1.6	0.175
1200000	Alfalfa	NA	0.03–0.41	0.09

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable.

a) Maximum Residue Level in Reg. (EU) No 2019/88 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA, 2011d, 2012g, 2014i, 2015h, 2016d,e, 2018f, 2021c, 2022g, 2025a; c) Residues quantified above the MRLs come from the reasoned opinions for acetamiprid (EFSA, 2022g, 2025a) that have not been considered by risk managers yet.

Occurrence of acetamiprid under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to acetamiprid are given in Regulation (EU) 2019/88⁶⁴ for the years 2020–2022. Regarding commodities not labelled as organic, 113,059 samples were collected and analysed for acetamiprid in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 104,034 (92.02%) were unprocessed and 9,025 (7.98%) processed commodities. No residues were quantified in 105,238 samples out of the 113,059 samples (93.08%). In 7,680 samples out of the 113,059 samples (6.79%) acetamiprid was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-12.1. MRLs were exceeded in 141 samples out of the 113,059 samples (0.12%). The highest concentration for

⁶⁴ Commission Regulation (EU) 2019/88 of 18 January 2019 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid in certain products. OJ L 22, 24.1.2019, p. 1–12.

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samples exceeding the MRLs was 8.1 mg/kg in leaf vegetables, herbs and edible flowers (grape leaves and similar species).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of acetamiprid are summarised in Table 3.12.3.2-2a, for unprocessed, and in Table 3.12.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on acetamiprid in feed not labelled as organic were submitted to EFSA.

Table 3.12.3.2-2a: Occurrence of acetamiprid monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Acetamiprid (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0110000	Citrus fruits	0.9	0.001	0.001–0.82	658	0.02
0130000	Pome fruits	0.4–0.8	0.001	0.001–0.4	2052	0.027
0140000	Stone fruits	0.01*–1.5	0.001	0.001–1.272	1814	0.027
0160000	Miscellaneous fruits	0.01*–3	0.001	0.002–0.24	67	0.035
0150000	Berries and small fruits	0.01*–2	0.001	0.001–2.3	941	0.033
0210000	Root and tuber vegetables	0.01*	0.001	0.001–0.01	6	0.007
0230000	Fruiting vegetables	0.01*–0.6	0.001	0.001–0.587	1117	0.025
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*–0.4	0.001	0.001–1.4	127	0.016
0250000	Leaf vegetables, herbs and edible flowers	0.01*–3	0.001	0.001–8.1	713	0.062
0260000	Legume vegetables	0.01*–0.6	0.001	0.004–0.33	27	0.018
0270000	Stem vegetables	0.01*–0.8	0.001	0.008–1.9	24	0.039
0300000	Pulses	0.15	0.001	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–3	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.01*–0.1	0.001	0.011–0.02	6	0.014
1040000	Honey and other apiculture products	0.05*	0.001	0.001–0.21	99	0.022
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
1200000	Alfalfa hay	NA	ND	ND	ND	ND
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of acetamiprid is not expected)						
0120000	Tree nuts	0.07	0.001	0.019	1	0.019
0220000	Bulb vegetables	0.01*–0.02	0.001	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.001	0.01–0.25	2	0.018
0290000	Algae and prokaryotes organisms	0.01*	0.005	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*	0.005	0.01–0.17	15	0.03
0700000	Hops (dried)	0.05*	0.005	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*–0.1	0.005	0.017–2.4	4	0.064
0900000	Sugar plants	0.01*	0.005	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2019/88 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

In addition to the pesticide monitoring data collection, an analysis of residues of acetamiprid in honey and other apiculture products was carried out in the framework of the VMPPR national control activities. For unprocessed products of conventional agriculture (969 samples), quantified residues were found for 36 samples. These results (ranging from 0.000011 to 0.093 mg/kg with

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LOQs between 0.00001 and 0.01 mg/kg), which are not reported in Table 3.12.3.2-2a, are consistent with the results from the pesticide data collection, i.e. the highest concentration reported in the VMPPR data collection is below the highest concentration reported in the pesticide data collection.

Table 3.12.3.2-2b: Occurrence of acetamiprid from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Acetamiprid (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0110000	Citrus fruits	0.9	0.001	0.006–0.062	18	0.017
0130000	Pome fruits	0.4–0.8	0.001	0.006–0.058	13	0.016
0140000	Stone fruits	0.01*–1.5	0.002	0.01–0.035	6	0.029
0150000	Berries and small fruits	0.01*–2	0.001	0.008–0.41	36	0.025
0160000	Miscellaneous fruits	0.01*–3	0.002	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*	0.001	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*–0.6	0.001	0.002–0.17	25	0.019
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*–0.4	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*–3	0.002	0.01–1.4	26	0.034
0260000	Legume vegetables	0.01*–0.6	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*–0.8	0.005	<LOQ	0	<LOQ
0300000	Pulses	0.15	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–3	0.002	0.003–0.032	6	0.007
0500000	Cereals	0.01*–0.1	0.001	0.02 ^{c)}	1	0.02 ^{d)}
1040000	Processed apiculture products	0.05*	0.001	0.001–0.07	15	0.019
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
1200000	Alfalfa hay	NA	ND	ND	ND	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of acetamiprid is not expected)						
0120000	Tree nuts	0.07	0.01	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*–0.02	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.005	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	0.005	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*–0.1	0.005	0.81	1	0.81
0900000	Sugar plants	0.01*	0.002	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2019/88 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Quantified result only in processed cereal-based foods for infants and young children (no quantified results in processed cereals).

In addition to the pesticide monitoring data collection, an analysis of residues of acetamiprid in honey and other apiculture products was carried out in the framework of the VMPPR national control activities. For processed products of conventional agriculture, no quantified residues of acetamiprid were found in the 29 samples collected.

Occurrence of acetamiprid in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 10,014 samples were collected and analysed for acetamiprid from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 8,318 (83.06%) were unprocessed and 1696 (16.94%) processed commodities. No residues were quantified in 9,986 samples out of the 10,014 samples (99.72%). In 26 samples out of the 10,014 samples (0.26%) acetamiprid was found at or above the analytical LOQ but below or at the MRL. MRLs were exceeded in two samples out of the 10,014 samples (0.02%). The highest concentration for samples exceeding the MRLs was 0.6 mg/kg in berries and small fruits (table and wine grapes). These findings are summarised in Appendix B, Table B-12.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.12.3.2-3a for unprocessed and in Table 3.12.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on acetamiprid in feed labelled as organic were submitted to EFSA.

Table 3.12.3.2-3a: Occurrence of acetamiprid from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Acetamiprid (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.9	0.001	0.011–0.124	3	0.075
0120000	Tree nuts	0.07	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.4–0.8	0.001	0.003–0.381	7	0.015
0140000	Stone fruits	0.01*–1.5	0.001	0.002	1	0.002
0150000	Berries and small fruits	0.01*–2	0.001	0.012–0.6	8	0.134
0160000	Miscellaneous fruits	0.01*–3	0.001	0.01	1	0.01
0210000	Root and tuber vegetables	0.01*	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*–0.02	0.001	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*–0.6	0.001	0.028	1	0.028
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*–0.4	0.001	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*–3	0.001	<LOQ	0	<LOQ
0260000	Legume vegetables	0.01*–0.6	0.001	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*–0.8	0.001	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.15	0.005	0.083	1	0.083
0400000	Oilseeds and oil fruits	0.01*–3	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.01*–0.1	0.001	0.023	1	0.023 ^{d)}
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*	0.01	0.019	1	0.019
0700000	Hops (dried)	0.05*	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*–0.1	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.001	0.004–0.008	4	0.005

*Limit of quantification in Reg. (EC) No 396/2005.

a) Maximum Residue Level in Reg. (EU) No 2019/88 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results

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are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Quantified result only in processed cereal-based foods for infants and young children (no quantified results in processed cereals).

In addition to the pesticide monitoring data collection, an analysis of residues of acetamiprid in honey and other apiculture products was carried out in the framework of the VMPP national control activities. For unprocessed products of organic agriculture, 2 out of the 13 samples collected had quantified residues at 0.011 and 0.029 mg/kg (LOQ at 0.01 mg/kg).

Table 3.12.3.2-3b: Occurrence of acetamiprid from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Acetamiprid (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.9	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.07	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.4–0.8	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*–1.5	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.01*–2	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*–3	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*	0.005	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*–0.02	ND	ND	ND	ND
0230000	Fruiting vegetables	0.01*–0.6	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*–0.4	0.005	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*–3	0.005	<LOQ	0	<LOQ
0260000	Legume vegetables	0.01*–0.6	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*–0.8	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.005	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0300000	Pulses (dried)	0.15	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–3	0.002	<LOQ	0	<LOQ
0500000	Cereals	0.01*–0.1	0.001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	ND	ND	ND	ND
0800000	Spices (dried)	0.05*–0.1	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.005	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2019/88 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of acetamiprid in the EU Organic Farming Information System

The EU OFIS reported 15 findings for acetamiprid in 2021 and 2022. Four of the products sampled and analysed had EU origin and 11 were of non-EU origin. Residues were found in two samples of tree nuts (pistachios), one sample of stone fruit (apricots), six samples of berries and small fruits (table grape, strawberries and others), one sample of miscellaneous fruits with inedible peel, small (prickly pears/cactus fruits), one sample of miscellaneous fruits with inedible peel, large (mangoes), one sample of oilseeds (soyabeans), one sample of herbal infusions from leaves and herbs from strawberry and two samples of honey and other apiculture products. The concentrations of acetamiprid residues were below the LOQ in one of these samples (detected,

but not quantified). The concentrations of acetamiprid residues were above LOQ but below MRL in 11 samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005³. MRLs were exceeded in four samples. The highest concentration was reported for a sample of moringa powder from non-EU origin, with the quantified level of 1.9 mg/kg. These findings are summarised in Table 3.12.3.2-4.

Table 3.12.3.2-4: Occurrence of acetamiprid from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
0120100	Pistachios	0.07	0.032; 1 sample with detected, but not quantified value – Pistachios	ND
0162040	Prickly pears/cactus fruits	0.01*	0.17 – Pitaya, white	ND
0163030	Mangoes	0.01*	1.6 – Mango	ND
Samples of non-EU origin				
0140010	Apricots	0.8	ND	0.036 – Apricots (frozen halves)
0151010	Table grapes	0.5	ND	0.29 – Sultans; 0.016 – Raisin sultan
0152000	Strawberries	0.5	0.017; 0.035; 0.013 – Strawberries	ND
0154990	Others	0.01*	0.0082 – Mixed berries	ND
0401070	Soyabeans	0.01*	-	1.9 – Moringa (powder)
0632010	Herbal infusions from leaves and herbs from strawberry	0.05*	0.086 – <i>Equisetum arvense</i> /horsetail herb	ND
1040000	Honey and other apiculture products	0.3	0.013; 0.021 – Honey	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2019/88 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of acetamiprid in untreated samples (control samples) from residue trials

Quantified findings in control (untreated) samples were observed for acetamiprid in three residue trials from Germany that were carried out in raspberry and blackberry. The quantified levels were 0.010 mg/kg and 0.038 mg/kg in raspberry (fruit) and 0.011 mg/kg in black currant (fruit) (Germany, 2023c). Additionally, quantified findings in the control samples were found in one trial on grape vines (vine grapes) from northern France at 0.02–0.05 mg/kg (Austria, 2023b).

No evidence-based explanations on the causes for these occurrences in control (untreated) samples were provided in the above-mentioned evaluation reports.

- Could the presence of acetamiprid and/or its residues be due to biocide use?

Acetamiprid is used as a biocidal product in France⁶⁵. There is no information for product authorisation in other EU countries.

In the ER on the use of acetamiprid as an insecticide against termites in buildings under construction underground, mitigation measures are proposed to prevent environmental exposure to acetamiprid (France, 2022a). These include proposals to restrict product applications to periods when no rain is expected, to restrict product uses only on surfaces that will be completely covered during construction, to immediately protect treated surfaces from rain after

⁶⁵ https://echa.europa.eu/information-on-chemicals/biocidal-products?p_id=dissbiocidalproducts_WAR_dissbiocidalproductsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&dissbiocidalproducts_WAR_dissbiocidalproductsportlet_javax.portlet.action=dissBiocidalProductsAction

application, and to collect any contaminated soil/water for disposal according to the local/national/international provisions.

The product is applied as a liquid formulation at concentrations 0.2% w/w. PEC values have been calculated to predict the potential contamination of water and soil from unintentional release of residues of acetamiprid after biocidal application (France, 2022a). These PECs are covered by those estimated for agricultural uses of the substance (see Section 3.12.3.6).

Based on the above, it can be concluded that the release of residues of acetamiprid in the water and/or soil after biocidal use cannot be excluded.

3.12.3.3 Behaviour in food and feed products

- What key physico-chemical properties of acetamiprid are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of acetamiprid are reported in Table 3.12.3.3.

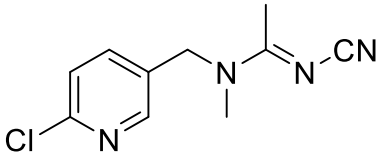
Acetamiprid is a water-soluble compound and shows very low to moderate persistence in soil (see also Section 3.12.3.5). Regarding sorption to soil, the geometric mean of K_{Foc} in Table 3.12.3.3 indicates that the substance has high mobility in soil (EFSA, 2016d).

The maximum calculated PEC_w for acetamiprid for the representative uses was 2.985 µg/L (spray application to pome fruits; 2 × 75 g a.s./ha) (EFSA, 2016d).

Acetamiprid was proved to be hydrolytically stable within a range of pH, temperatures and under standard conditions of pasteurisation, baking, brewing, boiling and sterilisation (EFSA, 2016d). Considering that acetamiprid is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Acetamiprid is considered a non-volatile compound (vapour pressure < 10⁻⁷ Pa) (EFSA, 2016d).

Table 3.12.3.3: Physico-chemical properties of acetamiprid

Structural formula	
Appearance (state purity)	Fine white powder (≥99.9%, pure) Very pale yellow fine powder (99.9%, tech)
Melting point (state purity)	98.9°C (99.7%, tech)
Boiling point	No boiling point observed before decomposition (≥99.9%)
Temperature of decomposition	> 200°C (≥99.9%)
Vapour pressure (state temperature, state purity)	1.73 × 10 ⁻⁷ Pa at 50°C (≥99%)
Henry's law constant (state temperature)	< 5.3 × 10 ⁻⁸ Pa m ³ mol ⁻¹ (25°C)
Solubility in water (state temperature, state purity and pH)	pH 5: 3.48 g/L at 25°C (≥99%) pH 7: 2.95 g/L at 25°C (≥99%)

	pH 9: 3.96 g/L at 25°C (≥99%)
Partition coefficient (state temperature, pH and purity)	log Pow = 0.80 at 25°C (pH 7) (>99%)
Partition coefficient (octanol/air)	Log Poa = 8.1 (EPISuite KOAWIN v1.10) (Debler et al. 2024)
Atmospheric half-life	DT ₅₀ of 3.4 hours derived by the Atkinson model (APOWIN version 1.70). OH radical (12 h) concentration assumed = $1.5 \times 10^6 \text{ mol cm}^{-3}$
Dissociation constant (state purity)	pKa = 0.7 at 25°C (>99%) (pyridinium protonated form)
Soil adsorption (geometric mean)	K _{Foc} = 102 mL/g
Hydrolytic degradation (>10%)	pH range 4–7 no hydrolytic degradation of the active substance at 20–45°C
	pH 9: 420 days at 25°C
	pH 9: 52.9 days at 35°C
	pH 9: 13 days at 45°C (calculated from Arrhenius plot)

DT₅₀ – Disappearance time of 50% of the substance in field studies; NA – not applicable; pH – Potential of Hydrogen; Pow – Octanol/water Partition Coefficient; Poa – Octanol/air Partition Coefficient

3.12.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from the soil surface at which it is applied).

The highest drift of acetamiprid to neighbouring fields may occur during its applications to fruit crops (up to 29.2 %), vegetables (up to 8.02 %) and field crops (up to 2.77 %). Drift values should be considered the rate received by neighbouring fields, expressed as a percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. buffer zones or spray drift-reducing nozzles).

If organic crops are present adjacent to the conventional crops treated, measurable residues of acetamiprid in the untreated crop cannot be excluded. However, since the nature of the potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

As authorised products are to be applied in liquid form, dust drift is not expected to occur.

3.12.3.5 Accumulated/historical residue levels in soil

- What is the persistence of acetamiprid and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

Since, according to available data (EFSA, 2016d), DT₉₀ of acetamiprid in field trials (carried out in eight different sites around Europe) is <1 year (worst-case field DT₉₀ = 43 days), acetamiprid is not expected to accumulate in soil when used over successive seasons.

Field rotational crop studies conducted in northern and southern EU with acetamiprid applied onto the bare soil at ca. 300 g a.s./ha did not show significant residues in spinach, turnip and wheat (<0.01 mg/kg). Therefore, residues of acetamiprid are not expected in rotational crops.

Based on the above, the probability of plant uptake of residues of acetamiprid from soil previously treated with acetamiprid is considered unlikely. This conclusion is also valid for organic crops, when planted in fields that were previously used acetamiprid for conventional agriculture, considering that it requires at least 2 years after the last chemical treatment in order for organic crops to be planted in such areas.²

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Evidence of acetamiprid in soil was provided by Silva et al. (2023) in a study carried out in the framework of the EU SPRINT project. The study assessed the presence of 209 pesticide residues in 100 soil samples from conventional agriculture and 63 soil samples from organic agriculture collected during the 2021 growing season across 10 study sites in Europe: Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark. Acetamiprid was quantified in nine conventional soil samples (9%) at concentrations from 0.0031 to 0.1225 mg/kg. The highest concentration was found in Spain.

Considering the available evidence, plant uptake of acetamiprid from soil under organic farming systems is not expected.

3.12.3.6 Residues from water used for irrigation

- Is there evidence that residues of acetamiprid present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for acetamiprid in water samples were considered:

- The EEA-WATERQUALITY³⁹³⁹ database (data retrieved on 10 April 2024) reports 140 analytical results from water samples collected in France (1), Ireland (5), Italy (58), Latvia (3), the Netherlands (50) and Spain (23) between 2019 and 2021;
- The EMPODAT database (data retrieved on 19 March 2024) reports 1531 analytical results from surface water samples collected in Austria (4), Bulgaria (14), Croatia (2), Czechia (4), Germany (1), Hungary (10), the Netherlands (1480), Romania (7) and Slovakia (9) between 2017 and 2019; 24 analytical results from groundwater samples collected in 2019 in Austria (4), Bulgaria (4), Croatia (4), Hungary (4), Romania (4) and Slovakia (4);
- The NAIADES database (data retrieved on 19 March 2024) reports 47,771 analytical results from surface water samples collected in France from 2020 to 2022;

Among the 49,466 analytical results for acetamiprid, 5,248 were disregarded as found to report quantitative values below the analytical LOQ. Therefore, the number of water samples considered is 44,218.

Based on the screening process described in section 'Data and methodologies', for 99.7% of water samples analysed and reported in EEA-WATERQUALITY, EMPODAT and NAIADES (44,096 samples), the residue concentrations were below the screening Cw of 0.09 µg/L.

For 0.3% of samples (122 out of 44,218 samples), the residue concentrations were found to be at or above the screening Cw of 0.09 µg/L and the potential transfer of residues to plant commodities if water containing residues at these levels is used for irrigation cannot be excluded.

Further evidence of acetamiprid in water was provided by Silva et al. (2023) in a study carried out under the framework of the EU SPRINT project. The study assessed the presence of 209 pesticide residues in 58 surface water samples collected in 2021 across 10 study sites in Europe (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). Acetamiprid was detected in four samples (7% detection frequency) from Czechia, Italy, the Netherlands and Spain at concentrations up to 0.09 µg/L in the Netherlands, with no samples found to contain residues above 0.1 µg/L.

Overall, considering that for 99.8% of water samples analysed and reported in EEA-WATERQUALITY, EMPODAT and NAIADES (44,218 samples), 100% of groundwater samples analysed for acetamiprid in EMPODAT and 100% of results of surface water samples analysed by Silva et al. (2023), the residue concentrations were below the screening Cw of 0.09 µg/L, it can be concluded that the transfer of acetamiprid residues from water sources to plant commodities when this water is used to irrigate plants is unlikely.

3.12.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *acetamiprid*, *industry/industrial*, and *air/atmosphere*) did not identify any relevant European study.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water. Based on conservative estimations of the possible transfer of residues from water used for irrigation to plant commodities, the transfer of residues of acetamiprid from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 7, 2025, using the keywords *acetamiprid*, *industry/industrial*, and *water*) did not identify any relevant European study.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Based on information on the possible plant uptake of acetamiprid from EU soil, the transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 17, 2025, using the keywords *acetamiprid*, *industry/industrial*, and *soil/sediment*) did not identify any relevant European study.

3.12.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Medium and long-range aerial transport of residues

Silva et al. (2023) investigated the presence of acetamiprid in 20 outdoor air samples collected during the 2021 growing season across 10 study sites in Europe of organic and conventional agriculture (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). The study was carried out under the framework of the EU SPRINT project. Organic fields had not been treated for 5 consecutive years. Acetamiprid was detected in two samples of conventional agriculture from Spain and Czechia at concentrations of 73.1 and 12.5 ng m⁻³, respectively.

In a study investigating the potential transport of pesticide residues from apple-growing fields in South Tyrol (Vinschgau Valley) to higher altitudes, an analysis of the soil showed an average concentration of 0.00037 mg/kg for acetamiprid in two out of 53 samples. In vegetation outside the treated areas, acetamiprid was found in six out of 53 samples at concentrations ranging up to 0.0361 mg/kg (Brühl et al. 2024).

In another study published under the EU SPRINT project, acetamiprid was quantified in air samples collected between April 2021 and June 2022 from two agricultural areas of conventional farming in Portugal (vineyard) and the Netherlands (potatoes, onions and sugar beet) (Debler et al., 2024). Detection frequencies were 5% in Portugal and 3% in the Netherlands with concentrations ranging from 11 to 105 pg/m³ and from 12 to 16 pg/m³, respectively. Gas-phase concentrations were significant in Portugal (105 pg/m³). This increases the likelihood of transfer to plants. It was noted that the two agricultural areas had not undergone acetamiprid treatment before the collection of samples from the surrounding area and measurement.

In a study by Mayer et al. (2024) residues of acetamiprid were quantified in air samples from 29 sampling sites classified as rural, coastal, mountain and polar. The samples were collected from 15 EU countries i.e. Austria, Czechia, Estonia, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Poland, Slovakia, Spain and Sweden, Switzerland and the United Kingdom during the main pesticide application period in spring 2020. To investigate aerial transport in polar sites, air samples from the European Arctic were also collected. Results showed the presence of acetamiprid at levels from 0.2 to 5 pg m⁻³ in the rural sites, from 0.3 to 20 pg m⁻³ in the coastal sites and at 30 pg m⁻³ in one sample from the mountain sites in Slovakia, being the highest concentration reported among all sites (the exact concentration ranges are not reported in the paper). For the rural area, the maximum concentration was quantified in Czechia, whilst for the coastal area, the highest concentration was reported in Spain. Acetamiprid was not quantified in the Arctic sites. The total frequency of findings for all areas was below 50% (the exact % detection frequency is not reported in the paper).

Based on the above, medium-range transport of residues of acetamiprid as aerosols in air to untreated crops cannot be excluded.

Uptake from organic fertilisers

In a study investigating pesticide residues in organic fertilisers, residues of acetamiprid and other pesticides were quantified (van der Blom et al., 2022, under 'Documentation as provided to

EFSA'). The authors attributed the origin of the residues to the presence of plant protection products in the composted crop or in composted manure due to transfer from animal feed after digestion, or in straw used in stables. Analysis of solid organic fertilisers gave an average concentration of 0.4 mg/kg for acetamiprid in three out of 147 samples. Considering that (according to the authors) the use of completely free from residues organic fertilisers is currently unsustainable, transfer of acetamiprid residues from fertilisers used in organic production to organic products cannot be excluded. On the other hand, no residues of acetamiprid were found in any of the products of the crops discussed in the study (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). As assessed above (see Section 3.12.3.5), available information from rotational crop studies indicates that the uptake of acetamiprid from soil by plants is very limited. It may be expected that the same would hold true for the uptake of the acetamiprid residues from soil compost.

Other sources of residues (not mentioned above)

In a study by Calliera et al. (2025), acetamiprid occurrence was monitored in wash water samples for the internal and external washing of sprayers used for pesticide applications in three vineyard areas located in Colli Tortonesi in the Piedmont Region (NW Italy). Acetamiprid was quantified in all washing water samples at concentrations up to 1611 mg/L (internal washing) and up to 369 mg/L (external washing).

3.12.4 Conclusions on acetamiprid

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use. Some of the residues quantified in the residue trials are higher than the implemented MRLs for the respective commodities. This is because these trials were evaluated in the recent reasoned opinions that have not been considered yet by the risk managers (see Section 3.12.3.2).
- Residue trials carried out to support the critical GAPs⁴ for acetamiprid, gave residue concentrations of up to 1.9 mg/kg (highest value for leaf vegetables, herbs and edible flowers). Concentrations in the ranges reported in Table 3.12.3.2-1 might be associated with active use of acetamiprid according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.
- Acetamiprid was quantified in the context of residue trials in untreated (control) samples with the highest concentrations observed for grape vines from northern France (up to 0.05 mg/kg).
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for acetamiprid in unprocessed commodities with authorised uses ranged from 0.007 mg/kg in roots and tuber vegetables to 0.062 mg/kg in leaf vegetables, herbs and edible flowers.
- In organic commodities that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings, the median concentrations for acetamiprid in unprocessed commodities ranged between 0.015 mg/kg in pome fruits to 0.134 mg/kg in berries and small fruits. Note was taken that the median values for quantified samples in organic berries and small fruits were considerably higher

than the residue concentrations in the same not labelled as organic commodity group (0.134 vs 0.033 mg/kg for the conventional commodity). Unauthorised use of acetamiprid for this group of crops cannot be ruled out as a possible explanation of these results.

- Without additional information on the individual samples' history and context, it is not possible to conclude if quantified results in organic commodities are associated with active use or unintentional presence of acetamiprid.
- In organic processed commodities, residues of acetamiprid were not quantified in any of the products labelled as organic and sampled under the EU monitoring programmes from 2020 to 2022. In samples from processed products not labelled as organic with five or more quantified findings, residues of acetamiprid ranged from 0.007 mg/kg in processed oilseeds and oil fruits up to 0.034 mg/kg in leaf vegetables, herbs and edible flowers. Considering that acetamiprid is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.
- Overall, in commodities labelled as organic, acetamiprid was quantified in 0.28% of samples (28 out of 10,014 samples). This percentage is around 25 times lower than the percentage reflecting the number of findings in samples not labelled as organic (6.92%) (see Appendix B, Tables B-12.1 and B-12.2). These results suggest that the occurrence of residues of acetamiprid in organic products is significantly less likely when compared with the conventional commodities.
- Potential sources of the unintentional presence of acetamiprid in organic products might relate to drift from conventional crops grown in the vicinity and the medium-range aerial transport of residues by aerosols.
- Acetamiprid is not persistent in soil. Plant uptake of residues of acetamiprid from contaminated soil or from organic fertilisers that contain acetamiprid residues is considered a less likely explanation for residues found in crops where acetamiprid has not been actively used.
- Transfer of acetamiprid residues from EU water sources used for irrigation to plant commodities is unlikely.
- Acetamiprid is used in biocidal products and biocidal products containing acetamiprid may result in the release of residues of acetamiprid into the environment.
- Conservative estimates of the possible transfer of residues of acetamiprid from water used for irrigation to plant commodities and information on the possible plant uptake of residues of acetamiprid from EU soil suggest that the transfer of residues from biocidal use and other non-pesticide uses as well as the transfer from industrial emissions to the environment and from the environment to plants and plant commodities is less likely.

The pathways of residues of acetamiprid to plants and plant commodities are summarised in Figure 12.

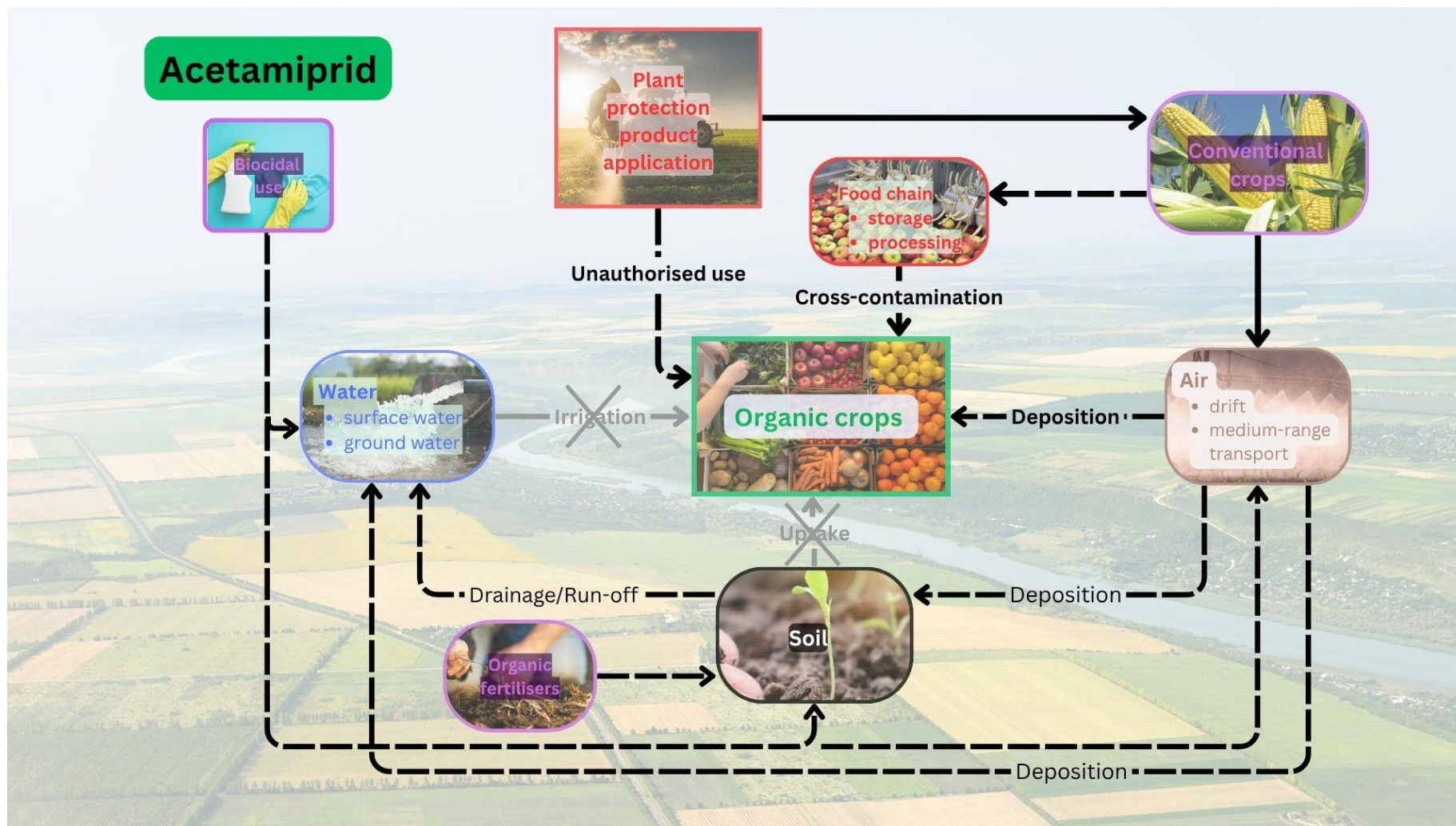


Figure 12: Pathways of residues of acetamiprid to plants and plant commodities

Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded



3.13 Chlormequat

3.13.1 Method(s)

- What is/are the residues to be monitored for the active substance chlormequat according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

For the active substance 'chlormequat', the residue definition for enforcement in food and feed of plant origin has been proposed as 'chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride)' in the EFSA peer review (EFSA, 2008b). This residue definition is applicable to primary, rotational crops and processed cereals (EFSA, 2016f, 2020d). This residue definition for enforcement is implemented in Regulation (EC) No 396/2005³. The same residue definition is also applicable to honey and other apiculture products.

Based on the above only residues of chlormequat as the sum of chlormequat and its salts, expressed as chlormequat-chloride are to be monitored in foods of plant origin, honey and other apiculture products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

Available methods of analysis based on HPLC-MS/MS, enable the quantification of residues of chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride) at LOQs ranging from 0.01 to 0.05 mg/kg in high water content, high oil content, and dry matrices. Nevertheless, an ILV for high water content matrices is lacking (EFSA, 2008b, 2020d). The method with the lower sensitivity (LOQ: 0.05 mg/kg) is also applicable to high acid content commodities (EFSA, 2008b). These methods were validated specifically for chlormequat, addressing MRL data requirements, with attributes that could be incorporated into a multi-residue method. However, no validated multi-residue method was provided (United Kingdom³⁵, 2024, under 'Documentation as provided to EFSA').

According to literature, there are multi-residue HPLC-MS/MS methods available for monitoring chlormequat residues in high water and high acid content at an LOQ of 0.02 mg/kg, and in dry commodities of plant origin at an LOQ of 0.08 mg/kg (Francesquett et al., 2019; Anagnostopoulos et al., 2013).

A single residue method based on the HPLC-MS/MS method is available in the database of the EURL for Residues of Pesticides for the determination of chlormequat (cation) in high water content and dry matrices. The method has been validated with an LOQ of 0.01 mg/kg (EFSA, 2014j; CRL, 2009). For honey and apiculture products, the EURL for Residues of Pesticides developed a single residue LC-MS/MS QuPpe method with an LOQ of 0.02 mg/kg for the analysis of chlormequat (Anastassiades et al., 2021).

Overall, there are multi-residue methods available for the monitoring of chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride) in high water, high acid content and dry plant commodities. LOQs for methods of analysis of chlormequat residues in products of plant origin and honey range from 0.01 to 0.08 mg/kg. For the analysis of residues of chlormequat in high oil content commodities, single residue methods are available.



3.13.2 Authorisation status and use

- Is chlormequat currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has chlormequat ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

a) Authorisations for plant protection use in conventional agriculture

Chlormequat has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of approval of the active substance is 28 February 2027, as indicated by the EU Pesticides Database⁵ (accessed 10 January 2024).

According to the EU Pesticides database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, France, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, the Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, and Slovakia.

b) Authorisations for purposes other than plant protection

Biocidal use

According to information from the ECHA website⁶, chlormequat and chlormequat-chloride have not been approved for use in biocidal products in the EU Member States, Iceland, Lichtenstein and Norway (accessed 6 June 2024).

Other uses

A search carried out on the ECHA website⁹ on 6 June 2024 showed that neither chlormequat nor chlormequat-chloride is currently registered under REACH.

- What is/was the actual use of chlormequat? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of chlormequat

Chlormequat is categorised within the quaternary ammonium compounds, known for their application as plant growth regulators. Its mode of action involves inhibiting the biosynthesis of gibberellins. Once applied, it is absorbed and distributed within the plant. Chlormequat acts as a growth retardant, commonly used in cereals to control excessive longitudinal shoot growth whilst maintaining overall plant productivity (EFSA, 2016f).

Conditions of use and applicable crops

The uses reported in the EFSA MRL review included outdoor foliar applications in both northern and southern Europe (EFSA, 2016f). Uses in food and feed commodities were reported for cereals and grass. After the MRL review, one application was submitted to EFSA to modify the existing MRLs in barley (EFSA, 2020d). Application rates of chlormequat range from 0.54 kg a.s./ha to 1.84 kg a.s./ha (EFSA, 2016f, 2020d, 2024e).



Note was taken that uses in grass were not supported by data (see Section 3.13.3.2 'Active use (all legitimate uses of the substance)').

Chlormequat had been used in pear orchards before 2003 and although residues declined over time, carry-over is still observed in pears (EFSA, 2009d, 2014j). This is mainly due to the slow degradation of chlormequat which results in its accumulation in the stem.

b) Uses for purposes other than plant protection

Biocidal use

Chlormequat and chlormequat-chloride are not approved for biocidal use, therefore, their use in biocidal products is not expected (see also 'authorisations for purposes other than plant protection/biocidal use').

Other uses

According to the ECHA website⁹, neither chlormequat nor chlormequat-chloride is registered under REACH (see 'authorisations for purposes other than plant protection/other uses').

3.13.3 Sources of residues in plants

3.13.3.1 Natural occurrence

- Is there evidence that chlormequat occurs naturally? What is known about the natural origin of this substance?

Chlormequat is a synthetic plant growth regulator produced industrially through chemical processes (Lewis et al., 2016). No information on the potential natural presence of chlormequat was found in the literature²².

3.13.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of chlormequat per food/feed product would be consistent with active use of chlormequat?

Results from analysis of residues of chlormequat in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.13.3.2-1 to 3.13.3.2-4. Findings relating to residues in control (untreated) samples are also discussed in this section.

In all matrices and for both residue trials and results from monitoring, chlormequat residue concentrations refer to the residue definition for enforcement (i.e. the sum of chlormequat and its salts, expressed as chlormequat-chloride).

Occurrence of chlormequat from residue trials carried out for the critical GAP per crop

Following product applications based on the critical GAPs⁴ reported to EFSA, quantified residues of chlormequat were found in cereals (EFSA, 2016f, 2020d, 2024e). Regarding feed commodities, residues above the LOQ occurred in cereal straw (EFSA, 2016f, 2020d, 2024e).

The results from residue trials carried out for the critical GAP per crop for chlormequat in commodities for which uses were submitted to EFSA are summarised in Table 3.13.3.2-1 'Occurrence of chlormequat from residue trials carried out for the critical GAP per crop'.

Table 3.13.3.2-1: Occurrence of chlormequat from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Chlormequat (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
Food				
0500000	Cereals	0.01*-15	<LOQ (0.05)-7.4	0.73
Feed				
1200000	Cereal straw	NA	<LOQ (0.05)-55	4.1
	Grass	NA	NR	-

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; NR – no residue trials are available; '-': not estimated due to lack of data.

a) Maximum Residue Level in Reg. (EU) No 2022/1290 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA, 2016f, 2020d, 2024e.

Occurrence of chlormequat under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to chlormequat are given in Regulation (EU) 2019/1561⁶⁶ for data in year 2020, Regulation (EU) 2020/1565⁶⁷ for data in year 2021 and Regulations (EU) 2020/1565⁶⁷ and (EU) 2022/1290⁶⁸ for data in year 2022.

Regarding commodities non-labelled as organic, 24,647 samples were collected and analysed for chlormequat in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 23,135 (93.87%) were unprocessed and 1512 (6.13%) processed commodities. No residues were quantified in 23,573 samples out of the 24,647 samples (95.64%). In 1046 samples out of the 24,647 samples (4.24%) chlormequat was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-13.1. MRLs were exceeded in 28 samples out of the 24,647 samples (0.11%). The highest concentration for samples exceeding the MRLs was 84 mg/kg in oilseeds and oil fruits (sunflower seeds).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of chlormequat are summarised in Table 3.13.3.2-2a for unprocessed, and in Table 3.13.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic.

⁶⁶ Commission Regulation (EU) 2019/1561 of 17 September 2019 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlormequat in cultivated fungi. OJ L 240, 18.9.2019, p. 1–12.

⁶⁷ Commission Regulation (EU) 2020/1565 of 27 October 2020 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1,4-diaminobutane, 1-methylcyclopropene, ammonium acetate, bifenazate, chlorantraniliprole, chlormequat, cyprodinil, limestone, mandipropamid, pepper, pyridaben, repellants: blood meal, seaweed extracts and trimethylamine hydrochloride in or on certain products. OJ L 358, 28.10.2020, p. 3–29

⁶⁸ Commission Regulation (EU) 2022/1290 of 22 July 2022 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, chlormequat, dodine, nicotine, profenofos and Spodoptera exigua multicapsid nucleopolyhedrovirus (SeMNPV) isolate BV-0004 in or on certain products. OJ L 358, 28.10.2020, p. 3–29.



Table 3.13.3.2-2a: Occurrence of chlormequat from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Chlormequat (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0500000	Cereals	0.01*-15	0.005	0.005-7.2	658	0.082
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
	Grass	NA	ND	ND	ND	ND
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of chlormequat is not expected)						
Food						
0110000	Citrus fruits	0.01*	0.005	<LOQ	0	<LOQ
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*-0.07	0.005	0.005-7.4	68	0.018
0140000	Stone fruits	0.01*	0.005	0.006	1	0.006
0150000	Berries and small fruits	0.01*-0.05	0.005	0.021	1	0.021
0160000	Miscellaneous fruits	0.01*	0.005	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*	0.005	0.011-0.051	2	0.031
0220000	Bulb vegetables	0.01*	0.005	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*	0.002	0.012-3.1248	4	0.575
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	0.005	0.012	1	0.012
0250000	Leaf vegetables, herbs and edible flowers	0.01*	0.005	<LOQ	0	<LOQ
0260000	Legume vegetables	0.01*	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*	0.005	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*-0.9	0.002	0.012-2.5	155	0.016
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0300000	Pulses (dried)	0.01*	0.005	0.079	1	0.079
0400000	Oilseeds and oil fruits	0.01*-7	0.005	0.003-84	6	2.165
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	0.025	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*	ND	ND	ND	ND
0900000	Sugar plants	0.01*	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; ND – no data available.

a) Maximum Residue Level for unprocessed commodities in Reg. (EU) No 2022/1290 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.13.3.2-2b: Occurrence of chlormequat from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Chlormequat (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0500000	Cereals	0.01*-15	0.001	0.01-2.089	163	0.064



Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Chlormequat (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
	Grass	NA	ND	ND	ND	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of chlormequat is not expected)						
Food						
0110000	Citrus fruits	0.01*	0.005	<LOQ	0	<LOQ
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*–0.07	0.005	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*	ND	ND	ND	ND
0150000	Berries and small fruits	0.01*–0.05	0.005	0.011–0.025	2	0.018
0160000	Miscellaneous fruits	0.01*	0.01	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*	0.005	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*	0.01	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*	0.005	0.04–2.2	11	0.12
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	ND	ND	ND	ND
0250000	Leaf vegetables, herbs and edible flowers	0.01*	0.01	<LOQ	0	<LOQ
0260000	Legume vegetables	0.01*	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*–0.9	0.01	0.057	1	0.057
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0300000	Pulses (dried)	0.01*	0.01	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–7	0.005	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*	ND	ND	ND	ND
0700000	Hops (dried)	0.05*	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*	ND	ND	ND	ND
0900000	Sugar plants	0.01*	ND	ND	ND	ND
1040000	Processed apiculture products	0.05*	ND	ND	ND	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2022/1290 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of chlormequat in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 2,852 samples were collected and analysed for chlormequat from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 2,424 (85%) were unprocessed and 428 (15%) processed commodities. No residues were quantified in 2,834 samples out of the 2,852 samples (99.37%). In 16 samples out of the 2,852 samples (0.56%) chlormequat was found at or above the analytical LOQ but below or at the MRL. MRLs were exceeded in two samples out of the 2,852 samples (0.07%). The highest concentration for samples exceeding the MRLs was 0.17 mg/kg in cereals (oat). These findings are summarised in Appendix B, Table B-13.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.13.3.2-3a for unprocessed and

in Table 3.13.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic.

Table 3.13.3.2-3a: Occurrence of chlormequat from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Chlormequat (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.01*	0.005	<LOQ	0	<LOQ
0120000	Tree nuts	0.01*	ND	ND	ND	ND
0130000	Pome fruits	0.01*–0.07	0.005	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*	0.005	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.01*–0.05	0.005	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*	0.005	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*	0.005	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*	0.005	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*	0.005	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	0.005	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*	0.005	<LOQ	0	<LOQ
0260000	Legume vegetables	0.01*	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*	0.005	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*–0.9	0.005	0.012–0.032	2	0.022
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0300000	Pulses (dried)	0.01*	0.01	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–7	0.01	<LOQ	0	<LOQ
0500000	Cereals	0.01*–15	0.005	0.01–0.17	11	0.035
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	ND	ND	ND	ND
0800000	Spices (dried)	0.05*	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*	ND	ND	ND	ND
1040000	Processed apiculture products	0.05*	0.01	<LOQ	0	<LOQ

*Limit of quantification in Reg. (EC) No 396/2005; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2022/1290 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.13.3.2-3b: Occurrence of chlormequat from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Chlormequat (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.01*	0.005	<LOQ	0	<LOQ
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*–0.07	0.005	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*	ND	ND	ND	ND
0150000	Berries and small fruits	0.01*–0.05	0.005	0.085	1	0.085
0160000	Miscellaneous fruits	0.01*	0.005	<LOQ	0	<LOQ

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Chlormequat (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0210000	Root and tuber vegetables	0.01*	0.008	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*	ND	ND	ND	ND
0230000	Fruiting vegetables	0.01*	0.01	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*	0.025	<LOQ	0	<LOQ
0260000	Legume vegetables	0.01*	ND	ND	ND	ND
0270000	Stem vegetables	0.01*	ND	ND	ND	ND
0280000	Fungi, mosses and lichens	0.01*–0.9	0.025	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0300000	Pulses (dried)	0.01*	0.01	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–7	0.01	<LOQ	0	<LOQ
0500000	Cereals	0.01*–15	0.01	0.015–0.051	4	0.038
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*	ND	ND	ND	ND
0700000	Hops (dried)	0.05*	ND	ND	ND	ND
0800000	Spices (dried)	0.05*	0.025	<LOQ		<LOQ
0900000	Sugar plants	0.01*	ND	ND	ND	ND
1040000	Processed apiculture products	0.05*	ND	ND	ND	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2022/1290 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of chlormequat in the EU Organic Farming Information System

The EU OFIS reported 13 findings for chlormequat in 2021 and 2022. Seven of the products sampled and analysed had EU origin and six were of non-EU origin. Residues were found in one sample of berries and small fruits (wine from white grapes), one sample of fruiting vegetables (sweet peppers/bell peppers), one sample of fungi, mosses and lichens (cultivated fungi), four samples of oilseeds and oil fruits (peanuts/groundnuts), four samples of cereals (oats) and two samples of products or part of products exclusively used for animal feed production (expeller soybean meal and wheat as feed). The concentrations of chlormequat residues above LOQ but below MRLs in seven of these samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005³. MRLs exceeded in four samples. For the samples of products or part of products exclusively used for animal feed production (expeller soybean meal and wheat as feed), no MRL is applicable according to Reg. (EU) 396/2005³. The highest concentration was reported for a sample of cereals (oats) of EU origin, with the quantified level of 0.2 mg/kg. These findings are summarised in Table 3.14.3.2–3.

Table 3.13.3.2-4: Occurrence of chlormequat from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
Chlormequat (sum)				
0151020	Wine grapes	0.05	ND	0.085 – White wine
Chlormequat				
0231020	Sweet peppers/bell peppers	0.01*	ND	0.062 – Pepper (powder)

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
0280010	Cultivated fungi	0.9	ND	0.034 – Pleurotus (cultivated fungi) (substrate)
0500050	Oat	15	0.2 – Oat	ND
Chlormequat chloride				
0500050	Oat	15	0.07; 0.025; 0.025 – Oats	ND
Samples of non-EU origin				
Chlormequat				
0401020	Peanuts/groundnuts	0.01*	0.017; 0.01; 0.009; 0.014 – Peanuts/groundnuts kernels	ND
1200000	Products or part of products exclusively used for animal feed production	NA	ND	0.012 – Expeller soybean meal (after extraction of soy oil) <0.005 – wheat as feed

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2022/1290 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of residues of chlormequat in untreated samples (control samples) from residue trials

Chlormequat residues (expressed as chlormequat-chloride) were found in control (untreated) cereal samples from residue trials across several European regions. Residues were quantified in rye (whole plant) samples and spring barley samples (whole plant, grain, straw, beer) from northern France, and in spring wheat and spring barley (whole plant) samples from Italy (EFSA, 2020d; United Kingdom³⁵, 2019). Furthermore, residues of chlormequat were present in winter wheat (grain) and triticale straw from Germany and in winter wheat straw from Poland and the UK (EFSA, 2020d).

It was reported that the quantified findings in rye from northern France were likely attributed to two applications of chlormequat by the farmer in 2015. The trial, conducted from October 2015 (sowing) to August 2016 (harvest), occurred approximately a year after the application. No other evidence-based explanations for these findings in control (untreated) samples were provided in the above Member State ERs and RARs.

The summary of the quantified findings of chlormequat-chloride in control (untreated) samples from residue trials carried out for the critical GAP⁴ per crop is given below in Table 3.13.3.2-5.

Table 3.13.3.2-5: Summary of the quantified findings of chlormequat-chloride in control (untreated) samples from residue trials carried out for the critical GAP per crop.

Commodity	Country/Area	Chlormequat-chloride (mg/kg)
Rye (whole plant)	Northern France	0.34–0.49 ^{a)}
Spring barley	Italy	0.0276–0.0339 (whole plant); 0.0276–0.0339 (whole plant)
	Northern France	0.129–0.645 (whole plant)
		0.111–0.130 (grain) 0.432–0.735 (straw)
Spring wheat (whole plant)	Italy	0.0244
Triticale (straw)	Germany	0.032, 0.026
Winter wheat	Germany	Up to 0.552 (grain)
	Poland	0.023 (straw)
	United Kingdom ³⁵	0.164–0.176 (straw) 0.0191–0.0200 (straw)

a) Quantified findings were likely due to two applications of chlormequat by the farmer in 2015, approximately 1 year before the residue trial.



- Could the presence of chlormequat and/or its residues be due to biocide use?

Chlormequat is not approved for use as a biocide, therefore, residues due to biocidal use are not expected for chlormequat.

3.13.3.3 Behaviour in food and feed products

- What key physico-chemical properties of chlormequat are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of chlormequat-chloride are reported in Table 3.13.3.3.

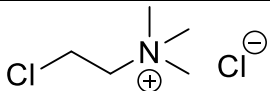
Chlormequat-chloride is a water-soluble compound and shows moderate persistence in soil (see also Section 3.13.3.5). Regarding sorption to soil, the range of K_{Foc} in Table 3.13.3.3 indicates that the substance has high to low mobility in soil (EFSA, 2008b).

Spring applications of chlormequat-chloride to winter and spring cereals (application rate of 1×1500 g a.s./ha) result in PECw values up to 85 µg/L (EFSA, 2014k; EC, 2014c).

Chlormequat-chloride is hydrolytically stable under standard processing conditions for pasteurisation, baking, brewing and boiling (EFSA, 2020d). Considering that chlormequat is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Chlormequat-chloride has a short half-life in the air and negligible vapour pressure (EFSA, 2008b).

Table 3.13.3.3: Physico-chemical properties of chlormequat-chloride (EFSA, 2008b)

Structural formula	
Appearance (state purity)	White crystalline solid (96.6%) Colourless crystalline solid (99.5%)
Melting point (state purity)	236°C (99.5%), 225°C (96.6%)
Boiling point	Not determined as material decomposes immediately after melting
Temperature of decomposition	> 240°C (99.5%)
Vapour pressure (state temperature, state purity)	Negligible
Henry's law constant (state temperature)	3.2×10^{-13} Pa m ³ mol ⁻¹ (20°C) (a)
Solubility in water (state temperature, state purity and pH)	>886 g/L at 25°C (97.2%) no pH specified
Partition coefficient (state temperature, pH and purity)	log Pow = -3.47 at 20°C (pH 7) (99.5%)
Partition coefficient (octanol/air)	NA
Atmospheric half-life	DT ₅₀ of 1.45 hours derived by the Atkinson model (software APOWIN v.1.90) assuming 12 hours of light per day and an atmospheric hydroxyl radical concentration of 1.5×10^6 radicals cm ⁻³
Dissociation constant (state purity)	NA
Soil adsorption (range)	K_{Foc} = 55–912 mL/g



Hydrolytic degradation (>10%)	hydrolytically stable under the test conditions of pH 4, 7 and 9; 5 days experiment at 50°C. <3% degradation after 5 days.

DT₅₀ – Disappearance time of 50% of the substance in field studies; NA – not applicable; pH – Potential of Hydrogen; P_{ow} – Octanol/water Partition Coefficient.

(a): 2001/1009201 Ohnsorge U, 2001. Volatility from water for Chlormequat-chloride, Date 16/5/2001.

3.13.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from the soil surface at which it is applied). The highest drift of chlormequat to neighbouring fields may occur during its applications to field crops (up to 2.77 %). Drift values should be considered the rate received by neighbouring fields, expressed as a percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. buffer zones or spray drift-reducing nozzles).

If organic crops are present adjacent to the conventional crops treated, measurable residues of chlormequat in the untreated crop cannot be excluded. However, since the nature of the potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

As authorised products are to be applied in liquid form, dust drift is not expected to occur.

3.13.3.5 Accumulated/historical residue levels in soil

- What is the persistence of chlormequat and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

According to available data (EFSA, 2008b, 2014k; EC, 2014c), the DT₉₀ of chlormequat-chloride in soil (carried out in seven laboratory dark aerobic experiments) is <1 year with a worst-case laboratory value of 133.6 days. This indicates that the substance is not expected to accumulate in soil when used over successive seasons.

In wheat treated with chlormequat, chlormequat chloride was the major component at the time of harvest in both grain and straw (EFSA, 2008b). The stability of the substance in plants is also seen from findings in orchard trees where residues were quantified in pears, years after uses had ceased (EFSA, 2014j). This seems to suggest that part of the observed dissipation of chlormequat in soil occurs through the formation of unextractable residues. These bound residues likely associated with plant tissue residues (maybe lignin and cellulose associated) have the potential to be slowly released in subsequent seasons.



Regarding uptake of residues from soil, confined rotational crop metabolism studies with chlormequat did not show significant residues in lettuce, radish, beans and carrots (TRR <0.05 mg eq/kg). Higher residues were found in wheat but these are not expected to be higher than those occurring after direct treatment (EFSA, 2008b).

Since the DT₉₀ of chlormequat in soil is less than 1 year, residues of chlormequat in plants planted or sown in soil treated with chlormequat in the previous season would, in principle, not be expected. However, the indications of a higher persistence in soil provided by the residues observed in cereals in rotational crop studies suggest that some uptake in cereals planted in short time intervals (PBI: 30 days) cannot be excluded. For longer PBIs, residues in rotational crops are not expected.

Therefore, for organic crops that are planted in fields at least 2 years after the last chemical treatment with chlormequat², residues of chlormequat are not expected.

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Accumulation of chlormequat in soil is not expected.

3.13.3.6 Residues from water used for irrigation

- Is there evidence that residues of chlormequat present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹²¹² the following databases providing occurrence data for chlormequat (expressed as chlormequat chloride)⁶⁹ in water samples were considered:

- The EEA-WATERQUALITY³⁹ database (data retrieved on 19 March 2024) reports 3 analytical results from surface water samples collected in Estonia between 2019 and 2020;
- The NAIADES database (data retrieved on 19 March 2024) reports 216 analytical results from surface water samples collected in France from 2020 to 2022.

Based on the screening process described in section 'Data and methodologies', for 100% of surface water samples analysed and reported in the EEA-WATERQUALITY and NAIADES (219 samples), the residue concentrations were below the screening Cw of 1.84 µg/L. Therefore, it can be concluded that transfer of chlormequat-chloride residues from EU surface water sources to plant commodities is unlikely.

More results for chlormequat on the EC's IPCHEM¹² were considered. However, since the parent refers to the cation, it is not clear whether these results are expressed as chlormequat-chloride (as above) or as another salt.

- The EMPODAT database (data retrieved on 19 March 2024) reports 130 analytical results from surface water samples collected in the Netherlands from 2017 to 2019.

⁶⁹ According to the European Commission's Review report for the active substance chlormequat, 'unless otherwise stated, the data refer to the variant chlormequat chloride' (EC, 2009). The fact that different analytical results are submitted for chlormequat and chlormequat chloride may relate to the conversion of the salt to the chlormequat cation.



- The NAIADES database (data retrieved on 15 April 2024) reports 783 analytical results from surface water samples collected in France from 2020 to 2022.

Although it is not possible to estimate a screening C_w for the parent cation considering that in the residue definition residues are expressed as chlormequat-chloride, the very low quantified values being all (except for one) at or below 0.1 µg/L suggest that transfer of residues of chlormequat in plant commodities if these water sources are used to irrigate plants is unlikely.

Note was taken that the number of water samples analysed for chlormequat is two to three orders of magnitude lower than the total samples analysed for most substances considered in this report.

Based on the above, it can be concluded that the transfer of chlormequat residues from water sources to plant commodities when this water is used to irrigate plants is unlikely.

3.13.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *chlormequat*, *industry/industrial*, and *air/atmosphere*) did not identify any relevant European study.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water. Based on conservative estimations of the possible transfer of residues from water used for irrigation to plant commodities, the transfer of residues of chlormequat from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 7, 2025, using the keywords *chlormequat*, *industry/industrial*, and *water*) did not identify any relevant European study.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via the soil. Based on information on the possible plant uptake of chlormequat from EU soil, the transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 17, 2025, using the keywords *chlormequat*, *industry/industrial*, and *soil/sediment*) did not identify any relevant European study.



3.13.4 Conclusions on chlormequat

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use.
- Residue trials carried out to support the critical GAP⁴ for chlormequat in cereals gave residue concentrations of up to 7.4 mg/kg (55 mg/kg in cereal straw). Concentrations in the ranges reported in Table 3.13.3.2-1 might be associated with active use of chlormequat according to the critical GAP. For less critical GAPs, lower concentrations may also indicate active use.
- Chlormequat was quantified in the context of residue trials in several European countries in untreated (control) samples with the highest concentration observed in one sample of spring barley straw from Northern France (0.735 mg/kg).
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentration for chlormequat in unprocessed cereals was 0.082 mg/kg.
- In organic unprocessed commodities that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings, residues were quantified only in cereals where a median of 0.035 mg/kg was estimated from 11 samples. Without additional information on the individual samples' history and context, it is not possible to conclude if quantified results in organic commodities are associated with active use or unintentional presence of chlormequat.
- In organic processed commodities, residues of chlormequat were not quantified or were quantified in fewer than five samples per commodity. In samples from processed products not labelled as organic with five or more quantified findings, the median concentration of residues of chlormequat ranged from 0.064 mg/kg in cereals to 0.12 mg/kg in fruiting vegetables. Considering that chlormequat is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.
- Overall, in commodities labelled as organic, chlormequat was quantified in 0.63% of samples (18 out of 2,852 samples). This percentage is almost 7 times lower than the percentage reflecting the number of findings in samples not labelled as organic (4.36%) (see Appendix B, Tables B-13.1 and B-13.2). These results suggest that organic products are significantly less likely to contain quantified concentrations of chlormequat when compared with the conventional commodities.
- Cereal straw previously treated with chlormequat can contaminate cultivated fungi for which no uses are reported. A temporary MRL of 0.9 mg/kg has been implemented in Reg. (EC) No 396/2005³ for this purpose.

- A temporary MRL of 0.07 mg/kg has been implemented in Reg. (EC) No 396/2005³ to cover potential carry-over of chlormequat residues from previously authorised uses in pears.
- A potential source of the unintentional presence of residues of chlormequat in commodities of plant origin is the potential transfer of residues due to drift from conventional crops grown in the vicinity.
- Chlormequat is not persistent in soil. Plant uptake of residues of chlormequat from soil containing chlormequat is considered a less likely explanation for residues found in crops where chlormequat has not been actively used.
- Transfer of residues of chlormequat from EU water sources used for irrigation to plant commodities is unlikely.
- Conservative estimates of the possible transfer of residues of chlormequat from water used for irrigation to plant commodities and information on the possible plant uptake of residues of chlormequat from EU soil suggest that the transfer of residues from industrial emissions to the environment and from the environment to plants and plant commodities is less likely.

The pathways of residues of chlormequat to plants and plant commodities are summarised in Figure 13.

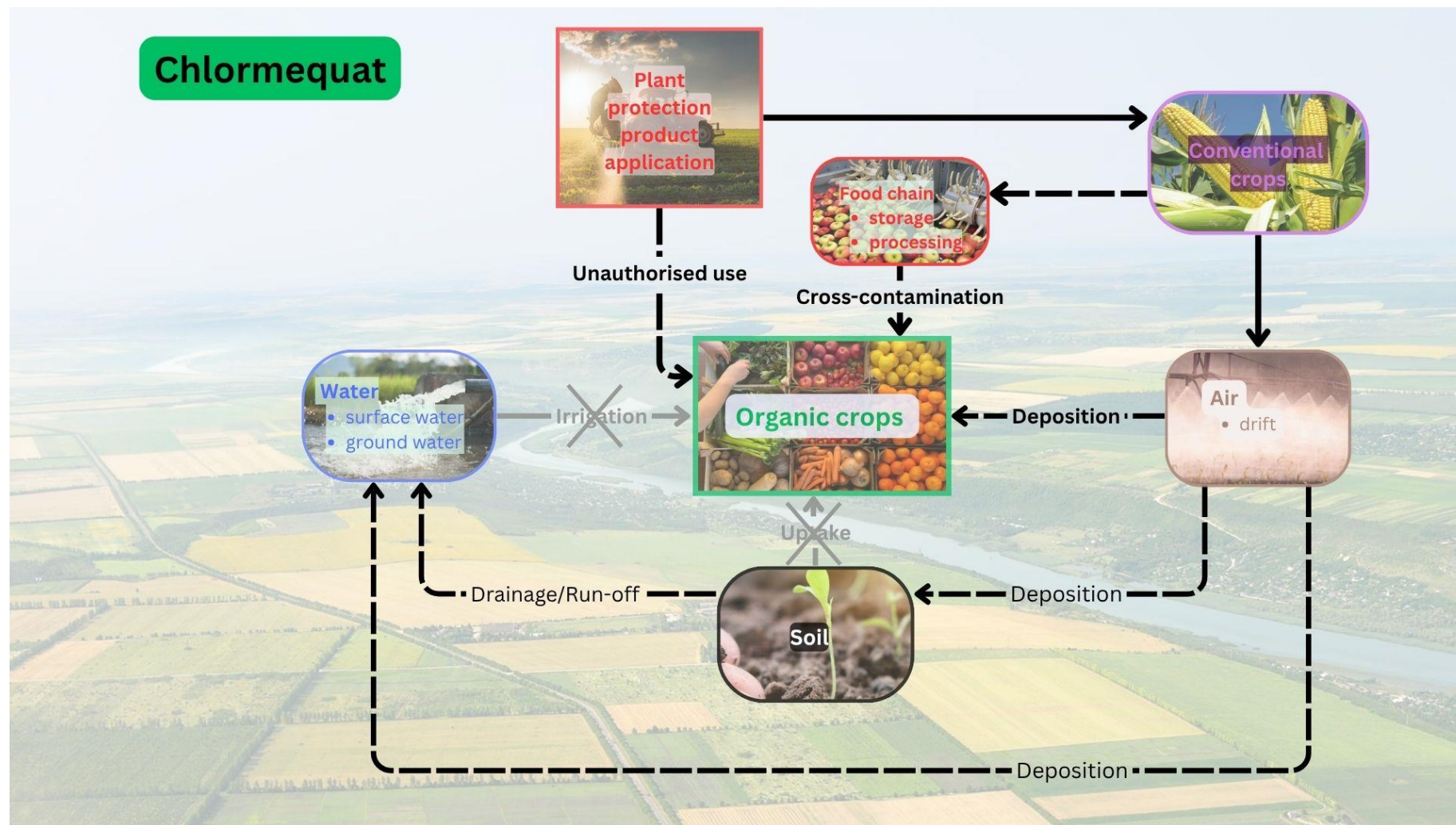


Figure 13: Pathways of residues of chlormequat to plants and plant commodities

Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded

3.14 Pendimethalin

3.14.1 Method(s)

- What is/are the residues to be monitored for the active substance pendimethalin according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

For the active substance 'pendimethalin (F)⁷⁰', the residue definition for enforcement in food and feed of plant origin has been proposed as 'pendimethalin' in the EFSA peer review conclusion (EFSA, 2016g). This residue definition is applicable to primary, rotational crops and processed products. This residue definition for enforcement is implemented in Regulation (EC) No 396/2005³. In the absence of specific metabolism studies on honey and other apiculture products, the same residue definition is also proposed for honey (EFSA, 2023j).

Based on the above only residues of pendimethalin are to be monitored in foods of plant origin, honey and other apiculture products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

A multi-residue QuEChERS method in combination with HPLC-MS/MS and GC-MSD is available for the determination of pendimethalin residues in high water content commodities at an LOQ of 0.005 mg/kg (EFSA, 2012h). The method is also applicable for acidic commodities (LOQ of 0.005 mg/kg) and dry commodities (LOQ of 0.01 mg/kg) (EFSA, 2012h).

Another multi-residue QuEChERS method using LC-MS/MS enables quantification of pendimethalin residues in high water, high acid, high oil and dry plant matrices at or above the LOQ of 0.01 mg/kg (EFSA, 2023j).

A multi-residue method (i.e. DFG S19 and GC-MSD) is available for the analysis of pendimethalin in complex matrices (spices and seeds of spices) with LOQs between 0.01 and 0.02 mg/kg (EFSA, 2013h).

According to the EURL for Residues of Pesticides (2024, under 'Documentation as provided to EFSA'), a multi-residue citrate-buffered QuEChERS method based on GC-MS/MS is validated to monitor pendimethalin residues in honey samples at an LOQ of 0.002 mg/kg. Lower sensitivities are achieved by utilising a multi-residue method based on LC-Q-TOF (LOQ: 0.005 mg/kg).

Overall, there are multi-residue methods for the monitoring of residues of pendimethalin in high water, high acid, high oil content, and dry food of plant/feed origin as well as for complex matrices (spices and seeds of spices) and honey and other apiculture products, with LOQs ranging from 0.002 to 0.02 mg/kg, depending on the food/feed matrix.

3.14.2 Authorisation status and use

- Is pendimethalin currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not,

⁷⁰ (F) indicates that the residue definition is fat soluble.

**has pendimethalin ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?****a) Authorisations for plant protection use in conventional agriculture**

Pendimethalin has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹³¹. The expiry date of approval of the active substance is on 15 January 2027, as indicated by the EU Pesticides Database⁵ (accessed on 27 November 2024).

According to the EU Pesticides Database⁵ at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, France, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Poland, Portugal, Romania, Slovenia, and Slovakia.

b) Authorisations for purposes other than plant protection**Biocidal use**

According to information from the ECHA website⁶ (accessed on 6 June 2024), pendimethalin has not been approved for biocidal use in the EU Member States, Iceland, Liechtenstein and Norway.

Other uses

According to a search carried out on the ECHA website⁹ (accessed on 6 June 2024), pendimethalin is not currently registered under REACH.

- What is/was the actual use of pendimethalin? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?**a) Use for plant protection purposes in conventional agriculture****Mode of action of pendimethalin**

Pendimethalin is a selective pre- and post-emergence herbicide for the control of a wide range of broad-leaved weeds in a wide variety of crops such as fruit and tree nuts, vegetables, pulses, oilseeds, cereals, herbal infusions, spices, and sugar plants. It interferes with the microtubule system and thereby inhibits cell division, cell elongation and finally plant growth. Pendimethalin is absorbed by leaves and roots but is not systemic within plants (EFSA, 2013h).

The phytotoxic effects of pendimethalin on commodities with authorised uses were investigated⁷¹. The available studies suggest that pendimethalin may have a negative impact on plant density and decrease crop yield if applied above recommended rates (Rajashekar and Murthy, 2010; Hammok et al., 2020; El-Nady and Belai, 2013; Hussain et al., 2010; Jursik et al., 2011; Ahmed and Chauhan, 2015; Awan et al., 2016). This information suggests that the use of pendimethalin is limited by its phytotoxic effects, and it is not expected that unauthorised uses above such levels could occur (neither in conventional nor organic agriculture).

⁷¹ A literature search was performed on Web of Science using terms 'pendimethalin AND phytotoxic*' for the timeframe 2010-2024.



Conditions of use and applicable crops

The uses reported in the EFSA MRL review for pendimethalin include food and feed commodities belonging to the following crop groups: citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds, cereals, herbal infusions from flowers, seed spices (dried), fruit spices (dried), maize for forage and alfalfa (EFSA, 2012h).

After the MRL review, applications were submitted to EFSA to modify the existing MRLs or support new uses for root and tuber vegetables, leaf vegetables, herbs and edible flowers (lettuce), legume vegetables, stem vegetables, herbal infusions from roots, seed spices, fruit spices (caraway), root and rhizome spices, and sugar plants (EFSA, 2013h, 2014l, 2015i, 2023j).

Note was taken that uses in herbal infusions from flowers and alfalfa were not supported by data (see Section 3.14.3.2-1 'Active use (all legitimate uses of the substance)').

Pendimethalin treatment included outdoor and indoor foliar and soil applications.

- Foliar applications were reported for berries and small fruits, root and tuber vegetables, bulb vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds, cereals, herbal infusions, seed spices (dried), fruits spices (dried) and alfalfa. Application rates range from 0.23 kg a.s./ha up to 2 kg a.s./ha (EFSA, 2012h, 2013h, 2014l, 2015i, 2018g, 2023j).
- Soil treatments were reported for citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, root and tuber vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds, cereals and sugar plants. The reported application rates range from 0.40 kg a.s./ha up to 2.4 kg a.s./ha (EFSA, 2012h, 2018g, 2023j).

b) Uses for purposes other than plant protection

Biocidal use

Pendimethalin is not approved for biocidal use, therefore, its use in biocidal products is not expected (see also 'authorisations for purposes other than plant protection/biocidal use').

Other use

A search carried out on the ECHA website⁹ for REACH registrations did not give any results for pendimethalin.

3.14.3 Sources of residues in plants

3.14.3.1 Natural occurrence

- Is there evidence that pendimethalin occurs naturally? What is known about the natural origin of this substance?



Pendimethalin is a synthetic chemical produced industrially through chemical processes (Lewis et al., 2016; Greim, 2024). No information on the potential natural presence of pendimethalin was found in the literature²².

3.14.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of pendimethalin per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of pendimethalin in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.14.3.2-1 to 3.14.3.2-4. Findings relating to residues in control (untreated) samples are also discussed in this section.

In all matrices and for both residue trials and results from monitoring, pendimethalin residue concentrations refer to the residue definition for enforcement (i.e. pendimethalin).

Occurrence of pendimethalin from residue trials carried out for the critical GAP per crop

Following product applications based on the critical GAPs⁴ reported to EFSA, residue levels of pendimethalin were below the LOQ in citrus fruits, tree nuts, pome fruits, stone fruits, fruiting vegetables, oilseeds and cereals (EFSA, 2012h, 2016g, 2018g).

Quantified residues of pendimethalin were found in berries and small fruits, root and tuber vegetables, bulb vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), herbal infusions from flowers and roots, seed spices, fruit spices (caraway), and sugar plants (EFSA, 2012h, 2013h, 2014l, 2015i, 2016g, 2018g, 2023j).

Regarding feed commodities, residues of pendimethalin were below the LOQ in maize forage (EFSA, 2012h); residues were quantified in cereal straw (EFSA, 2012h, 2016g).

Although EU GAPs were reported for all uses indicated under 3.14.2 'Conditions of use and applicable crops', data on residue trials for herbal infusions from flowers and alfalfa were not submitted and evaluated in the EFSA MRL review (EFSA, 2012h).

The results from residue trials carried out for the critical GAP per crop for pendimethalin in commodities for which uses were submitted to EFSA are summarised in Table 3.14.3.2-1 'Occurrence of pendimethalin from residue trials carried out for the critical GAP per crop'.

Table 3.14.3.2-1: Occurrence of pendimethalin from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pendimethalin (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
Food				
0110000	Citrus fruits	0.05*	<LOQ (0.01) –<LOQ (0.05)	<LOQ (0.01)
0120000	Tree nuts	0.05*	<LOQ (0.01) –<LOQ (0.05)	<LOQ (0.05)
0130000	Pome fruits	0.05*	<LOQ (0.01) –<LOQ (0.05)	<LOQ (0.05)
0140000	Stone fruits	0.05*	<LOQ (0.01) –<LOQ (0.05)	<LOQ (0.05)
0150000	Berries and small fruits ^{c)}	0.05*	<LOQ (0.01) – <LOQ (0.05)	<LOQ (0.05)
0210000	Root and tuber vegetables	0.05*- 0.7	0.005–0.41	0.05
0220000	Bulb vegetables ^{c)}	0.05*	<LOQ (0.02) – <LOQ (0.05)	<LOQ (0.05)
0230000	Fruiting vegetables	0.05*	<LOQ (0.01) –<LOQ (0.05)	<LOQ (0.01)



Findings of not authorised substances in organic products

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pendimethalin (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.05*- 0.5	<LOQ (0.05)–0.25	0.05
0250000	Leaf vegetables, herbs and edible flowers	0.05*- 4	<LOQ (0.02)–0.76	0.05
0260000	Legume vegetables	0.05*- 0.09	<LOQ (0.01)–0.06	0.01
0270000	Stem vegetables	0.05*- 0.3	<LOQ (0.01)–0.23	0.02
0300000	Pulses (dried)	0.15	<LOQ (0.01)–0.07	0.06
0401000	Oilseeds	0.05*	<LOQ (0.01) to <LOQ (0.05)	<LOQ (0.05)
0500000	Cereals	0.05*	<LOQ (0.01) to <LOQ (0.05)	<LOQ (0.05)
0631000	Herbal infusions from flowers ^{d)}	0.05*	NR	-
0633000	Herbal infusions from roots	0.5	<LOQ (0.1)–0.3	0.13
0810000	Seed spices (dried)	0.05*	<LOQ (0.01)–0.024	0.02
0820030	Caraway	0.05*	<LOQ (0.01)–0.024	0.02
0900000	Sugar plants	0.05*- 0.2	<LOQ (0.05)–0.14	0.05
Feed				
1200000	Cereal straw	NA	<LOQ (0.05)–0.19	0.05
	Maize forage	NA	<LOQ (0.05)	<LOQ (0.05)
	Alfalfa	NA	NR	-

* Limit of quantification in Reg. (EC) No 396/2005; NA – not applicable; NR – no residue trials are available; '-': not estimated due to lack of data.

a) Maximum Residue Level in Reg. (EU) No 2023/1049 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA, 2012h, 2013h, 2014l, 2015i, 2016g, 2018g, 2023j; c) Quantified residues between the two analytical LOQs of 0.01 and 0.05 mg/kg were also measured in the residue trials; d) For uses not supported by data, the MRLs were lowered to the LOQ.

Occurrence of pendimethalin under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to pendimethalin are given by Regulation (EU) 2019/1791⁵⁹ for the years 2020–2022.

Regarding commodities not labelled as organic, 113,338 samples were collected and analysed for pendimethalin in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 104,341 (92.06%) were unprocessed and 8,997 (7.94%) processed commodities. No residues were quantified in 112,123 samples out of the 113,338 samples (98.93%). In 1209 samples out of the 113,338 samples (1.07%) pendimethalin was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-14.1. MRLs were exceeded in six samples out of the 113,338 samples (0.01%). The highest concentrations for samples exceeding the MRLs were 0.53 mg/kg in leafy brassica (kales and similar) and 0.71 mg/kg and 1.77 mg/kg in herbs and edible flowers (dried herbs).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of pendimethalin are summarised in Table 3.14.3.2-2a for unprocessed and in Table 3.14.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on pendimethalin in feed not labelled as organic were submitted to EFSA.



Table 3.14.3.2-2a: Occurrence of pendimethalin monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pendimethalin (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0110000	Citrus fruits	0.05*	0.001	0.001–0.037	9	0.002
0120000	Tree nuts	0.05*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.05*	0.001	0.001–0.033	56	0.002
0140000	Stone fruits	0.05*	0.001	0.001–0.048	25	0.002
0150000	Berries and small fruits	0.05*	0.001	0.001–0.096	48	0.002
0210000	Root and tuber vegetables	0.05*- 0.7	0.001	0.001–0.169	300	0.012
0220000	Bulb vegetables	0.05*	0.001	0.001–0.046	10	0.021
0230000	Fruiting vegetables	0.05*	0.001	0.001–0.02	29	0.003
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.05*- 0.5	0.001	0.001–0.53	103	0.01
0250000	Leaf vegetables, herbs and edible flowers	0.05*- 4	0.001	0.001–1	483	0.016
0260000	Legume vegetables	0.05*- 0.09	0.001	0.003–0.01	2	0.007
0270000	Stem vegetables	0.05*- 0.3	0.001	0.001–0.25	98	0.012
0300000	Pulses (dried)	0.15	0.003	0.01–0.061	3	0.017
0401000	Oilseeds	0.05*	0.003	<LOQ	0	<LOQ
0500000	Cereals	0.05*	0.001	<LOQ	0	<LOQ
0631000	Herbal infusions from flowers ^{d)}	0.05*	0.005	0.045	1	0.045
0633000	Herbal infusions from roots ^{d)}	0.5	ND	ND	ND	ND
0810000	Seed spices (dried) ^{d)}	0.05*	0.005	<LOQ	0	<LOQ
0820030	Caraway ^{d)}	0.05*	ND	ND	ND	ND
0900000	Sugar plants	0.05*- 0.2	0.005	<LOQ	0	<LOQ
Feed						
1200000	Cereal straw	NA	ND	ND	NA	ND
	Maize forage	NA	ND	ND	NA	ND
	Alfalfa	NA	ND	ND	NA	ND
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of pendimethalin is not expected)						
0160000	Miscellaneous fruits	0.05*	0.001	0.002–0.025	2	0.014
0280000	Fungi, mosses and lichens	0.05*	0.001	0.013	1	0.013
0290000	Algae and prokaryotes organisms	0.05*	0.01	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.05*	0.003	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs ^{d)}	0.05*- 0.5	0.005	0.011–0.045	4	0.026
0700000	Hops (dried)	0.05*	0.01	<LOQ	0	<LOQ
0800000	Spices (dried) ^{d)}	0.05*	0.005	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.002	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2023/1049 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Oilseeds, herbal infusions and spices (dried) appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0401000, 0631000, 0633000, 0810000 and 0820030 and non-use of the substance for all other commodities '040N000', '06N0000' or '08N0000' that are reported under the 'broader' categories 0400000, 0600000 and 0800000 on the table. This creates an inconsistency in the results indicating non-uses which are overestimated.



Table 3.14.3.2-2b: Occurrence of pendimethalin from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pendimethalin (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0110000	Citrus fruits	0.05*	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.05*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.05*	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.05*	0.005	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.05*	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.05*- 0.7	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.05*	0.01	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.05*	0.001	0.004–0.041	8	0.014
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.05*- 0.5	0.01	0.056	1	0.056
0250000	Leaf vegetables, herbs and edible flowers	0.05*- 4	0.002	0.01–1.765	31	0.123
0260000	Legume vegetables	0.05*- 0.09	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.05*- 0.3	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.15	0.008	<LOQ	0	<LOQ
0401000	Oilseeds	0.05*	0.01	0.02	1	0.02
0500000	Cereals	0.05*	0.002	<LOQ	0	<LOQ
0631000	Herbal infusions from flowers ^{d)}	0.05*	0.01	0.014	1	0.014
0633000	Herbal infusions from roots ^{d)}	0.5	ND	ND	ND	ND
0810000	Seed spices (dried) ^{d)}	0.05*	0.005	<LOQ	0	<LOQ
0820030	Caraway ^{d)}	0.05*	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.05*- 0.2	0.008	<LOQ	0	<LOQ
Feed						
1200000	Cereal straw	NA	ND	ND	NA	ND
	Maize forage	NA	ND	ND	NA	ND
	Alfalfa	NA	ND	ND	NA	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of pendimethalin is not expected)						
0160000	Miscellaneous fruits	0.05*	0.004	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.05*	0.01	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.05*	ND	ND	ND	ND
0400000	Oilseeds and oil fruits	0.05*	0.002	0.02	1	0.02
0600000	Teas, coffee, herbal infusions, cocoa and carobs ^{d)}	0.05*- 0.5	0.005	0.014	1	0.014
0700000	Hops (dried)	0.05*	0.05	<LOQ	0	<LOQ
0800000	Spices (dried) ^{d)}	0.05*	0.005	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.004	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2023/1049 amending Annex II of Reg. (EC) No 396/2005;

b) Residue concentrations below the applicable MRL of 0.05* mg/kg for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Oilseeds, herbal infusions and spices (dried) appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0401000, 0631000, 0633000, 0810000 and 0820030 and non-use of the substance for all other commodities '040N000', '06N0000' or '08N0000' that are reported under the 'broader' categories 0400000, 0600000 and 0800000 on the table. This creates an inconsistency in the results indicating non-uses which are overestimated.

Occurrence of pendimethalin in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 10,217 samples were collected and analysed for pendimethalin from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 8,504 (83.23%) were unprocessed and 1713 (16.77%) processed commodities. No residues were quantified in 10,191 samples out of the 10,217 samples (99.75%). In 26 samples out of the 10,217 samples (0.25%) pendimethalin was found at or above the analytical LOQ but below or at the MRL. No samples labelled as organic were above MRLs. These findings are summarised in Appendix B, Table B-14.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.14.3.2-3a for unprocessed and in Table 3.14.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on pendimethalin in feed labelled as organic were submitted to EFSA.

Table 3.14.3.2-3a: Occurrence of pendimethalin from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pendimethalin (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.05*	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.05*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.05*	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.05*	0.001	0.001	2	0.001
0150000	Berries and small fruits	0.05*	0.001	0.001–0.012	2	0.007
0160000	Miscellaneous fruits	0.05*	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.05*- 0.7	0.001	0.001–0.013	2	0.007
0220000	Bulb vegetables	0.05*	0.001	0.0075	1	0.008
0230000	Fruiting vegetables	0.05*	0.005	0.001–0.006	2	0.004
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.05*- 0.5	0.001	0.001–0.01	8	0.002
0250000	Leaf vegetables, herbs and edible flowers	0.05*- 4	0.001	0.001–0.16	7	0.002
0260000	Legume vegetables	0.05*- 0.09	0.001	<LOQ	0	<LOQ
0270000	Stem vegetables	0.05*- 0.3	0.001	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.05*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.05*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.15	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.05*	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.05*	0.001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*- 0.5	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.05*- 0.2	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities.

a) Maximum Residue Level in Reg. (EU) No 2023/1049 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with



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higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.14.3.2-3b: Occurrence of pendimethalin from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pendimethalin (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.05*	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.05*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.05*	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.05*	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.05*	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.05*	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.05*- 0.7	0.01	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.05*	0.002	0.012	1	0.012
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.05*- 0.5	0.005	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.05*- 4	0.005	0.038	1	0.038
0260000	Legume vegetables	0.05*- 0.09	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.05*- 0.3	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.05*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.15	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.05*	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.05*	0.002	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*- 0.5	0.005	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.05*- 0.2	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2023/1049 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of pendimethalin in the EU Organic Farming Information System

The EU OFIS reported 11 findings for pendimethalin in 2021 and 2022. Ten of the products sampled and analysed had EU origin and one was of non-EU origin. Residues were found in one sample of fruiting vegetables (chilli), seven samples of leaf vegetables, herbs and edible flowers (spinach, parsley, thyme and barley grass), one sample of teas, coffee, herbal infusions, cocoa and carobs (rose essential oil), and one sample of products or part of products exclusively used for animal feed production (apple pomace) and one non-EU sample of brassica vegetables (excluding brassica roots and brassica baby leaf crops) (broccoli). The concentrations of pendimethalin residues were above LOQ but below MRL in 10 samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005³. MRL exceeded in one sample of EU origin. The highest concentration was reported for a sample of rose essential oil of EU origin, with the quantified level of 0.2 mg/kg. These findings are summarised in Table 3.14.3.2-4.

Table 3.14.3.2-4: Occurrence of pendimethalin from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
0231020	Sweet peppers/bell peppers	0.05*	0.011 – Chilli peppers	ND
0252010	Spinaches	0.05*	ND	0.032; 0.032 – Spinach (powder)
0250000	Leaf vegetables, herbs and edible flowers	0.05*–4	ND	0.013 – Cereals grasses (barley grass) (dried)
0256040	Parsley	2	0.1; 0.1 – Parsley	ND
0256070	Thyme	0.6	ND	0.084; 0.12 – Thyme (dried)
0630000	Herbal infusions	0.05*	ND	0.20 – Rose (essential oil)
1200000	Products or part of products exclusively used for animal feed production	NA	ND	0.027 – Apple (pomace) (Feed-related matrix)
Samples of non-EU origin				
0241010	Broccoli	0.05	0.016 – Broccoli	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2023/1049 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of pendimethalin in untreated samples (control samples) from residue trials

Quantified findings in control (untreated) samples were observed for pendimethalin in residue trials that were carried out in carrots: two carrot samples (whole plants with roots) from northern France and Germany, one carrot top sample from northern France and three carrot roots from Germany, Greece, and northern France (Netherlands, 2015). In carrot roots, residues in control (untreated) samples were reported in trials carried out in Germany (Netherlands, 2011), Italy and the United Kingdom³⁵ (Netherlands, 2015). The trial in Italy was conducted on a field that was treated with an herbicide containing pendimethalin in April 2011, before the residue trial that was carried out in August 2012 (Netherlands, 2015).

Other commodities with findings of pendimethalin in control (untreated) samples were peas (whole plant) from Germany (Germany, 2012a), green peas (plant without pods) from northern France (France, 2021), green peas with pods from southern France, the UK and Italy (France, 2021; the Netherlands, 2015), green beans plant (without roots) from Germany, green beans pods without seeds from the United Kingdom³⁵ (France, 2021), bulb onions from Italy (Netherlands, 2017), two samples of fennel seed from Germany (Germany, 2012b), leeks from Germany and southern France (France, 2021; the Netherlands, 2017), winter wheat (whole plant) from northern France and Spain (Netherlands, 2015), maize foliage and two samples of sunflowers from Germany (Germany, 2012a).

No other evidence-based explanations on the causes for these occurrences in control (untreated) samples were provided in the above Member State ERs and DARs.

The summary of the quantified findings of pendimethalin in control (untreated) samples from residue trials carried out for the critical GAP⁴ per crop is given below in Table 3.14.3.2-5.

Table 3.14.3.2.5: Summary of the quantified findings of pendimethalin in control (untreated) samples from residue trials carried out for the critical GAP per crop.

Crop	Country/area	Result (mg/kg)
Bulb onion	Italy	0.014
Carrot	Germany	0.01 (root), 0.07 (root), 0.076 (whole plant with roots)
	Greece	0.01 (root)



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Crop	Country/area	Result (mg/kg)
	Italy	0.015–0.014 ^{a)} (root)
	Northern France	0.01 (top), 0.034 (root), 0.067 (whole plant with roots)
	United Kingdom ³⁵	0.023 (root)
Fennel seed	Germany	0.024; 0.23
Green bean	Germany	0.053 (plant without roots)
	United Kingdom ³⁵	0.027 (pods without seeds)
Green pea	Germany	0.13 (whole plant)
	Northern France	<0.05–0.09; <0.05–0.14 (plant without pods)
	Southern France	0.036 (whole plant without roots)
	Italy	0.011; 0.011 (seeds)
	United Kingdom ³⁵	0.011 (whole plant)
Leek	Germany	0.07
	Southern France	0.015
Maize foliage	Germany	<0.02–0.03 ^{b)}
Sunflower	Germany	0.06; 0.06
Winter wheat	Northern France	0.03 (whole plant)
	Spain	0.06 (whole plant)

a) Pendimethalin concentration was 0.015 mg/kg at day 0 and 0.014 mg/kg at 42 days after application. b) The number of quantified findings in (untreated) control samples was not reported.

- Could the presence of pendimethalin and/or its residues be due to biocide use?

Pendimethalin is not approved for use as a biocide, therefore, residues due to biocidal use are not expected for pendimethalin.

3.14.3.3 Behaviour in food and feed products

- What key physico-chemical properties of pendimethalin are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of pendimethalin are reported in Table 3.14.3.3.

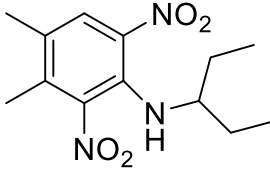
Pendimethalin is lipophilic ($\log P_{ow}=5.4$) and exhibits medium to high persistence in soil (see also Section 3.14.3.6). Regarding sorption to soil, the geometric mean of K_{Foc} in Table 3.14.3.3 indicates that the substance is immobile in soil (EFSA, 2016g).

The maximum calculated PEC_w for pendimethalin for the representative uses was 42 µg/L (pre- and post-emergence applications of pendimethalin to winter cereals; 1 × 1,600 g a.s./ha) (EFSA, 2016g).

Pendimethalin is hydrolytically stable in the whole range of pHs (pH 4, 5, 7 and 9) and at higher temperatures (20 min, 90°C, pH 4; 60 min, 100°C, pH 5; 20 min, 120°C, pH 6). Considering that pendimethalin is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Pendimethalin is considered to exhibit medium volatility (EFSA, 2016g).

Table 3.14.3.3: Physico-chemical properties of pendimethalin

Structural formula	
Appearance (state purity)	Orange-brown solid
Melting point (state purity)	56°C (99.6%)
Boiling point	246–251°C
Temperature of decomposition	Decomposes in the above-mentioned temperature range
Vapour pressure (state temperature, state purity)	3.34×10^{-3} Pa at 25°C
Henry's law constant (state temperature)	1.27×10^{-3} kPa m ³ mol ⁻¹ 25°C
Solubility in water (state temperature, state purity and pH)	pH 4: 0.260 mg/L at 20°C pH 6: 0.309 mg/L at 20°C pH 9: 0.265 mg/L at 20°C
Partition coefficient (octanol/water) (state temperature, pH and purity)	log Pow = 5.4, at 20°C pH 6.5
Partition coefficient (octanol/air)	Log Poa = 9.6 (EPISuite KOAWIN v1.10) (Debler et al. 2024)
Atmospheric half-life	DT ₅₀ of 4.2 hours derived by the Atkinson model (APOWIN version 1.88). OH (12 h) concentration assumed = 1.5×10^6 mol cm ⁻³ Whereas the calculated atmospheric half-life is below 2 d, published studies have indicated higher persistence of pendimethalin in the atmosphere when it is adsorbed to particle aerosols (Socorro et al., 2015a and 2015b)
Dissociation constant (state purity)	pKa = 2.8
Soil adsorption (geometric mean)	K _{Foc} = 12,943 mL/g
Hydrolytic degradation (>10%)	pH 4: no hydrolytic degradation of the active substance No transformation products formed pH 5: no hydrolytic degradation of the active substance No transformation products formed pH 7: no hydrolytic degradation of the active substance No transformation products formed pH 9: no hydrolytic degradation of the active substance No transformation products formed

DT₅₀ – Disappearance time of 50% of the substance in field studies; pH – Potential of Hydrogen; P_{ow} – Octanol/water Partition Coefficient; P_{oa} – Octanol/air Partition Coefficient

3.14.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from the soil surface at which it is applied).

Since only field crops are among the representative peer review uses, only field crops drift values are relevant for the assessment of potential drift of pendimethalin to non-treated neighbouring crops.



The worst-case drift for field crops is 2.77 % of the single application rate in a field separated 1 m from the treated one. This suggests that around 3% of the applicable concentrations would be expected to be transferred to non-treated crops that are in 1 m distance from the treated ones.

Therefore, when conventional field crops are treated pre- or immediately after emergence it is unlikely that residues of pendimethalin are transferred from these crops to untreated organic crops that are at close distance in the same growth stage. However, if the organic crop is in an advanced growing stage (e.g. about to be harvested), then transfer of measurable residues from the treated to the organic crop could not be completely excluded. Information necessary to assess the likelihood of such a scenario is not available to EFSA and would require a landscape level analysis of the distribution of land dedicated to organic and conventional farming at regional level together with an analysis of the different crop cycles.

For non-field crops, pendimethalin applications are done by spraying soil with capsule suspension formulations (CS) (EFSA, 2013h, 2014l, 2015i, 2023j). No higher transfer by drift is expected from these crops than from the field crops, but crops where drift is deposited might be more likely to be at more mature growth stages than is the case for field crops.

There is no granular formulation reported for pendimethalin application, therefore, dust drift is not expected.

3.14.3.5 Accumulated/historical residue levels in soil

- What is the persistence of pendimethalin and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

According to data from field soil dissipation studies carried out in 17 different sites around Europe, the DT₉₀ of pendimethalin is > 1 year (worst-case field DT₉₀ = 621 days) (EFSA, 2016g). This indicates a potential for accumulation in soil and the possible persistence of residues in soil after the use of the substance is discontinued.

In order to investigate the potential uptake of residues of pendimethalin by plants, studies on the nature of residues in rotational crops were carried out with lettuce, wheat, carrots, radishes and snap beans planted at different intervals after application of the active substance in soil. Application rates were as high as 2200 g a.s./ha to cover the potential accumulation expected to result from continuous seasonal application at rates up to 1650 g a.s./ha. Low uptake of residues was reported from wheat grain (<1% Total Radioactive Residue (TRR) for a plant-back interval (PBI) of 120 days and a higher but still low uptake of the substance (up to 19% TRR) from immature lettuce for a PBI of 365 days. As these findings for a PBI of 120 and 365 days might relate to degradation products of pendimethalin, they did not trigger the need for studies on the magnitude of residues in rotational crops for pendimethalin (EFSA, 2016g).

The above suggest that the presence of pendimethalin in untreated crops is less likely to be associated with plant uptake from contaminated soil. This is also valid for organic crops, when planted in fields that were previously used for conventional agriculture, considering that it requires at least 2 years after the last chemical treatment for organic crops to be planted in such area².



- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Monitoring data for pendimethalin in soil are available from the LUCAS pesticides 2018 (JRC, 2023) on IPCHEM¹²¹². Franco et al. (2024) reported pendimethalin as being among the most frequently detected substances in the LUCAS soil survey, with a detection frequency of 25% in European soil.

The data from LUCAS soil show background levels of the substance in soil samples from 20 EU countries: Austria (9 samples), Belgium (3 samples), Bulgaria (54 samples), Cyprus (1 sample), Czechia (33 samples), Denmark (33 samples), France (236 samples), Germany (53 samples), Greece (23 samples), Hungary (41 samples), Italy (60 samples), Latvia (5 samples), Lithuania (3 samples), the Netherlands (10 samples), Poland (41 samples), Portugal (31 samples), Romania (15 samples), Slovakia (13 samples), Spain (140 samples) and Sweden (2 samples) at levels ranging from 0.001 mg/kg to 0.91 mg/kg. The highest concentration was found in a sample from Germany.

On the other hand, pendimethalin is considered a non-systemic herbicide and as demonstrated by rotational crop metabolism studies (see previous question), plant uptake of pendimethalin residues from soil is very limited. Therefore, transfer of soil residues to the edible parts of the plants is expected to be of low relevance in relation to other potential sources of presence in food and feed of plant origin, honey and apiculture products. In LUCAS soil, the lack of information on the agricultural use history of the sites where soil was sampled precluded knowing whether the reported quantified findings were related to recent active use or historical levels in soil for pendimethalin.

Evidence on the occurrence of pendimethalin residues in soil is provided by Chiaia-Hernandez et al. (2017), who analysed 29 archived agricultural soil samples collected from 14 monitoring sites from 1995 to 2008 in Switzerland. The sites were selected from locations where crops had been regularly treated with pesticides. Selection was based on land use characteristics and long-term patterns of pesticide application. Pendimethalin was one of the 20 most frequently detected pesticides, detected in 14 samples (48%) from cropland and vegetable land use sites, with levels ranging from 0.002 to 0.160 mg/kg. Pendimethalin was applied and detected in 34% of cases, whilst it was not applied and detected in 14% of cases. Additionally, a minor transformation product of pendimethalin was detected in 12 samples (41%) from all land use sites, including cropland, orchard, vegetable and viticulture.

Additional evidence on the occurrence of pendimethalin in soil is provided by Silva et al. (2023) in a study carried out in the framework of the EU SPRINT project. The study assessed the presence of 209 pesticide residues in 100 soil samples from conventional agriculture and 63 soil samples from organic agriculture collected during the 2021 growing season across 10 study sites in Europe: Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark. Pendimethalin was quantified in nine conventional soil samples (9%) at concentrations from 0.004 to 0.659 mg/kg and two soil samples under organic farming systems (3%) at concentrations of 0.0032 and 0.0487 mg/kg. The highest concentration was found in conventional soil from Portugal and soil under organic farming systems from Denmark.

Considering the available evidence, plant uptake of pendimethalin from soil containing pendimethalin is not expected even if the crop is grown in soil that contain residues at the levels quantified in these studies.

3.14.3.6 Residues from water used for irrigation

- Is there evidence that residues of pendimethalin present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹²¹² the following databases providing occurrence data for pendimethalin in water samples were considered:

- The EEA-WATERQUALITY³⁹ database (data retrieved on 10 April 2024) reports 25,607 analytical results from water samples collected in Belgium (209 samples), Bulgaria (93 samples), Finland (20 samples), France (14,212 samples), Italy (9,786 samples), the Netherlands (795 samples), Slovakia (268 samples), Slovenia (206 samples) and Sweden (18 samples) between 2018 and 2020;
- The EMPODAT database (data retrieved on 25 March 2024) reports 67 analytical results from surface water samples collected in the Netherlands between 2017 and 2019;
- The NAIADES database (data retrieved on 2 April 2024) reports 45,084 analytical results from surface water samples collected in France from 2020 to 2022.

Among the 70,758 analytical results for pendimethalin, 859 were disregarded as found to report quantitative values below the analytical LOQ and 3,804 were disregarded as found to report quantified residues equal to LOQs as high as 1 µg/L and above. Therefore, the number of water samples considered is 66,095.

Based on the screening process described in section 'Data and methodologies', for 100% of water samples analysed and reported in EEA-WATERQUALITY, EMPODAT and NAIADES (66,095 samples), the residue concentrations were below the screening Cw of 6.94 µg/L.

In a study by Silva et al. (2023) carried out under the framework of the EU SPRINT project the authors assessed the presence of 209 pesticide residues in 58 surface water samples collected during the 2021 growing season across 10 study sites in Europe (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). Pendimethalin was quantified in 11 samples (19% detection frequency) at concentrations ranging between 0.002 and 0.016 µg/L with the highest level found in the Netherlands. No sample was found to contain residues above 0.1 µg/L.

Therefore, it can be concluded that the transfer of pendimethalin residues from EU water sources to plant commodities when this water is used to irrigate plants is unlikely.

3.14.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *pendimethalin*,



industry/industrial, and air/atmosphere) identified only one European study, which was considered irrelevant for this section.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water. Based on conservative estimations of the possible transfer of residues from water used for irrigation to plant commodities, the transfer of residues of pendimethalin from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 7, 2025, using the keywords *pendimethalin, industry/industrial, and water*) did not identify any relevant European study.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Based on information on the possible plant uptake of pendimethalin from EU soil, the transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 17, 2025, using the keywords *pendimethalin, industry/industrial, and soil/sediment*) did not identify any relevant European study.

3.14.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Medium and long-range aerial transport of residues

Although pendimethalin is considered to exhibit medium volatility, studies by Asman et al., 2005 and by Hofmann and Schlechtriemen, 2015 that were presented in the pendimethalin RAR (Netherlands, 2015) describe findings of pendimethalin in agricultural areas where it has not been applied. In some instances, measurable residues in the crops placed in these areas (up to 11 km away from application sites) have been described (see Appendix C). Some results in Appendix C make plausible the occurrence of residues in non-treated crops at levels above LOQ, even at some kilometres away from the treated field.

Findings of pendimethalin in the Baltic Sea and the Arctic Sea cores suggest aerial transport of pendimethalin from farmlands located about 2000 km away (Socorro et al., 2015a,b). This could explain the midrange transport (< 1000 km) and the isolated cases of potential long-range transport (deposition measured in ice cores) observed in the available environment monitoring studies (EFSA, 2016g).

More studies have been published on the occurrence of residues of pendimethalin in the air since then.

Figueiredo et al. (2021) investigated pesticide presence in air samples during periods of use and non-use of pendimethalin in the surrounding area (up to 500 m distance) from the agricultural field (bulb field) in the Netherlands between May 2016 and December 2017. According to the



figures in the paper, outdoor aerial concentrations of pendimethalin appeared to decrease with the distance from the field and between use and non-use periods.

In a study by Zaller et al. (2022) passive air samplers were set up across 15 regions in Austria with varying land uses over a period of up to 8 months (March to November 2020). Pendimethalin was quantified in all samples from the passive samplers, regardless of land use around each sampler location, including a site located in a city centre surrounded solely by residential areas. Pendimethalin concentrations ranged from a minimum of 44.9 ng/sample to a maximum of 3932 ng/sample. The authors identified conventional agriculture as the likely source, as the compound is approved for conventional but not for organic farming.

Silva et al. (2023) investigated the presence of pendimethalin in 20 outdoor air samples collected during the 2021 growing season across 10 study sites in Europe of organic and conventional agriculture (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). The study was carried out under the framework of the EU SPRINT project. Organic fields had not been treated for 5 consecutive years. Pendimethalin was quantified in 67% of the samples at concentrations ranging between 13.6 and 1417 ng m⁻³. The highest level was found in air samples from Spain. The high concentrations and positive findings indicate a significant airborne presence of pendimethalin. Among the 14 samples with quantified residues, seven were from fields of organic agriculture in Switzerland (504 ng m⁻³), Czechia (37.9 ng m⁻³), Italy (187 ng m⁻³), the Netherlands (247.4 ng m⁻³), Portugal (13.6 ng m⁻³), Slovenia (87.4 ng m⁻³) and Spain (174.9 ng m⁻³).

In a study investigating the potential transport of pesticide residues from apple-growing fields in South Tyrol (Vinschgau Valley) to higher altitudes, there were no quantified residues of pendimethalin in any of the soil and vegetations sampled and analysed (Brühl et al., 2024).

In another study published under the EU SPRINT project, pendimethalin was quantified in air samples collected from an agricultural area of conventional farming in the Netherlands (potatoes, onions and sugar beet) between April 2021 and June 2022 (Debler et al., 2024). Pendimethalin's detection frequency (14%) and total concentration range (24–4,758 pg/m³) indicated significant presence of the substance in the air, particularly in the particulate phase. Note was taken that the field had undergone pendimethalin treatment before the collection of the sample and measurement.

In a study by Mayer et al. (2024) residues of pendimethalin were quantified in air samples from 29 sampling sites classified as rural, coastal, mountain and polar. The samples were collected from 15 EU countries i.e. Austria, Czechia, Estonia, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Poland, Slovakia, Spain and Sweden, Switzerland and the United Kingdom during the main pesticide application period in spring 2020. To investigate aerial transport in polar sites, air samples from the European Arctic were also collected. Results showed the presence of pendimethalin at levels from 0.5 to 100 pg m⁻³ in the rural sites, from 5 to 30 pg m⁻³ in the coastal sites and at 1 pg m⁻³ in one sample from a remote mountain site in Switzerland (the exact concentration ranges are not reported in the paper). For both the rural and coastal areas, the maximum concentrations were quantified in the United Kingdom. Pendimethalin was not quantified in the Arctic sites. The total frequency of findings for all areas was below 50% (the exact % detection frequency is not reported in the paper).



Overall, the results of most studies suggest that transfer of pendimethalin to plants via aerial transport cannot be excluded and that long-range atmospheric transport to remote areas may occur when considering adsorption to aerosol particles.

3.14.4 Conclusions on pendimethalin

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use.
- Residue trials carried out to support the critical GAPs⁴ for pendimethalin, gave residue concentrations of up to 0.76 mg/kg (highest value for leaf vegetables, herbs and edible flowers). Concentrations in the ranges reported in Table 3.14.3.2-1 might be associated with active use of pendimethalin according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.
- Pendimethalin was quantified in the context of residue trials in several European countries in untreated (control) samples with the highest concentrations observed for one sample of fennel seed from Germany (0.23 mg/kg).
- Applications of pendimethalin at rates above the recommended GAP rates are unlikely as they can cause phytotoxicity to the treated crops.
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for pendimethalin in unprocessed commodities with authorised uses ranged from 0.002 mg/kg in citrus, pome and stone fruits as well as in berries and small fruits to 0.021 mg/kg in bulb vegetables.
- In organic commodities that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings, the median concentrations for pendimethalin in unprocessed commodities were 0.002 mg/kg in brassica vegetables (excluding brassica roots and brassica baby leaf crops) and leaf vegetables, herbs and edible flowers. In all other commodities residues were not quantified or were quantified in fewer than five samples per commodity.
- Without additional information on the individual samples' history and context, it is not possible to conclude if quantified results in organic commodities are associated with active use or unintentional presence of pendimethalin.
- In organic processed commodities, residues of pendimethalin were not quantified in most commodities. In samples from processed products not labelled as organic with five or more quantified findings, the median concentrations of residues of pendimethalin ranged from 0.014 mg/kg in fruiting vegetables to 0.123 mg/kg in leaf vegetables, herbs and edible flowers. Considering that pendimethalin is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.



Findings of not authorised substances in organic products

- Overall, in commodities labelled as organic, pendimethalin was quantified in 0.25% of samples (26 out of 10,217 samples). This percentage is four times lower than the percentage reflecting the number of findings in samples not labelled as organic (1.1%) (see Appendix B, Tables B-14.1 and B-14.2). These results suggest that the occurrence of residues of pendimethalin in organic products is less likely when compared with the conventional commodities.
- Plant uptake of residues of pendimethalin due to drift from conventional crops grown in the vicinity or from soil containing residues is considered a less likely explanation for residues found in crops where pendimethalin has not been actively used.
- A potential source of the unintentional presence of residues of pendimethalin in commodities of plant origin is via aerosol transport in the air.
- Pendimethalin is persistent in soil, however, not all substances accumulating in soil are taken up by plants. Studies assessed by EFSA on crops growing in rotation showed that plant uptake of pendimethalin from soil containing residues is unlikely.
- Transfer of pendimethalin residues from EU water sources used for irrigation to plant commodities is unlikely.
- Conservative estimates of the possible transfer of residues of pendimethalin from water used for irrigation to plant commodities and information on the possible plant uptake of residues of pendimethalin from EU soil suggest that the transfer of residues of pendimethalin from industrial emissions to the environment and from the environment to plants and plant commodities is less likely.

The pathways of residues of pendimethalin to plants and plant commodities are summarised in Figure 14.



Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded

3.15 Spirotetramat

3.15.1 Method(s)

- What is/are the residues to be monitored for the active substance spirotetramat according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

For the active substance 'spirotetramat' (BYI08330), the residue definition for enforcement in food and feed of plant origin has been proposed as 'sum of spirotetramat and spirotetramat-enol, expressed as spirotetramat' in the EFSA peer review conclusion and the EFSA MRL review (EFSA, 2013i, 2020e). This residue definition is applicable to primary, rotational crops and processed commodities. It is also applicable to honey (EFSA, 2021d). This residue definition for enforcement was implemented in Regulation (EC) No 396/2005 in 2021⁷².

Before 2021, the residue definition for enforcement implemented in Regulation (EC) No 396/2005 was 'spirotetramat and its 4 plant metabolites spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat'⁶³.

Note was taken that spirotetramat and spirotetramat-enol constitute the major proportion of spirotetramat residues. The ketohydroxy and monohydroxy plant metabolites of spirotetramat are minor metabolites, in addition spirotetramat-enol-glucoside degrades to spirotetramat-enol under storage (EFSA, 2013i, 2020e).

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

Analytical methods based on HPLC-MS/MS have been validated for the quantification of residues of spirotetramat and spirotetramat-enol, expressed as spirotetramat. These methods achieve an LOQ of 0.01 mg/kg for each analyte in high water, high acid, and high oil content commodities. The sensitivity of the methods in dry and difficult matrices (hops) is lower (LOQ of 0.1 mg/kg) (EFSA, 2013i, 2020e). More recently, the EURLs developed a multi-residue QuEChERS method based on HPLC-MS/MS and with the same sensitivity for the determination of spirotetramat and spirotetramat-enol, in high water, high acid, high oil content, and dry matrices (EFSA, 2022h).

HPLC-MS/MS methods for the analysis of spirotetramat and spirotetramat-enol have been validated in honey with an LOQ of 0.01 mg/kg for each analyte (EFSA, 2021d).

According to the DAR, analytical methods based on HPLC-ESI-MS/MS can be used for the analysis of residues of spirotetramat-enol-glycoside, spirotetramat-ketohydroxy and spirotetramat-monohydroxy that were part of the residue definition for enforcement before 2021 as implemented in Regulation (EC) No 396/2005³. The reported LOQ is 0.01 mg/kg per analyte in high water, high acid and high oil content matrices (EFSA, 2014m).

According to the EURL for Residues of Pesticides (EURL, 2024, under 'Documentation as provided to EFSA'), a multi-residue citrate-buffered QuEChERS method based on LC-Q-TOF is validated to monitor spirotetramat in honey samples at an LOQ of 0.001 mg/kg as well as its 4 plant

⁷² Commission Regulation (EU) 2021/644 of 15 April 2021 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fluxapyroxad, hymexazol, metamitron, penflufen and spirotetramat in or on certain products. OJ L 133, 20.4.2021, p. 9–28

metabolites spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy, and spirotetramat-enol-glucoside residues, with individual LOQs of 0.002 mg/kg. The sum of LOQs was 0.01 mg/kg.

Overall, multi-residue methods of analysis are available for the monitoring of residues of spirotetramat, across high water, high acid, high oil content commodities, and dry matrices of plant origin, as well as in honey and other apiculture products. LOQs for methods of analysis of spirotetramat residues in products of plant origin and honey range from 0.001 to 0.1 mg/kg per analyte with the lower sensitivities observed for hops.

3.15.2 Authorisation status and use

- Is spirotetramat currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has spirotetramat ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

a) Authorisations for plant protection use in conventional agriculture

Based on information from the EU Pesticides Database⁵ (accessed 18 July 2024), spirotetramat is not approved for plant protection purposes in the EU as no application for renewal of the approval was submitted in accordance with Article 5(1) of Implementing Regulation (EU) 2020/1740⁷³. The expiry date of the approval of the active substance was on 30 April 2024³.

According to the EU Pesticides database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, France, Hungary, Italy, Lithuania, Luxembourg, Latvia, Malta, Norway, Poland, Portugal, Sweden, Slovenia and Slovakia. According to Reg. (EU) 2022/489⁷⁴ a grace period is applicable to the sale, distribution, disposal, storage and use of existing stocks of the plant protection products that contain spirotetramat following the expiry date of the approval of the active substance. This period should not exceed 18 months from the expiry of the approval (from 30 April 2024).

b) Authorisations for purposes other than plant protection

Biocidal use

According to the ECHA website⁶ (accessed 12 February 2024), spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside have not been authorised for use as biocidal products in the EU Member States, Iceland, Liechtenstein and Norway.

⁷³ Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012. OJ L 392, 23.11.2020, p. 20–3.

⁷⁴ Commission Implementing Regulation (EU) 2022/489 of 25 March 2022 amending Implementing Regulation (EU) No 540/2011 as regards the approval periods of the active substances flubendiamide, L-ascorbic acid, spinetoram and spirotetramat. OJ L 100, 28.3.2022, p. 7–9.

Other uses

According to the search carried out on the ECHA website⁹ on 6 June 2024, spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy or spirotetramat-enol-glucoside are not currently registered under REACH.

- What is/was the actual use of spirotetramat? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of spirotetramat

Spirotetramat is a systemic active substance belonging to the group of tetracyclic acid insecticides/acaricides. Following its oral ingestion by the insect, it acts on acetyl CoA carboxylase and inhibits lipid biosynthesis (EFSA, 2014m).

Conditions of use and applicable crops

The uses reported in the EFSA MRL review for spirotetramat included applications in northern and southern Europe belonging to the following crop groups: citrus fruits, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oil fruits, herbal infusions from leaves, herbs and flowers, hops (dried), and sugar plants (EFSA, 2020e). After the EFSA MRL review, applications were submitted to EFSA to modify the existing MRLs for bulb vegetables, leaf vegetables, herbs and edible flowers, stem vegetables and honey and other apiculture products (EFSA, 2021d, 2022h). Note was taken that the uses for herbal infusions from flowers were not supported by data (see Section 3.15.3.2 'Active use (all legitimate uses of the substance)') (EFSA, 2020e).

Spirotetramat treatment included outdoor and indoor foliar applications (EFSA, 2020e, 2021d, 2022h). Application rates ranged from 45 g a.s./ha to 270 g a.s./ha for outdoor uses and from 75 g a.s./ha to 150 g a.s./ha for indoor uses.

b) Uses for purposes other than plant protection

Biocidal use

Spirotetramat and the spirotetramat transformation products considered in this report are not approved for biocidal use, therefore, their use in biocidal products is not expected (see also 'authorisations for purposes other than plant protection/biocidal use').

Other use

A search carried out on the ECHA website⁹ on 6 June 2024 did not give any results for the registration under REACH of spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy or spirotetramat-enol-glucoside.

3.15.3 Sources of residues in plants

3.15.3.1 Natural occurrence

- Is there evidence that spirotetramat occurs naturally? What is known about the natural origin of this substance?

Spirotetramat is a synthetic chemical produced industrially through chemical processes (Lewis et al., 2016). No information on the potential natural presence of spirotetramat and its transformation product spirotetramat-enol was found in the literature²².

3.15.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of spirotetramat per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of spirotetramat (BYI08330) in the context of residue trials carried out for the critical GAP⁴ per crop, and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.15.3.2-1 to 3.15.3.2-4. The presence of residues in control (untreated) samples is also discussed in this section.

In all matrices and for both residue trials and results from monitoring, spirotetramat residue concentrations refer to the residue definitions for enforcement before 2021 and after 2021, respectively (see also Section 3.15.1): 'spirotetramat and its 4 metabolites spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat' (before 2021) and 'spirotetramat and its metabolite spirotetramat-enol expressed as spirotetramat' (after 2021).

Occurrence of spirotetramat from residue trials carried out for the critical GAP per crop

Following product applications based on the critical GAPs⁴ reported to EFSA, residues of spirotetramat for both residue definitions (before and after 2021) were quantified in citrus fruits, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oil fruits, herbal infusions from leaves and herbs, hops (dried), sugar plants and honey and other apiculture products (EFSA, 2020e, 2021d, 2022h).

Regarding the individual substances (parent and metabolites in plants),

- Residues of spirotetramat (BYI08330) were not quantified in root and tuber vegetables, pulses (dried), sugar plants, and honey and other apiculture products (Austria, 2019; EFSA, 2020e, 2021d).
- Residues of spirotetramat-enol (BYI08330-enol) were quantified in all commodities for which uses were reported (see above) (Austria, 2013b, 2019, 2020; Belgium, 2018b; EFSA, 2020e, 2021d; Germany, 2022b).
- Residues of spirotetramat-ketohydroxy (BYI08330-ketohydroxy) were below the LOQ in sugar plants and honey and other apiculture products (Austria, 2019, 2020; EFSA, 2020e, 2021d).
- Residues spirotetramat-monohydroxy (BYI08330-monohydroxy) were below the LOQ in citrus fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), stem vegetables, oil

fruits, herbal infusions from leaves and herbs, hops (dried), and sugar plants (Austria, 2013b, 2019; Belgium, 2018b; EFSA, 2020e).

- Residues of spirotetramat-enol-glucoside (BYI08330-enol-glucoside) were below the LOQ in bulb vegetables, fruiting vegetables, pulses (dried), sugar plants, and honey and other apiculture products (Austria, 2013b, 2019, 2020; EFSA, 2020e, 2021d).

Although EU GAPs were reported for all uses indicated under 3.15.2 'Conditions of use and applicable crops', no data on residue trials for herbal infusions from flowers were submitted and evaluated in the EFSA MRL review (EFSA, 2020e).

The results from residue trials carried out for the critical GAP per crop for spirotetramat in commodities for which uses were submitted to EFSA are summarised in Table 3.15.3.2-1 'Occurrence of spirotetramat from residue trials carried out for the critical GAP per crop'.



Findings of not authorised substances in organic products

Table 3.15.3.2-1: Occurrence of spirotetramat (RD) from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Spirotetramat (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop													
			Spirotetramat and its metabolite spirotetramat - enol expressed as spirotetramat ^{c)}		Spirotetramat and metabolites spirotetramat - enol, spirotetramat -ketohydroxy, spirotetramat - monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat ^{d)}		Spirotetramat (BYI08330)		Spirotetramat - enol expressed as spirotetramat		Spirotetramat - ketohydroxy expressed as spirotetramat		Spirotetramat - monohydroxy expressed as spirotetramat		Spirotetramat-enol-glucoside expressed as spirotetramat	
			Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)
Food																
110000	Citrus fruits	0.5	0.032–0.24	0.089	0.064–0.33	0.14	0.01–0.12	0.03	0.012–0.16	0.057	<LOQ (0.012)–0.035	0.013	<LOQ (0.012)	<LOQ (0.012)	<LOQ (0.008)–0.044	0.008
130000	Pome fruits	0.7	0.022–0.17	0.063	0.054–0.25	0.096	0.01–0.14	0.05	<LOQ (0.012)–0.052	0.012	0.012–0.041	0.015	<LOQ (0.012)–0.04	0.012	<LOQ (0.008)–0.008	0.008
140000	Stone fruits	3	0.044–0.60	0.21	0.11–1.45	0.42	<LOQ (0.01)–0.15	0.04	0.021–0.58	0.15	<LOQ (0.01)–0.13	0.021	<LOQ (0.01)–0.32	0.078	<LOQ (0.008)–0.43	0.044
150000	Berries and small fruits	0.02*–2	<LOQ (0.02)–0.52	0.15	0.05–0.64	0.18	<LOQ (0.01)–0.47	0.065	<LOQ (0.01)–0.21	0.036	<LOQ (0.01)–0.07	0.012	<LOQ (0.01)–0.012	0.012	<LOQ (0.008)–0.18	0.01
160000	Miscellaneous fruits	0.02*–15	0.022–1.64	0.17	0.052–2.5	0.23	<LOQ (0.01)–0.87	0.11	<LOQ (0.01)–0.77	0.054	<LOQ (0.01)–0.85	0.024	<LOQ (0.01)–<LOQ (0.012)	<LOQ (0.01)	<LOQ (0.008)–0.1	0.01
210000	Root and tuber vegetables	0.02*–0.8	<LOQ (0.02)–0.18	0.02	<LOQ (0.05)–0.21	0.05	<LOQ (0.01)	<LOQ (0.01)	<LOQ (0.01)–0.17	0.01	<LOQ (0.01)–0.012	0.01	<LOQ (0.01)–<LOQ (0.012)	<LOQ (0.01)	<LOQ (0.008)–0.008	0.01
220000	Bulb vegetables	0.02*–0.9	<LOQ (0.02)–0.17	0.066	<LOQ (0.05)–0.20	0.1	<LOQ (0.01)–0.02	0.01	<LOQ (0.012)–0.16	0.056	<LOQ (0.012)–0.017	0.012	<LOQ (0.012)	<LOQ (0.012)	<LOQ (0.008)	<LOQ (0.008)
230000	Fruiting vegetables	0.02*–1.5	<LOQ (0.022)–0.68	0.052	<LOQ (0.05)–0.82	0.082	<LOQ (0.01)–0.27	0.02	<LOQ (0.012)–0.54	0.02	<LOQ (0.01)–0.062	0.012	<LOQ (0.01)–0.062	0.012	<LOQ (0.008)–0.14	<LOQ (0.008)



Findings of not authorised substances in organic products

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Spirotetramat (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop													
			Spirotetramat and its metabolite spirotetramat - enol expressed as spirotetramat ^{c)}		Spirotetramat and metabolites spirotetramat - enol, spirotetramat - ketohydroxy, spirotetramat - monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat ^{d)}		Spirotetramat (BYI08330)		Spirotetramat - enol expressed as spirotetramat		Spirotetramat - ketohydroxy expressed as spirotetramat		Spirotetramat - monohydroxy expressed as spirotetramat		Spirotetramat-enol-glucoside expressed as spirotetramat	
			Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)
240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.02*-1.5	0.027-0.62	0.08	0.067-0.77	0.14	<LOQ (0.01)-0.5	0.01	0.017-0.52	0.07	<LOQ (0.012)-0.12	0.031	<LOQ (0.012)	<LOQ (0.012)	<LOQ (0.008)-0.039	0.008
250000	Leaf vegetables, herbs and edible flowers	0.02*-10	<LOQ (0.02)-5.5	0.2	0.05-5.50	0.34	<LOQ (0.01)-4.9	0.09	<LOQ (0.01)-0.60	0.12	<LOQ (0.01)-0.21	0.031	<LOQ (0.01)-0.35	0.012	<LOQ (0.008)-0.077	0.014
260000	Legume vegetables	0.02*-2	0.025-0.42	0.11	0.08-0.62	0.2	<LOQ (0.01)-0.15	0.015	0.015-0.29	0.085	0.02-0.12	0.063	<LOQ (0.01)-0.017	0.011	<LOQ (0.008)-0.067	0.01
270000	Stem vegetables	0.02*-4	<LOQ (0.022)-1.36	0.051	0.05-1.44	0.09	<LOQ (0.01)-1.28	0.022	<LOQ (0.012)-0.31	0.033	<LOQ (0.01)-0.22	0.017	<LOQ (0.01)-<LOQ (0.012)	<LOQ (0.01)	<LOQ (0.008)-0.06	0.01
300000	Pulses (dried)	2	0.13	0.13	0.19	0.19	<LOQ (0.01)	<LOQ (0.01)	0.12	0.12	0.015	0.015	0.028	0.028	<LOQ (0.01)	<LOQ (0.01)
402000	Oil fruits	0.02*-4	0.1-0.91	0.28	0.11-0.97	0.3	0.01-0.67	0.18	0.06-0.31	0.11	0.004-0.05	0.01	<LOQ (0.01)	<LOQ (0.01)	<LOQ (0.01)-0.10	0.01
631000	Herbal infusions from flowers ^{e)}	0.1*	NR	-	NR	-	NR	-	NR	-	NR	-	NR	-	NR	-
632000	Herbal infusions from leaves and herbs	50	1.06-21.8	11	1.63-23.3	12.3	0.5-17	7.75	0.56-10	1.7	0.31-8.2	0.98	<LOQ (0.01)-<LOQ (1.2)	<LOQ (0.012)	<LOQ (0.08)-7.7	0.14



Findings of not authorised substances in organic products

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Spirotetramat (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop													
			Spirotetramat and its metabolite spirotetramat - enol expressed as spirotetramat ^{c)}		Spirotetramat and metabolites spirotetramat - enol, spirotetramat - ketohydroxy, spirotetramat - monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat ^{d)}		Spirotetramat (BYI08330)		Spirotetramat - enol expressed as spirotetramat		Spirotetramat - ketohydroxy expressed as spirotetramat		Spirotetramat - monohydroxy expressed as spirotetramat		Spirotetramat-enol-glucoside expressed as spirotetramat	
			Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)
700000	Hops (dried)	15	0.73–2.92	1.49	1.11–4.34	2.32	0.61–2.6	1.02	0.12–0.75	0.28	<LOQ (0.12)–0.88	0.47	<LOQ (0.12)	<LOQ (0.12)	0.08–1.30	0.35
900000	Sugar plants	0.02*–0.07	<LOQ (0.02)–0.048	0.02	<LOQ (0.05)–0.078	0.05	<LOQ (0.01)	<LOQ (0.01)	<LOQ (0.01)–0.038	0.01	<LOQ (0.01)	<LOQ (0.01)	<LOQ (0.01)	<LOQ (0.01)	<LOQ (0.01)	<LOQ (0.01)
1040000	Honey and other apiculture products	0.5	0.056–0.25	0.094	0.086–0.32	0.13	<LOQ (0.01)	<LOQ (0.01)	0.046–0.24	0.084	<LOQ (0.01)	<LOQ (0.01)	<LOQ (0.01)–0.041	0.012	<LOQ (0.01)	<LOQ (0.01)

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NR – no residue trials are available; '-': not estimated due to lack of data.

a) Maximum Residue Level in Reg. (EU) No 2023/1049 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA 2020e, 2021d, 2022h; c) Current residue definition for enforcement, implemented in Regulation (EC) No 396/2005 in 2021; d) Residue definition for enforcement before 2021, implemented in Regulation (EC) No 396/2005; e) For uses not supported by data, the MRLs were lowered to the LOQ.

Occurrence of spirotetramat under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to spirotetramat are given in Regulations (EU) 2017/1016⁷⁵ and 2019/1015⁶³⁶³ for the year 2020, Regulations (EU) 2019/1015⁶³ and 2021/644⁷² for the year 2021 and Regulations (EU) 2022/93³⁴ and 2022/1324²⁸ for the year 2022. Also here, monitoring results were based on the residue definitions in place before and after 2021.

Regarding commodities not labelled as organic, 65,138 samples were collected and analysed for spirotetramat in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 61,516 (94.44%) were unprocessed and 3,622 (5.56%) processed commodities. No residues were quantified in 61,546 samples out of the 65,138 samples (94.49%). In 3,583 samples out of the 65,138 samples (5.5%) spirotetramat was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-15.1. MRLs were exceeded in nine samples out of the 65,138 samples (0.01%). The highest concentration for samples exceeding the MRLs was 3.3 mg/kg in brassica vegetables (excluding brassica roots and brassica baby leaf crops) (flowering brassica – cauliflowers).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of spirotetramat are summarised in Table 3.15.3.2-2a for unprocessed and in Table 3.15.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on spirotetramat in feed not labelled as organic were submitted to EFSA.

Although analysis of spirotetramat based on the residue definition for monitoring before 2021 (which includes four plant metabolites for spirotetramat) would be expected to indicate higher residue concentrations for the same sample than analysis based on the currently in place residue definition (which includes one plant metabolite of spirotetramat), the monitoring results do not indicate significant differences in the occurrence of spirotetramat in food and feed of plant origin between years 2020 and 2022. This is in line with the outcome of studies on the nature of residues in plants, suggesting as major residues the parent and its plant metabolite spirotetramat-enol (EFSA, 2013i). However, monitoring results for the two different residue definitions are not directly comparable because not all labs implemented the amendment of the residue definition at the same point in time. Thus, some labs analysed residues based on the old residue definition and some based on the more recent one.

⁷⁵ Commission Regulation (EU) 2017/1016 of 14 June 2017 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzovindiflupyr, chlorantraniliprole, deltamethrin, ethofumesate, haloxyfop, Mild Pepino Mosaic Virus isolate VC1, Mild Pepino Mosaic Virus isolate VX1, oxathiapiprolin, penthiopyrad, pyraclostrobin, spirotetramat, sunflower oil, tolclofos-methyl and trinexapac in or on certain products. OJ L 159, 21.6.2017, p. 1–47.



Findings of not authorised substances in organic products

Table 3.15.3.2-2a: Occurrence of spirotetramat (BYI08330) monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic based on the residue definitions before and after 2021.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Spirotetramat (BYI08330) (spirotetramat and its metabolites spirotetramat – enol, spirotetramat - ketohydroxy, spirotetramat – monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat) ^{b)} occurrence results from the monitoring of unprocessed commodities not labelled as organic				Spirotetramat (BYI08330) (spirotetramat and its metabolite spirotetramat – enol expressed as spirotetramat) ^{c)} occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{d)} only (mg/kg)	Total no. of quantified results ^{e)}	Median of results from samples with quantified residues only (mg/kg)	Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{d)} only (mg/kg)	Total no. of quantified results ^{e)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA										
Food										
0110000	Citrus fruits	0.5	0.001	0.003–0.27	257	0.029	0.001	0.005–0.2	177	0.028
0130000	Pome fruits	0.7	0.001	0.002–0.148	68	0.017	0.001	0.002–0.11	27	0.02
0140000	Stone fruits	3	0.001	0.002–0.67	108	0.049	0.001	0.001	86	0.03
0150000	Berries and small fruits	0.02*–2	0.001	0.002–1.84	362	0.069	0.001	0.004–1.1	149	0.041
0160000	Miscellaneous fruits	0.02*–15	0.001	0.003–0.29	35	0.021	0.001	0.003–0.073	11	0.017
0210000	Root and tuber vegetables	0.02*–0.8	0.001	0.002–0.05	11	0.014	0.001	0.004–0.047	9	0.014
0220000	Bulb vegetables	0.02*–0.9	0.001	0.007–0.15	83	0.03	0.001	0.007–0.15	53	0.022
0230000	Fruiting vegetables	0.02*–1.5	0.001	0.002–0.94	153	0.047	0.001	0.004–1.0	129	0.042
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.02*–1.5	0.001	0.002–3.3	694	0.045	0.001	0.004–1.2	470	0.049
0250000	Leaf vegetables, herbs and edible flowers	0.02*–10	0.001	0.002–4.5	352	0.029	0.001	0.004–3.3	220	0.042
0260000	Legume vegetables	0.02*–2	0.001	0.021–0.036	2	0.029	0.001	0.021–0.027	2	0.024
0270000	Stem vegetables	0.02*–4	0.001	0.003–0.083	49	0.019	0.001	0.007–0.1	22	0.021
0300000	Pulses (dried)	2	0.001	0.059	1	0.059	0.003	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.02*–4	0.005	<LOQ	0	<LOQ	0.005	<LOQ	0	<LOQ
0631000	Herbal infusions from flowers ^{d)}	0.1*	0.01	<LOQ	0	<LOQ	0.01	<LOQ	0	<LOQ
0632000	Herbal infusions from leaves and herbs ^{d)}	50	0.01	<LOQ	0	<LOQ	0.01	0.12	1	0.12
0700000	Hops (dried)	15	0.025	0.014–0.35	6	0.036	0.022	0.021–3.3	5	0.094
0900000	Sugar plants	0.02*–0.07	0.005	<LOQ	0	<LOQ	0.001	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.5	0.005	0.016	1	0.016	0.01	0.019–0.077	2	0.048
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of spirotetramat is not expected)										
0120000	Tree nuts	0.5	0.01	0.082–0.42	4	0.27	0.01	0.016–0.49	2	0.253
0280000	Fungi, mosses and lichens	0.02*	0.001	<LOQ	0	<LOQ	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.02*	0.003	<LOQ	0	<LOQ	ND	ND	ND	ND
0500000	Cereals	0.02*	0.001	0.051	1	0.051	0.001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs ^{f)}	0.1*–50	0.01	<LOQ	0	<LOQ	0.005	0.12	1	0.12



Findings of not authorised substances in organic products

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Spirotetramat (BYI08330) (spirotetramat and its metabolites spirotetramat – enol, spirotetramat – ketohydroxy, spirotetramat – monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat) ^{b)} occurrence results from the monitoring of unprocessed commodities not labelled as organic				Spirotetramat (BYI08330) (spirotetramat and its metabolite spirotetramat – enol expressed as spirotetramat) ^{c)} occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{d)} only (mg/kg)	Total no. of quantified results ^{e)}	Median of results from samples with quantified residues only (mg/kg)	Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{d)} only (mg/kg)	Total no. of quantified results ^{e)}	Median of results from samples with quantified residues only (mg/kg)
0800000	Spices (dried)	0.1*	0.01	<LOQ	0	<LOQ	0.012	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities.

a) Maximum Residue Level in Reg. (EU) No 2023/1049 amending Annex II of Reg. (EC) No 396/2005; b) Current residue definition for enforcement, implemented in Regulation (EC) No 396/2005 in 2021; c) Residue definition for enforcement before 2021, implemented in Regulation (EC) No 396/2005; d) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); e) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); f) Herbal infusions from flowers and herbal infusions from leaves and herbs appear in both higher and lower parts of the table to indicate the use of the substance for commodities 06310000 and 06320000 and non-use of the substance for all other commodities '06N0000' that are reported under the 'broader' category 060000 on the table. This creates an inconsistency where the results indicating non-uses are overestimated.

Table 3.15.3.2-2b: Occurrence of spirotetramat (BYI08330) monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic based on the residue definitions before and after 2021.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Spirotetramat (BYI08330) (spirotetramat and its metabolites spirotetramat – enol, spirotetramat – ketohydroxy, spirotetramat – monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat) ^{b)} occurrence results from the monitoring of unprocessed commodities not labelled as organic				Spirotetramat (BYI08330) (spirotetramat and its metabolite spirotetramat – enol expressed as spirotetramat) ^{c)} occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{d)} only (mg/kg)	Total no. of quantified results ^{e)}	Median of results from samples with quantified residues only (mg/kg)	Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{d)} only (mg/kg)	Total no. of quantified results ^{e)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities										
Food										
0110000	Citrus fruits	0.5	0.001	0.004–0.17	13	0.01	0.003	0.004–0.042	15	0.011
0130000	Pome fruits	0.7	0.001	<LOQ	0	<LOQ	0.003	<LOQ	0	<LOQ
0140000	Stone fruits	3	0.001	<LOQ	0	<LOQ	0.004	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.02*–2	0.001	0.01–0.53	6	0.073	0.001	0.02	1	0.02
0160000	Miscellaneous fruits	0.02*–15	0.01	<LOQ	0	<LOQ	0.005	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.02*–0.8	0.001	<LOQ	0	<LOQ	0.004	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.02*–0.9	0.01	<LOQ	0	<LOQ	0.03	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.02*–1.5	0.002	0.011–0.033	3	0.024	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.02*–1.5	0.01	<LOQ	0	<LOQ	0.022	0.042	1	0.042



Findings of not authorised substances in organic products

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Spirotetramat (BYI08330) (spirotetramat and its metabolites spirotetramat – enol, spirotetramat – ketohydroxy, spirotetramat – monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat) ^{b)} occurrence results from the monitoring of unprocessed commodities not labelled as organic				Spirotetramat (BYI08330) (spirotetramat and its metabolite spirotetramat – enol expressed as spirotetramat) ^{c)} occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{d)} only (mg/kg)	Total no. of quantified results ^{e)}	Median of results from samples with quantified residues only (mg/kg)	Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{d)} only (mg/kg)	Total no. of quantified results ^{e)}	Median of results from samples with quantified residues only (mg/kg)
0250000	Leaf vegetables, herbs and edible flowers	0.02*–10	0.001	0.01	1	0.01	0.001	<LOQ	0	<LOQ
0260000	Legume vegetables	0.02*–2	0.01	<LOQ	0	<LOQ	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.02*–4	0.003	<LOQ	0	<LOQ	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	2	0.003	<LOQ	0	<LOQ	0.003	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.02*–4	0.001	<LOQ	0	<LOQ	0.001	<LOQ	0	<LOQ
0631000	Herbal infusions from flowers ^{f)}	0.1*	ND	ND	ND	ND	0.01	<LOQ	0	<LOQ
0632000	Herbal infusions from leaves and herbs ^{f)}	50	ND	ND	ND	ND	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	15	0.025	<LOQ	0	<LOQ	ND	ND	ND	ND
0900000	Sugar plants	0.02*–0.07	0.055	<LOQ	0	<LOQ	0.004	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.5	0.01	<LOQ	0	<LOQ	0.01	<LOQ	0	<LOQ
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of spirotetramat is not expected)										
0120000	Tree nuts	0.5	0.01	<LOQ	0	<LOQ	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.02*	0.01	<LOQ	0	<LOQ	0.01	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.02*	ND	ND	ND	ND	ND	ND	ND	ND
0500000	Cereals	0.02*	0.001	<LOQ	0	<LOQ	0.001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs ^{f)}	0.1*–50	0.055	<LOQ	0	<LOQ	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.1*	0.01	<LOQ	0	<LOQ	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2023/1049 amending Annex II of Reg. (EC) No 396/2005; b) Current residue definition for enforcement, implemented in Regulation (EC) No 396/2005 in 2021; c) Residue definition for enforcement before 2021, implemented in Regulation (EC) No 396/2005; d) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); e) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); f) Herbal infusions from flowers and herbal infusions from leaves and herbs appear in both higher and lower parts of the table to indicate the use of the substance for commodities 06310000 and 06320000 and non-use of the substance for all other commodities '06N0000' that are reported under the 'broader' category 060000 on the table. This creates an inconsistency where the results indicating non-uses are overestimated.

Occurrence of spirotetramat in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 6,838 samples were collected and analysed for spirotetramat from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 5,694 (83.27%) were unprocessed and 1,144 (16.73%) processed commodities. No residues were quantified in 6,832 samples out of the 6,838 samples (99.91%). In six samples out of the 6,838 samples (0.09%) spirotetramat was found at or above the analytical LOQ but below or at the MRL. No samples labelled as organic were above MRLs. These findings are summarised in Appendix B, Table B-15.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.15.3.2-3a for unprocessed and in Table 3.15.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on spirotetramat in feed labelled as organic were submitted to EFSA.

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Table 3.15.3.2-3a: Occurrence of spirotetramat (BYI08330) from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic based on the residue definitions before and after 2021.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Spirotetramat (BYI08330) (spirotetramat and its metabolites spirotetramat – enol, spirotetramat - ketohydroxy, spirotetramat – monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat) ^{b)} occurrence results from the monitoring of unprocessed commodities labelled as organic				Spirotetramat (BYI08330) (spirotetramat and its metabolite spirotetramat – enol expressed as spirotetramat) ^{c)} occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{d)} only (mg/kg)	Total no. of quantified results ^{e)}	Median of results from samples with quantified residues only (mg/kg)	Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{d)} only (mg/kg)	Total no. of quantified results ^{e)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA										
Food										
0110000	Citrus fruits	0.5	0.001	0.055	1	0.055	0.001	<LOQ	0	<LOQ
0130000	Pome fruits	0.7	0.001	0.025	1	0.025	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	3	0.001	<LOQ	0	<LOQ	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.02*-2	0.001	<LOQ	0	<LOQ	0.001	0.015	1	0.015
0160000	Miscellaneous fruits	0.02*-15	0.001	<LOQ	0	<LOQ	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.02*-0.8	0.001	<LOQ	0	<LOQ	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.02*-0.9	0.001	<LOQ	0	<LOQ	0.001	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.02*-1.5	0.001	<LOQ	0	<LOQ	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.02*-1.5	0.001	0.021-0.037	3	0.028	0.001	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.02*-10	0.001	<LOQ	0	<LOQ	0.001	<LOQ	0	<LOQ
0260000	Legume vegetables	0.02*-2	0.001	<LOQ	0	<LOQ	0.001	<LOQ	0	<LOQ
0270000	Stem vegetables	0.02*-4	0.001	<LOQ	0	<LOQ	0.001	<LOQ	0	<LOQ
0300000	Pulses (dried)	2	0.001	<LOQ	0	<LOQ	0.01	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.02*-4	0.005	<LOQ	0	<LOQ	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	15	0.05	<LOQ	0	<LOQ	0.022	<LOQ	0	<LOQ
0900000	Sugar plants	0.02*-0.07	0.055	<LOQ	0	<LOQ	ND	ND	ND	ND
1040000	Honey and other apiculture products	0.5	0.01	<LOQ	0	<LOQ	0.012	<LOQ	0	<LOQ
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of spirotetramat is not expected)										
0120000	Tree nuts	0.5	0.05	<LOQ	0	<LOQ	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.02*	0.001	<LOQ	0	<LOQ	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.02*	0.01	<LOQ	0	<LOQ	ND	ND	ND	ND
0500000	Cereals	0.02*	0.001	<LOQ	0	<LOQ	0.001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*-50	0.01	<LOQ	0	<LOQ	0.012	<LOQ	0	<LOQ
0800000	Spices (dried)	0.1*	0.001	<LOQ	0	<LOQ	ND	ND	ND	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

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a) Maximum Residue Level in Reg. (EU) No 2023/1049 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Current residue definition for enforcement, implemented in Regulation (EC) No 396/2005 in 2021; c) Residue definition for enforcement before 2021, implemented in Regulation (EC) No 396/2005; c) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); d) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.15.3.2-3b: Occurrence of spirotetramat (BYI08330) from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic based on the residue definitions before and after 2021.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Spirotetramat (BYI08330) (spirotetramat and its metabolites spirotetramat – enol, spirotetramat - ketohydroxy, spirotetramat – monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat) ^{b)} occurrence results from the monitoring of processed commodities labelled as organic				Spirotetramat (BYI08330) (spirotetramat and its metabolite spirotetramat – enol expressed as spirotetramat) ^{c)} occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{d)} only (mg/kg)	Total no. of quantified results ^{e)}	Median of results from samples with quantified residues only (mg/kg)	Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{d)} only (mg/kg)	Total no. of quantified results ^{e)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA										
Food										
0110000	Citrus fruits	0.5	0.002	<LOQ	0	<LOQ	0.003	<LOQ	0	<LOQ
0130000	Pome fruits	0.7	0.001	<LOQ	0	<LOQ	0.003	<LOQ	0	<LOQ
0140000	Stone fruits	3	0.01	<LOQ	0	<LOQ	ND	ND	ND	ND
0150000	Berries and small fruits	0.02*–2	0.002	<LOQ	0	<LOQ	0.003	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.02*–15	0.002	<LOQ	0	<LOQ	0.022	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.02*–0.8	0.003	<LOQ	0	<LOQ	0.01	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.02*–0.9	ND	ND	ND	ND	ND	ND	ND	ND
0230000	Fruiting vegetables	0.02*–1.5	0.01	<LOQ	0	<LOQ	0.01	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.02*–1.5	0.055	<LOQ	0	<LOQ	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.02*–10	0.01	<LOQ	0	<LOQ	0.045	<LOQ	0	<LOQ
0260000	Legume vegetables	0.02*–2	0.01	<LOQ	0	<LOQ	ND	ND	ND	ND
0270000	Stem vegetables	0.02*–4	0.01	<LOQ	0	<LOQ	ND	ND	ND	ND
0300000	Pulses (dried)	2	0.055	<LOQ	0	<LOQ	0.02	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.02*–4	0.001	<LOQ	0	<LOQ	0.004	<LOQ	0	<LOQ
0700000	Hops (dried)	15	ND	ND	ND	ND	ND	ND	ND	ND
0900000	Sugar plants	0.02*–0.07	0.055	<LOQ	0	<LOQ	ND	ND	ND	ND
1040000	Honey and other apiculture products	0.5	ND	ND	ND	ND	0.01	<LOQ	0	<LOQ
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of spirotetramat is not expected)										
0120000	Tree nuts	0.5	0.01	<LOQ	0	<LOQ	0.022	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.02*	0.01	<LOQ	0	<LOQ	0.05	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.02*	ND	ND	ND	ND	ND	ND	ND	ND

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Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Spirotetramat (BYI08330) (spirotetramat and its metabolites spirotetramat – enol, spirotetramat – ketohydroxy, spirotetramat – monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat) ^{b)} occurrence results from the monitoring of processed commodities labelled as organic				Spirotetramat (BYI08330) (spirotetramat and its metabolite spirotetramat – enol expressed as spirotetramat) ^{c)} occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{d)} only (mg/kg)	Total no. of quantified results ^{e)}	Median of results from samples with quantified residues only (mg/kg)	Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{d)} only (mg/kg)	Total no. of quantified results ^{e)}	Median of results from samples with quantified residues only (mg/kg)
0500000	Cereals	0.02*	0.0001	<LOQ	0	<LOQ	0.001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*–50	0.005	<LOQ	0	<LOQ	ND	ND	ND	ND
0800000	Spices (dried)	0.1*	0.05	<LOQ	0	<LOQ	0.05	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2023/1049 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Current residue definition for enforcement, implemented in Regulation (EC) No 396/2005 in 2021; c) Residue definition for enforcement before 2021, implemented in Regulation (EC) No 396/2005; d) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); e) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of spirotetramat in the EU Organic Farming Information System

The EU OFIS reported 9 findings for spirotetramat (BYI08330) in 2021 and 2022, 2 samples of spirotetramat and spirotetramat-enol and one sample of spirotetramat and its 4 plant metabolites spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside, expressed as spirotetramat. Eight of the products sampled and analysed had EU origin and one was of non-EU origin. Residues were found in two samples of citrus fruits (lemons), 4 samples of tree nuts (pistachios), 1 sample of fruiting vegetables (tomatoes), 1 sample of leaf vegetables, herbs and edible flowers (spinaches) and one sample of products or part of products exclusively used for animal feed production (hop pellets). Two samples of bulb vegetables (onions) were analysed for spirotetramat and spirotetramat-enol and one sample of bulb vegetables (onions) was analysed for spirotetramat and its 4 plant metabolites spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat. The concentrations of spirotetramat residues were above LOQ but below MRL in all nine samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005³. The highest concentration was reported for a sample of tomatoes of EU origin, with the quantified level of 0.17 mg/kg. These findings are summarised in Table 3.15.3.2-4.

Table 3.15.3.2-4: Occurrence of spirotetramat from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
Spirotetramat				
0110030	Lemons	0.5	0.028; 0.032 – Lemons	ND
0120100	Pistachios	0.5	0.036; 0.04; 0.036 – Pistachios	ND
0231010	Tomatoes	1	0.17 – Tomatoes	ND
0252010	Spinaches	7	0.013 – Spinaches	ND
1200000	Products or part of products exclusively used for animal feed production	NA	ND	0.036 – Hop pellets (Feed-related matrix)
Spirotetramat and spirotetramat-enol ^{c)}				
0220020	Onions	0.4	0.04; 0.041 – Onions (red)	ND
Spirotetramat and its 4 metabolites spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat ^{d)}				
0220020	Onions	0.4	0.05 – Onions (red)	ND
Samples of non-EU origin				
Spirotetramat				
0120100	Pistachios	0.5	ND	0.067 – Pistachios (roasted)

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2023/1049 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) Current residue definition for enforcement, implemented in Regulation (EC) No 396/2005 in 2021; d) Residue definition for enforcement before 2021, implemented in Regulation (EC) No 396/2005.

Occurrence of spirotetramat in untreated samples (control samples) from residue trials

Spirotetramat residues were found in control (untreated) samples across several European regions. Residues were quantified in an orange control sample from Portugal and several pear control samples from southern France (Italy, 2018b). Additionally, residues were detected in apple control samples from the United Kingdom³⁵, a cherry control sample from Spain and several melon control samples from Greece and Spain (Austria, 2019; Italy, 2018b). A kale control sample from Germany, a kohlrabi control sample from the Netherlands and a cucumber control sample from Italy also showed quantified residues (Austria, 2019; Italy, 2018b).

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Regarding the trial on apples from the United Kingdom³⁵, it was reported that the treated and untreated specimens had been switched (Austria, 2019). No other evidence-based explanations on the causes for these occurrences in control (untreated) samples were provided in the above-mentioned evaluation reports.

The summary of the quantified findings of spirotetramat residues in control (untreated) samples from residue trials carried out for the critical GAP⁴ per crop is given below in Table 3.15.3.2-5.



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Table 3.15.3.2-5: Summary of the quantified findings of spirotetramat (or BYI08330) in control (untreated) samples from residue trials carried out for the critical GAP per crop based on the residue definitions before and after 2021.

Commodity	Country/Area	Spirotetramat (BYI08330) (mg/kg)	Spirotetramat-enol expressed as spirotetramat (mg/kg)	Spirotetramat-ketohydroxy expressed as spirotetramat (mg/kg)	Spirotetramat-monohydroxy expressed as spirotetramat (mg/kg)	Spirotetramat-enol-glucoside, expressed as spirotetramat (mg/kg)	Spirotetramat (BYI08330) (spirotetramat and its metabolite spirotetramat-enol expressed as spirotetramat) (mg/kg) ^{a)}	Spirotetramat (BYI08330) (spirotetramat and its metabolites spirotetramat-enol, spirotetramat - ketohydroxy, spirotetramat - monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat) (mg/kg) ^{b)}
Apple (fruit)	United Kingdom ³⁵	0.03 ^{c)} ; 0.07	0.012 ^{c)} ; 0.026	0.012 ^{c)} ; 0.013	ND	ND	0.044 ^{c)} ; 0.097	0.076 ^{c)} ; 0.13
Cherry (fruit)	Spain	0.04	0.083	0.060	0.28	0.083	0.13	0.55
Cucumber	Italy	ND	ND	ND	ND	ND	ND	0.055
Kale (leaf)	Germany	0.01	ND	ND	ND	ND	0.024	0.056
Kohlrabi (leaf)	Netherlands	0.01	0.012	ND	ND	ND	0.022	0.055
Melon (peel)	Greece	ND	0.015	0.017	0.019	0.011	0.025	0.072
	Spain	0.01; 0.01	0.024	0.026	0.027	0.017	0.023; 0.035	0.055, 0.10
Orange (peel)	Portugal	0.01	ND	ND	ND	ND	0.022	0.055
Pear (fruit)	Southern France	0.06; 0.07; 0.28	0.017; 0.018; 0.080	0.052	0.016, 0.016, 0.81	0.014	0.079; 0.090; 0.36	0.12, 0.13, 0.53

ND – no data available

a) Current residue definition for enforcement, implemented in Regulation (EC) No 396/2005 in 2021; b) Residue definition for enforcement before 2021, implemented in Regulation (EC) No 396/2005; c) The treated and untreated specimens had been switched.



- Could the presence of spirotetramat and/or its residues be due to biocide use?

Spirotetramat and its transformation products considered in this report are not authorised for biocidal use, therefore, residues due to biocidal use are not expected for spirotetramat.

3.15.3.3 Behaviour in food and feed products

- What key physico-chemical properties of spirotetramat are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of **spirotetramat** are reported in Table 3.15.3.3a.

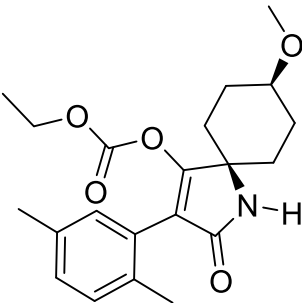
Spirotetramat shows very low persistence in soil ($DT_{90} < 1$ year) (see also Section 3.15.3.5). Regarding sorption to soil, the geometric mean of K_{Foc} in Table 3.15.3.3a indicates that the substance has medium mobility in soil (EFSA, 2013i).

The maximum calculated PEC_w for spirotetramat for the representative uses was 8.43 µg/L (application to citrus; 2 × 288 g a.s./ha) (EFSA, 2013i).

Spirotetramat is hydrolytically stable under the standard food/feed processing condition of pasteurisation, but it degrades to spirotetramat-enol under baking (15% AR) and sterilisation (85% AR) (EFSA, 2013i). Considering that spirotetramat may degrade under some food/feed processing conditions, a potential formation of degradation products would not be captured by the analytical methods because these products are not included in the residue definition for monitoring and, therefore, are not analysed. This would be expected to result in a decrease in the measured residues in the processed commodity when compared with the raw commodity. On the other hand, some processes such as drying may result in higher concentrations of residues in the processed commodities. Therefore, both possibilities (decrease or increase of residues) are plausible in this case, depending on the process.

Spirotetramat has a low vapour pressure (5.6×10^{-9} Pa at 20°C) (EFSA, 2013i).

Table 3.15.3.3a: Physico-chemical properties of spirotetramat (EFSA, 2013i)

Structural formula	
Isomeric composition	Only the cis-isomer here represented is the active substance
Appearance (state purity)	Pure material: light beige powder (99.1 %) Technical material: white powder (97.5 %)
Melting point (state purity)	142°C (99.2%)
Boiling point	NA
Temperature of decomposition	235°C (99.2 %)
Vapour pressure (state temperature, state purity)	5.6 × 10 ⁻⁹ Pa for 20°C (99.2%) 1.5 × 10 ⁻⁸ Pa for 25°C (99.2%) 1.5 × 10 ⁻⁶ Pa for 50°C (99.2%)



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Henry's law constant (state temperature)	at pH 4: $6.24 \times 10^{-8} \text{ Pa} \times \text{m}^3 \times \text{mol}^{-1}$ at pH 7: $6.99 \times 10^{-8} \text{ Pa} \times \text{m}^3 \times \text{mol}^{-1}$ at pH 9: $1.09 \times 10^{-7} \text{ Pa} \times \text{m}^3 \times \text{mol}^{-1}$
Solubility in water (state temperature, state purity and pH)	pH 4: 33.5 mg/L at 20°C (99.1%) pH 7: 29.9 mg/L at 20°C (99.1%) pH 9: 19.9 mg/L at 20°C (99.1%)
Partition coefficient (state temperature, pH and purity)	$\log \text{Pow} = 2.5$ at 20°C (pH=4–9; 99.1%)
Partition coefficient (octanol/air)	NA
Atmospheric half-life	$\text{DT}_{50} = 1.69$ hours derived by the Atkinson model (version 1.9), OH (12 h) radical ion concentration assumed = $1.5 \times 10^6 \text{ cm}^{-3}$
Dissociation constant (state purity)	$\text{pK}_a = 10.7$ (99.1 %)
Soil adsorption (geometric mean)	$K_{\text{Foc}} = 254 \text{ mL/g}$
Hydrolytic degradation (>10%)	DT_{50} (pH 4, 25°C): 32.5 d (SFO, $r_2 = 1$) DT_{50} (pH 7, 25°C): 8.6 d (SFO, $r_2 = 1$) DT_{50} (pH 9, 25°C): 0.32 d (SFO, $r_2 = 1$)

DT_{50} – Disappearance time of 50% of the substance in field studies; NA – not applicable; pH – Potential of Hydrogen;
 P_{ow} – Octanol/water Partition Coefficient.

Spirotetramat-enol

The physico-chemical properties of spirotetramat-enol are reported in Table 3.15.3.3b.

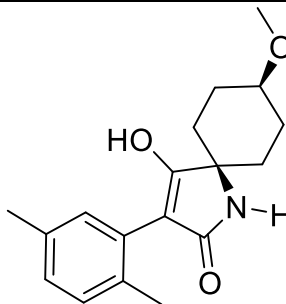
Spirotetramat-enol shows very low to moderate persistence in soil ($\text{DT}_{90} < 1$ year) (see also Section 3.15.3.5). Regarding sorption to soil, the range of $K_{\text{doc, OC}}$ in Table 3.15.3.3b indicates that the substance has very high mobility in soil (EFSA, 2013i).

The maximum PEC_w of spirotetramat-enol is 15.6 µg/L (application to citrus; $2 \times 288 \text{ g a.s./ha}$) (EFSA, 2013i).

The substance is hydrolytically stable under boiling/brewing/baking and sterilisation conditions (EFSA, 2013i). Considering that spirotetramat-enol is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Spirotetramat-enol is considered to have low volatility (EFSA, 2013i).

Table 3.15.3.3b: Physico-chemical properties of spirotetramat-enol (EFSA, 2013i; Sigma-Aldrich, 2023)

Structural formula	
Isomeric composition	Only cis-isomer (shown above) considered
Appearance (state purity)	Odourless white to light yellow to light beige solid ($\geq 98\%$)
Melting point (state purity)	227–233°C ($\geq 98\%$)
Boiling point	NA
Temperature of decomposition	NA



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Vapour pressure (state temperature, state purity)	5.6×10^{-4} Pa (no temperature specified) ($\geq 98\%$)
Henry's law constant (state temperature)	NA
Solubility in water (state temperature, state purity and pH)	33.4 mg/L (no temperature or pH specified) ($\geq 98\%$)
Partition coefficient (state temperature, pH and purity)	$\log P_{ow} = 0.3$ (no temperature pH 7) ($\geq 98\%$)
Partition coefficient (octanol/air)	NA
Atmospheric half-life	$DT_{50} = 1.72$ hours derived by the Atkinson model (version 1.9), OH (12 h) radical concentration assumed = $1.5 \times 10^6 \text{ cm}^{-3}$
Dissociation constant (state purity)	NA
Soil adsorption (geometric mean)	$K_{doc} = 47 \text{ mL/g}$
Hydrolytic degradation (>10%)	Hydrolytically stable at pH 4, 7 and 9

DT_{50} – Disappearance time of 50% of the substance in field studies; NA – not applicable; pH – Potential of Hydrogen; P_{ow} – Octanol/water Partition Coefficient.

Spirotetramat-ketohydroxy

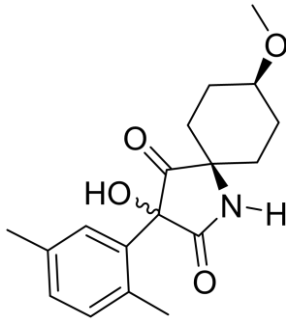
The physico-chemical properties of spirotetramat-ketohydroxy are reported in Table 3.15.3.3c.

Spirotetramat-ketohydroxy exhibits low to moderate persistence ($DT_{90} < 1$ year) (EFSA, 2013i). Regarding sorption to soil, the range of K_{Foc} in Table 3.15.3.3c indicates that the substance has high mobility in soil (EFSA, 2013i).

The maximum PEC_w of spirotetramat-ketohydroxy is 8.59 $\mu\text{g/L}$ (application to citrus; $2 \times 288 \text{ g a.s./ha}$) (EFSA, 2013i).

It is stable under pasteurisation but degrades almost completely to spirotetramat-MA-amide⁷⁶ under sterilisation (99%AR) and slightly under cooking/boiling/baking conditions (5%AR) (EFSA, 2013i, 2020e). Considering that spirotetramat-ketohydroxy may degrade under some food/feed processing conditions, a potential formation of degradation products would not be captured by the analytical methods because these products are not included in the residue definition for monitoring and, therefore, are not analysed. This would be expected to result in a decrease in the measured residues in the processed commodity when compared with the raw commodity. On the other hand, some processes such as drying may result in higher concentrations of residues in the processed commodities. Therefore, both possibilities (decrease or increase of residues) are plausible in this case, depending on the process.

Table 3.15.3.3c: Physico-chemical properties of spirotetramat-ketohydroxy (EFSA, 2013i; Sigma-Aldrich, 2023)

Structural formula	
Isomeric composition	Enantiomer composition unspecified
Appearance (state purity)	White solid (98%)
Melting point (state purity)	NA

⁷⁶ cis-1-[(2,5-dimethylphenyl) (hydroxy)acetyl]amino}-4 methoxycyclohexanecarboxylic acid



Findings of not authorised substances in organic products

Boiling point	NA
Temperature of decomposition	NA
Vapour pressure (state temperature, state purity)	NA
Henry's law constant (state temperature)	NA
Solubility in water (state temperature, state purity and pH)	228 mg/L (no temperature or pH specified) (98%)
Partition coefficient (state temperature, pH and purity)	log Pow = 1.3 (no temperature pH 7) (98%)
Partition coefficient (octanol/air)	NA
Atmospheric half-life	NA
Dissociation constant (state purity)	pKa = 11.0 (98 %)
Soil adsorption (geometric mean)	K _{Foc} = 59 mL/g
Hydrolytic degradation (>10%)	DT ₅₀ (pH 4, 25°C): No degradation observed DT ₅₀ (pH 7, 25°C): 82.7 d (SFO, chi ² -error = 0.8) DT ₅₀ (pH 9, 25°C): 4.9 d (SFO, chi ² -error = 4.9)

DT₅₀ – Disappearance time of 50% of the substance in field studies; NA – not applicable/available; pH – Potential of Hydrogen;
P_{ow} – Octanol/water Partition Coefficient.

Spirotetramat-monohydroxy

The physico-chemical properties of spirotetramat-monohydroxy are reported in Table 3.15.3.3d.

It is stable under boiling/brewing/baking and sterilisation (EFSA, 2013i). Considering that spirotetramat-monohydroxy is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Table 3.15.3.3d: Physico-chemical properties of spirotetramat-monohydroxy (EFSA, 2013i; Sigma-Aldrich, 2023)

Structural formula	
Isomeric composition	Isomer composition unspecified
Appearance (state purity)	White to light yellow solid (98%)
Melting point (state purity)	176–184°C (98%)
Boiling point	NA
Temperature of decomposition	NA
Vapour pressure (state temperature, state purity)	NA
Henry's law constant (state temperature)	NA
Solubility in water (state temperature, state purity and pH)	NA
Partition coefficient (state temperature, pH and purity)	log Pow = 2.6 (no temperature or pH specified) (98%)
Partition coefficient (octanol/air)	Log Poa = 15.6 (EPISuite KOAWIN v1.10) (Debler et al. 2024)
Atmospheric half-life	NA
Dissociation constant (state purity)	NA
Soil adsorption (geometric mean)	NA
Hydrolytic degradation (>10%)	NA

NA – not applicable; pH – Potential of Hydrogen; P_{ow} – Octanol/water Partition Coefficient; P_{oa} – Octanol/air Partition Coefficient.

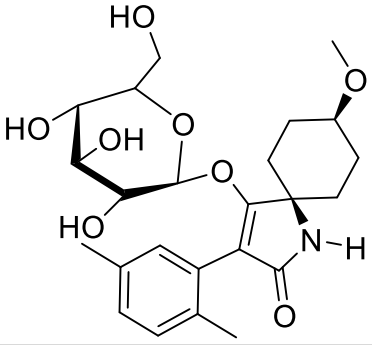


Spirotetramat-enol-glucoside

The physico-chemical properties of spirotetramat-enol-glucoside are reported in Table 3.15.3.3e.

Spirotetramat-enol-glucoside is stable under pasteurisation, but it degrades to spirotetramat-enol under cooking/boiling/baking (10% AR) and sterilisation conditions (40% AR) (EFSA, 2013i, 2020e). Considering that spirotetramat-enol-glucoside may degrade under some food/feed processing conditions, a potential formation of degradation products would not be captured by the analytical methods because these products are not included in the residue definition for monitoring and, therefore, are not analysed. This would be expected to result in a decrease in the measured residues in the processed commodity when compared with the raw commodity. On the other hand, some processes such as drying may result in higher concentrations of residues in the processed commodities. Therefore, both possibilities (decrease or increase of residues) are plausible in this case, depending on the process.

Table 3.15.3.3e: Physico-chemical properties of spirotetramat-enol-glucoside (EFSA, 2013i; Sigma-Aldrich, 2023)

Structural formula	
Isomeric composition	Only cis-isomer (shown above) considered
Appearance (state purity)	White to light yellow solid (95%)
Melting point (state purity)	NA
Boiling point	NA
Temperature of decomposition	NA
Vapour pressure (state temperature, state purity)	NA
Henry's law constant (state temperature)	NA
Solubility in water (state temperature, state purity and pH)	Slightly soluble
Partition coefficient (state temperature, pH and purity)	NA
Partition coefficient (octanol/air)	NA
Atmospheric half-life	NA
Dissociation constant (state purity)	NA
Soil adsorption (geometric mean)	NA
Hydrolytic degradation (>10%)	NA

NA – not applicable; pH – Potential of Hydrogen

3.15.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion



of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. The highest drift of spirotetramat to neighbouring fields may occur during its applications to fruit crops (up to 29.2 %), hops (19.33%), vineyards and vegetables (up to 8.02 %) and field crops (up to 2.77 %).

Drift values should be considered the rate received by a neighbouring field, expressed as a percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. Buffer zones or spray drift-reducing nozzles).

If organic crops are present adjacent to the conventional crops treated, measurable residues of spirotetramat in the untreated crop cannot be excluded. However, since the nature of the potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

As authorised products are to be applied in liquid form, dust drift is not expected to occur.

3.15.3.5 Accumulated/historical residue levels in soil

- What is the persistence of spirotetramat and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

Since, according to available data (EFSA, 2013i), the individual DT_{90s} of spirotetramat and its transformation products spirotetramat-enol and spirotetramat-ketohydroxy are <1 year, they are not expected to accumulate in soil over successive seasons. For their sum, however, the DT₉₀ may exceed 100 days, therefore, the nature and magnitude of residues in rotational crops were investigated.

Field rotational crop studies conducted with spirotetramat did not show significant residues above the LOQ (0.01 mg/kg) in mustard green, turnips and wheat sown as rotational crops 30 days after the last application of spirotetramat to a primary crop (EFSA, 2013i). It was noted, however, that these trials were underdosed when compared to the most critical authorised GAP⁴ (EFSA, 2020e).

Overall, the presence of spirotetramat and spirotetramat-enol in untreated crops is less likely to be associated with plant uptake from contaminated soil. This is also valid for organic crops, when planted in fields that were previously used for conventional agriculture, considering that it requires at least 2 years after the last chemical treatment in order for organic crops to be planted in such area².

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Accumulation of spirotetramat in soil is not expected.

3.15.3.6 Residues from water used for irrigation

- Is there evidence that residues of spirotetramat present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for spirotetramat in water samples were identified:

- The EMPODAT database (data retrieved on 25 March 2024) reports 71 analytical results from surface water samples collected in the Netherlands between 2017 and 2019;
- The NAIADES database (data retrieved on 25 March 2024) reports 948 analytical results from surface water samples collected in France between 2020 and 2022.

Based on the screening process described in section 'Data and methodologies', for 91.1% of surface water samples analysed and reported in the above-mentioned databases (928 samples), the residue concentrations in these waters were below the screening Cw of 0.07 µg/L and, therefore, transfer of residues from surface water sources to plant commodities is unlikely.

For 8.9% of samples (91 out of 1019 results), the residue concentrations were found to be at or above the screening Cw of 0.07 µg/L and the potential transfer of residues to plant commodities if water containing residues at these levels is used for irrigation cannot be excluded. Since Cw is a screening value derived from worst-case calculations it requires experimental evidence in order to confirm or rule out the potential transfer of residues from the specific water sources. Therefore, if spirotetramat residues are quantified in organic commodities, analysis of the water source used to irrigate the plant is recommended.

On the EC's IPCHEM¹², NAIADES database provides results for spirotetramat-enol (309 surface water samples, retrieved on 4 April 2024) and for spirotetramat-ketohydroxy (602 surface water samples, retrieved on 15 October 2024) collected in France from 2020 to 2022. All results had quantified values below 0.1 µg/L. The very low quantified values suggest that transfer of residues of spirotetramat-enol and spirotetramat-ketohydroxy in plant commodities if these water sources are used to irrigate plants is unlikely.

Note was taken that the total number of surface water samples analysed for spirotetramat, spirotetramat-enol and spirotetramat-ketohydroxy on IPCHEM was 2 to 3 orders of magnitude lower than the total samples analysed for most substances considered in this report.

Based on the above and considering the limitations of the data, it can be concluded that the transfer of residues of spirotetramat from water sources to plant commodities when this water is used to irrigate plants cannot be excluded.

3.15.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *spirotetramat*, *industry/industrial*, and *air/atmosphere*) did not identify any relevant European study.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water.

A mapping exercise was conducted by overlaying georeferenced water sampling data from IPCHEM (2020–2022) with georeferenced data on chemical industry facilities from the European Industrial Emissions Portal. Of the 91 relevant water samples (exceeding the screening value, as reported in Table 2.1), 30 were collected between 2020–2022. For the conducted spatial analysis, it is important to note that these numbers reflect the total number of sampling events rather than distinct sampling locations, as some sites were monitored multiple times during the study period. Of the 30 samples, none were found within a 1 km or 5 km radius of a chemical facility.

A literature review was conducted to gather additional relevant information. A search in the Scopus database (conducted on February 7, 2025, using the keywords *spirotetramat*, *industry/industrial*, and *water*) did not identify any relevant European study.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Based on information on the possible plant uptake of spirotetramat from EU soil, the transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 17, 2025, using the keywords *spirotetramat*, *industry/industrial*, and *soil/sediment*) did not identify any relevant European study.

3.15.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Medium and long-range aerial transport of residues

In a study investigating the potential transport of pesticide residues from apple-growing fields in South Tyrol (Vinschgau Valley) to higher altitudes, an analysis of vegetation showed spirotetramat concentrations up to 0.0027 mg/kg in five out of 53 samples analysed (Brühl et al. 2024). The results of this study indicate that aerial transport (through aerosols) as a potential source of residues of spirotetramat in vegetation outside the treated areas cannot be excluded.

3.15.4 Conclusions on spirotetramat

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use.
- Residue trials carried out to support the critical GAPs⁴ for spirotetramat, gave residue concentrations up to 21.8 mg/kg and 5.5 mg/kg (highest values for herbal infusions from leaves and herbs and for leaf vegetables, herbs and edible flowers, respectively, based on the residue definition from 2021 onwards). Concentrations in the ranges reported in Table



3.15.3.2-1 might be associated with active use of spirotetramat according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.

- Spirotetramat was quantified in the context of residue trials in several European countries in untreated (control) samples with the highest concentration observed in one control sample of pears from Southern France (0.36 mg/kg) based on the residue definition from 2021 onwards.
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for spirotetramat in unprocessed commodities with authorised uses ranged from 0.014 mg/kg in root and tuber vegetables to 0.094 mg/kg in hops (dried) analysed based on the applicable residue definition from 2021 onwards.
- In unprocessed products labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 there were no commodity groups with five or more quantified findings.
- In processed commodities, residues of spirotetramat were not quantified in any of the products labelled as organic and sampled under the EU monitoring programmes from 2020 to 2022. In samples from processed products not labelled as organic, the median concentration of residues of spirotetramat in citrus fruits (the only commodity with five or more quantified findings) was 0.011 mg/kg based on the residue definition from 2021 onwards. In general, when present in the raw commodity, residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can be so low that analytical methods with high sensitivity cannot quantify them. On the other hand, spirotetramat can degrade under certain food/feed processing conditions, forming degradation products not captured by analytical methods, leading to lower measured residues of spirotetramat.
- Overall, in commodities labelled as organic, spirotetramat was quantified in 0.09% of samples (6 out of 6,838 samples). This percentage is 63 times lower than the percentage reflecting the number of findings in samples not labelled as organic (5.51%) (see Appendix B, Tables B-15.1 and B-15.2). These results suggest that the occurrence of residues of spirotetramat in organic products is less likely when compared with conventional commodities.
- Potential sources of the unintentional presence of residues of spirotetramat in commodities of plant origin are drift from applications in conventional crops in the vicinity to organic cultures and medium-range aerosol transport.
- Spirotetramat is not persistent in soil. Plant uptake of residues of spirotetramat from contaminated soil is considered a less likely explanation for residues found in crops where spirotetramat has not been actively used.
- A potential source of the unintentional presence of residues of spirotetramat in commodities of plant origin is transferred from water used for irrigation. If spirotetramat residues are quantified in organic commodities, analysis of the water source used to irrigate the plant is recommended.

Findings of not authorised substances in organic products

- A mapping of the locations of samples analysed for spirotetramat on IPCHEM with georeferenced data from the EEA's industrial emissions portal did not show associations between environmental occurrence and industrial activity in the surrounding areas. No study was identified in the literature showing the transfer of residues of spirotetramat from industrial activity to the environment and from the environment to plants.
- Considering that spirotetramat is no longer approved for plant protection purposes in the EU, residues of spirotetramat should gradually decrease from October 2025 onwards.

The pathways of residues of spirotetramat and spirotetramat-enol to plants and plant commodities are summarised in Figures 15.1 and 15.2.



Figure 15.1: Pathways of residues of spirotetramat to plants and plant commodities

Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded



Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded



3.16 Cyprodinil

3.16.1 Method(s)

- What is/are the residues to be monitored for the active substance cyprodinil according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

For the active substance 'cyprodinil', the residue definition for enforcement in food and feed of plant origin has been proposed as 'cyprodinil' in the EFSA peer review and the EFSA MRL review (EFSA, 2006, 2013j, 2025b). This residue definition is applicable to primary, rotational crops, processed products. This residue definition for enforcement is implemented in Regulation (EC) No 396/2005³ and is also applicable to honey.

Based on the above only residues of cyprodinil are to be monitored in foods of plant origin, honey and other apiculture products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

Multi-residue methods using QuEChERS, in combination with HPLC-MS/MS and GC-MS are validated for the determination of residues of cyprodinil (LOQ of 0.01 mg/kg) in high water, high acid content and dry plant commodities (EFSA, 2013j, 2021e) with HPLC-MS/MS also having been validated for the determination of residues of cyprodinil (LOQ of 0.01 mg/kg) in high oil content and no group (straw) commodities (EFSA, 2025b).

Another multi-residue method (DFG S19) has been sufficiently validated in high water, high acid, high oil content, and dry commodities. This method reaches an LOQ of 0.02 mg/kg based on full scan GC-MS (EFSA, 2006, 2013j).

An HPLC-UV method is also sufficiently validated for the analysis of residues of cyprodinil with an LOQ of 0.01 mg/kg in high water and high acid content commodities, and an LOQ of 0.02 mg/kg in dry commodities (EFSA, 2013j).

According to the EURL for Residues of Pesticides (2024, under 'Documentation as provided to EFSA'), a multi-residue citrate-buffered QuEChERS method based on GC-MS/MS is validated for monitoring cyprodinil residues in honey samples at an LOQ of 0.002 mg/kg. Higher sensitivities are achieved by utilising multi-residue methods based on LC-Q-TOF (LOQ: 0.001 mg/kg). A multi-residue QuEChERS method based on GC-MS/MS is available to monitor cyprodinil residues in pollen collected by bees with an LOQ of 0.005 mg/kg.

Overall, there are multi-residue methods for the monitoring of residues of cyprodinil in high water, high acid, high oil content and dry plant commodities, as well as in honey and other apiculture products. LOQs for methods of analysis of cyprodinil residues in products of plant origin and honey and other apiculture products range from 0.001 to 0.02 mg/kg.

3.16.2 Authorisation status and use

- Is cyprodinil currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has cyprodinil ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?



a) Authorisations for plant protection use in conventional agriculture

Cyprodinil has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of approval of the active substance is on 31 October 2026 as indicated by the EU Pesticides Database⁵ (accessed on 28 February 2025). The application for the renewal of the approval of cyprodinil is under assessment.

According to the EU Pesticides Database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, France, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, and Slovakia.

b) Authorisations for uses other than plant protection

Biocidal use

According to the information from the ECHA website⁶ (accessed on 12 February 2024) cyprodinil has not been approved for biocidal use in the EU Member States, Iceland, Liechtenstein and Norway.

Other uses

According to the search carried out on the ECHA website⁹ on 6 June 2024, cyprodinil is not currently registered under REACH.

- What is/was the actual use of cyprodinil? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of cyprodinil

Cyprodinil is a fungicide that belongs to the anilinopyrimidine group of compounds used in a wide spectrum of crops (both foliar and seed treatment). It is systemically absorbed through the leaves and functions by inhibiting the penetration and mycelial growth of the fungi. Cyprodinil is effective against fungi in the *Ascomycetes*, *Basidiomycetes*, and *Deuteromycetes* classes. It is applied as foliar and seed treatment (EFSA, 2013j).

Conditions of use and applicable crops

The uses reported in the EFSA MRL review for cyprodinil included applications in the northern and southern EU in food and feed commodities belonging to the following crop groups: pome fruits, stone fruits, berries and small fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, leaf vegetables, herbs, and edible flowers, legume vegetables, stem vegetables, pulses (dried), cereals, herbal infusions from roots, and root and rhizome spices (dried) (EFSA, 2013j). After the EFSA MRL review, applications were submitted to EFSA to modify the existing MRLs for stem vegetables and berries and small fruits (EFSA, 2015j, 2019e,f, 2021e).

Cyprodinil treatment included outdoor and indoor foliar applications, a local treatment and a seed treatment.

- Foliar applications were reported for commodities belonging to the following crop groups: pome fruits, stone fruits, berries and small fruits, root and tuber vegetables, bulb



vegetables, fruiting vegetables, leaf vegetables, herbs, and edible flowers, legume vegetables, stem vegetables, pulses (dried), cereals, herbal infusions from roots, and root and rhizome spices (dried). Application rates range from 0.06 kg a.s./ha to 0.75 kg a.s./ha for outdoor cultivation and from 0.06 kg a.s./ha to 0.38 kg a.s./ha for indoor cultivation (EFSA, 2013j, 2015j, 2019e,f, 2021e, 2025b).

- A local treatment (indoor) of cyprodinil was reported for leaf vegetables, herbs and edible flowers (witloofs) at 0.03 kg a.s./hL (EFSA, 2013j).
- An outdoor seed treatment of cyprodinil was reported for cereals (barley) at 5 g a.s./100 kg seeds (EFSA, 2013j).

b) Uses for purposes other than plant protection

Biocidal use

Cyprodinil is not approved for biocidal use, therefore, its use in biocidal products is not expected (see also 'authorisations for purposes other than plant protection/biocidal use').

Other use

A search carried out on the ECHA website⁹ for REACH registrations did not give any results for cyprodinil.

3.16.3 Sources of residues in plants

3.16.3.1 Natural occurrence

- Is there evidence that cyprodinil occurs naturally? What is known about the natural origin of this substance?

Cyprodinil is a synthetic chemical produced industrially through chemical processes (Lewis et al., 2016). No information on the potential natural presence of cyprodinil was found in the literature²².

3.16.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of cyprodinil per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of cyprodinil in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.16.3.2-1 to 3.16.3.2-4. Findings relating to residues in control (untreated) samples are also discussed in this section.

In all matrices and for both residue trials and results from monitoring, cyprodinil residue concentrations refer to the residue definition for enforcement (i.e. cyprodinil)

Occurrence of cyprodinil from residue trials carried out for the critical GAP per crop

Residues of cyprodinil were quantified in pome fruits, stone fruits, berries and small fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, leaf vegetables, herbs, and edible flowers, legume vegetables, stem vegetables, pulses (dried), cereals (both in grain and straw), herbal infusions from roots, and root and rhizome spices (EFSA, 2013j, 2015j, 2019e,f, 2021e, 2025b).



Findings of not authorised substances in organic products

The results from residue trials carried out for the critical GAP⁴ per crop for cyprodinil in commodities for which uses were submitted to EFSA are summarised in Table 3.16.3.2-1 'Occurrence of cyprodinil from residue trials carried out for the critical GAP per crop'.

Table 3.16.3.2-1: Occurrence of cyprodinil from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Cyprodinil (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
Food				
0130000	Pome fruits	2	0.04–0.88	0.32
0140000	Stone fruits	2	0.10–0.50	0.17
0150000	Berries and small fruits	0.02*–8	<LOQ (0.01)–4.1	0.68
0210000	Root and tuber vegetables	0.02*–1.5	0.013–1.04	0.11
0220000	Bulb vegetables	0.02*–0.8	<LOQ (0.02)–0.43	0.045
0230000	Fruiting vegetables	0.02*–1.5	0.02–0.97	0.16
0250000	Leaf vegetables, herbs and edible flowers	0.02*–40	<LOQ (0.02)–8.9	0.39
0260000	Legume vegetables	0.02*–2	<LOQ (0.02)–1.15	0.13
0270000	Stem vegetables	0.02*–30	<LOQ (0.01)–3.12	0.21
0300000	Pulses (dried)	0.2	<LOQ (0.02)–0.11	0.03
0500000	Cereals	0.02*–4	<LOQ (0.02)–2.2	0.32
0633000	Herbal infusions from roots ^{c)}	1.5–3	0.21–1.04	0.45
0840000	Root and rhizome spices (dried) ^{c)}	1.5	0.21–1.04	0.45
Feed				
1200000	Cereal straw	NA	0.06–5.78	0.56

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; NR: no residue trials data are available.

a) Maximum Residue Level in Reg. (EU) No 2023/1069 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA, 2013j, 2015j, 2019e,f, 2021e, 2025b; c) Uses in herbal infusions from roots and root and rhizome spices were supported from residue trials in root and tuber vegetables (carrots) (EFSA, 2013j).

Occurrence of cyprodinil under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to cyprodinil are given in Regulations (EU)2019/1791⁵⁹, 2020/856⁷⁷ and 2020/1565⁶⁷ for the year 2020, Regulations (EU) 2020/1565⁶⁷ and 2021/1810⁷⁸ for 2021 and Regulations (EU) 2021/1810^{78,78} and 2022/1435⁷⁹ for 2022.

Regarding commodities not labelled as organic, 118,413 samples were collected and analysed for cyprodinil in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 108,609 (91.72%) were unprocessed and 9,804 (8.28%) processed commodities. No residues were quantified in 111,614 samples out of the 118,413 samples (94.26%). In 6,782 samples out of the 118,413 samples (5.73%) cyprodinil was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-16.1. MRLs were exceeded in 17 samples out of the 118,413 samples (0.01%). The highest concentration for samples

⁷⁷ Commission Regulation (EU) 2020/856 of 9 June 2020 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cyazofamid, cyprodinil, fenpyroximate, fludioxonil, fluxapyroxad, imazalil, isofetamid, kresoxim-methyl, lufenuron, mandipropamid, propamocarb, pyraclostrobin, pyriofenone, pyriproxyfen and spinetoram in or on certain products. OJ L 195, 19.6.2020, p. 9–51.

⁷⁸ Commission Regulation (EU) 2021/1810 of 14 October 2021 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards the maximum residue levels for cyprodinil in blueberries, cranberries, currants and gooseberries. OJ L 366, 15.10.2021, p. 2–16.

⁷⁹ Commission Regulation (EU) 2022/1435 of 26 August 2022 amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for calcium carbonate, carbon dioxide, cyprodinil and potassium hydrogen carbonate in or on certain products. OJ L 224, 30/08/2022, p. 1–15.

exceeding the MRLs was 4.004 mg/kg in berries and small fruits (raspberries (red and yellow) – cane fruits).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of cyprodinil are summarised in Table 3.16.3.2-2a for unprocessed and in Table 3.16.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on cyprodinil in feed not labelled as organic were submitted to EFSA.

Table 3.10.3.2-2a: Occurrence of cyprodinil monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Cyprodinil (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0130000	Pome fruits	2	0.001	0001–1	840	0.06
0140000	Stone fruits	2	0.001	0.001–1.6	731	0.046
0150000	Berries and small fruits	0.02*–8	0.001	0.001–4.004	2,982	0.082
0210000	Root and tuber vegetables	0.02*–1.5	0.001	0.001–0.47	154	0.03
0220000	Bulb vegetables	0.02*–0.8	0.001	0.004–0.892	44	0.043
0230000	Fruiting vegetables	0.02*–1.5	0.001	0.001–1.4	935	0.027
0250000	Leaf vegetables, herbs and edible flowers	0.02*–40	0.001	0.001–9.965	618	0.042
0260000	Legume vegetables	0.02*–2	0.001	0.005–0.598	170	0.03
0270000	Stem vegetables	0.02*–30	0.001	0.002–0.45	183	0.042
0300000	Pulses (dried)	0.2	0.003	0.03	2	0.03
0500000	Cereals	0.02*–4	0.001	0.008–0.022	7	0.009
0633000	Herbal infusions from roots ^{d)}	1.5–3	ND	ND	ND	ND
0840000	Root and rhizome spices ^{d)}	1.5	0.01	<LOQ	0	<LOQ
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of cyprodinil is not expected)						
0110000	Citrus fruits	0.02*	0.001	0.02	1	0.02
0120000	Tree nuts	0.02*–0.04	0.005	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.02*–5	0.001	0.01–0.11	8	0.019
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.02*–2	0.001	0.011–0.46	8	0.071
0280000	Fungi, mosses and lichens	0.02*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.02*	0.01	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.02*–0.3	0.005	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*–3	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	0.1*	0.05	<LOQ	0	<LOQ
0800000	Spices (dried)	0.1*–1.5	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.02*	0.005	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.005	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2023/1069 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Herbal infusions from roots and root and rhizome spices appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0633000 and 0840000 and non-use of the substance for all other commodities '06N0000' or '08N0000' that are reported under the 'broader' category 0600000 or 0800000 on the table. This creates an inconsistency in the results indicating non-uses which are overestimated.



Table 3.16.3.2-2b: Occurrence of cyprodinil from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Cyprodinil (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0130000	Pome fruits	2	0.001	0.004–0.011	3	0.004
0140000	Stone fruits	2	0.005	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.02*–8	0.001	0.001–2.5	104	0.019
0210000	Root and tuber vegetables	0.02*–1.5	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.02*–0.8	0.01	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.02*–1.5	0.001	0.101–0.228	5	0.16
0250000	Leaf vegetables, herbs and edible flowers	0.02*–40	0.002	0.098–0.82	4	0.459
0260000	Legume vegetables	0.02*–2	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.02*–30	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.2	0.002	<LOQ	0	<LOQ
0500000	Cereals	0.02*–4	0.001	<LOQ	0	<LOQ
0630000	Herbal infusions from roots ^{d)}	1.5–3	ND	ND	ND	ND
0840000	Root and rhizome spices ^{d)}	1.5	ND	ND	ND	ND
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of cyprodinil is not expected)						
0110000	Citrus fruits	0.02*	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.02*–0.04	0.01	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.02*–5	0.002	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.02*–2	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.02*	0.005	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.02*	ND	ND	ND	ND
0400000	Oilseeds and oil fruits	0.02*–0.3	0.002	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*–3	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	0.1*	0.05	<LOQ	0	<LOQ
0800000	Spices (dried)	0.1*–1.5	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.02*	0.008	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2023/1069 amending Annex II of Reg. (EC) No 396/2005;

b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Herbal infusions from roots and root and rhizome spices appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0630000 and 0840000 and non-use of the substance for all other commodities '06N0000' or '08N0000' that are reported under the 'broader' category 0600000 or 0800000 on the table. This creates an inconsistency in the results indicating non-uses which are overestimated.

Occurrence of cyprodinil in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 10,280 samples were collected and analysed for cyprodinil from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 8,460 (82.3%) were unprocessed and 1,820 (17.7%) processed commodities. No residues were quantified in 10,262 samples out of the 10,280 samples (99.82%). In 18 samples out of the 10,280 samples (0.18%) cyprodinil was found at or above the analytical LOQ but below or at



the MRL. No samples labelled as organic were above MRLs. These findings are summarised in Appendix B, Table B-16.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.16.3.2-3a for unprocessed and in Table 3.16.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on cyprodinil in feed labelled as organic were submitted to EFSA.

Table 3.16.3.2-3a: Occurrence of cyprodinil from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Cyprodinil (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.02*	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.02*-0.04	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	2	0.001	0.018-0.22	2	0.119
0140000	Stone fruits	2	0.001	0.001-0.055	6	0.012
0150000	Berries and small fruits	0.02*-8	0.001	0.012-0.41	6	0.052
0160000	Miscellaneous fruits	0.02*-5	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.02*-1.5	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.02*-0.8	0.001	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.02*-1.5	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.02*-2	0.001	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.02*-40	0.001	0.033	2	0.033
0260000	Legume vegetables	0.02*-2	0.001	<LOQ	0	<LOQ
0270000	Stem vegetables	0.02*-30	0.001	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.02*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.02*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.2	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.02*-0.3	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.02*-4	0.002	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*-3	0.003	<LOQ	0	<LOQ
0700000	Hops (dried)	0.1*	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.1*-1.5	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.02*	ND	ND	ND	ND
1040000	Honey and other apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2023/1069 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.16.3.2-3b: Occurrence of cyprodinil from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Cyprodinil (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.02*	0.001	<LOQ	0	<LOQ

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Cyprodinil (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0120000	Tree nuts	0.02*-0.04	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	2	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	2	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.02*-8	0.001	0.001	2	0.001
0160000	Miscellaneous fruits	0.02*-5	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.02*-1.5	0.01	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.02*-0.8	ND	ND	ND	ND
0230000	Fruiting vegetables	0.02*-1.5	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.02*-2	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.02*-40	0.005	<LOQ	0	<LOQ
0260000	Legume vegetables	0.02*-2	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.02*-30	ND	ND	ND	ND
0280000	Fungi, mosses and lichens	0.02*	0.01	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.02*	ND	ND	ND	ND
0300000	Pulses (dried)	0.2	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.02*-0.3	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.02*-4	0.0001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*-3	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	0.1*	ND	ND	ND	ND
0800000	Spices (dried)	0.1*-1.5	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.02*	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2023/1069 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of cyprodinil in the EU Organic Farming Information System

The EU OFIS reported nine findings for cyprodinil in 2021 and 2022. Four of the products sampled and analysed had EU origin and five were of non-EU origin. Residues were found in one sample of citrus fruits (lemons), 1 sample of stone fruits (plums), 6 samples of berries and small fruits (table and wine grapes and strawberries) and one sample of herbal infusions from leaves and herbs (strawberry). In two samples cyprodinil residues were detected, but not quantified. The concentrations of cyprodinil residues were above LOQ but below MRL in all 9 samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005³. No samples labelled as organic were above MRLs set for conventional agriculture. The highest concentration was reported in a sample of herbal infusion from leaves and herbs (strawberry) from non-EU origin, with the quantified level of 0.032 mg/kg. These findings are summarised in Table 3.16.3.2-4.

Table 3.16.3.2-4: Occurrence of cyprodinil from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
0110030	Lemons	0.02*	0.012 – Bergamot lemons	ND
0151020	Wine grapes	3	ND	1 sample with detected, but not quantified value – Red wine
0152000	Strawberries	5	0.008 – Strawberries	0.019 – Strawberries (dried, freeze)
Samples of non-EU origin				
0140040	Plums	2	ND	0.01 – Plums (dehydrated)
0151010	Table grapes	3	ND	0.01; 0.023 – Sultanas (drying)

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
0152000	Strawberries	5	0.032 – Strawberries	ND
0632010	Strawberry	0.1*	1 sample with detected, but not quantified value – <i>Equisetum arvense</i> /horsetail herb	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2023/1069 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of cyprodinil in untreated samples (control samples) from residue trials

Quantified findings in control (untreated) samples of cyprodinil were observed in barley samples (grain and straw) from northern France and the United Kingdom³⁵ (France, 2013b, 2017d), and in celery control samples from northern and southern France (France, 2014b). Additionally, residues of cyprodinil were found in a raspberry control sample from a residue trial carried out in northern France (Germany, 2013b).

No evidence-based explanations on the causes for these occurrences in control (untreated) samples were provided in the above Member State ERs and RARs.

The summary of the quantified findings of cyprodinil in control (untreated) samples from residue trials carried out for the critical GAP⁴ per crop is given below in Table 3.16.3.2-5.

Table 3.16.3.2-5: Summary of the quantified findings of cyprodinil in control (untreated) samples from residue trials carried out for the critical GAP per crop.

Crop	Country/Area	Cyprodinil concentration (mg/kg)
Barley	Northern France	0.04 (grain), 0.16 (straw)
	United Kingdom ³⁵	0.01 (straw)
Celery (leaf and stem)	Northern France	0.026, 0.026
	Southern France	0.011
Raspberries (fruit)	Northern France	0.02

- Could the presence of cyprodinil and/or its residues be due to biocide use

Cyprodinil is not authorised for use as a biocide, therefore, residues due to biocidal use are not expected for cyprodinil.

3.16.3.3 Behaviour in food and feed products

- What key physico-chemical properties of cyprodinil are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

Cyprodinil exhibits moderate to high persistence in soil (see Section 3.16.3.5). There is evidence that its persistence is pH dependent, with significantly higher persistence (DT₉₀ up to >900 days) observed in acidic soil (pH < 6.7) (EFSA, 2006). Regarding sorption to soil, the range of K_{Foc} in Table 3.16.3.3 indicates that the substance has low mobility in soil (EFSA, 2006).

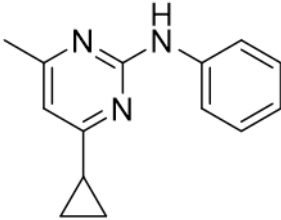
The maximum calculated PEC_w for cyprodinil for the representative uses was 50.3 µg/L (spray drift application to apples; 4 × 225 g a.s./ha) (EFSA, 2006).



Cyprodinil is hydrolytically stable under standard conditions of pasteurisation, baking, brewing, boiling and sterilisation (EFSA, 2013j). Considering that cyprodinil is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Cyprodinil showed low volatilisation from soil, but evidence suggests it may volatilise from plants due to its vapour pressure (10^{-4} Pa) (EFSA, 2006).

Table 3.16.3.3: Physico-chemical properties of cyprodinil (EFSA, 2025b)

Structural formula	
Appearance (state purity)	Beige fine powder with agglomerates (99.2%) and white fine crystals (99.9%)
Melting point (state purity)	75.9°C (99.9%)
Boiling point	No boiling point < 360°C (99.9%)
Temperature of decomposition	No decomposition < 360°C (99.2%)
Vapour pressure (state temperature, state purity)	$4.7\text{--}5.1 \times 10^{-4}$ Pa at 25°C (crystal modification, respectively)
Henry's law constant (state temperature)	6.6×10^{-3} to 7.2×10^{-3} Pa m ³ mol ⁻¹ calculated at 25°C
Solubility in water (state temperature, state purity and pH)	pH 5: 20 mg/L at 25°C (99.9%) pH 7: 13 mg/L at 25°C (99.9%) pH 9: 15 mg/L at 25°C (99.9%)
Partition coefficient (state temperature, pH and purity)	log Pow = 3.9–4.0, at 25°C for pH range 5–9 (99.9%)
Partition coefficient (octanol/air)	NA
Atmospheric half-life	DT ₅₀ of 0.5–2.1 hours derived by the Atkinson model (APOWIN version 1.88). OH (12 h) radical concentration assumed = 1.5×10^6 mol cm ⁻³
Dissociation constant (state purity)	pKa = 4.4 (99.9%)
Soil adsorption (geometric mean)	K _{roc} = 1781 mL/g
Hydrolytic degradation (>10%)	No degradation observed in the pH range 4–9 at temperatures between 25–50°C

DT₅₀ – Disappearance time of 50% of the substance in field studies; NA – not applicable; pH – Potential of Hydrogen; P_{ow} – Octanol/water Partition Coefficient.

3.16.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from the soil surface at which it is applied).



The highest drift of cyprodinil to neighbouring fields may occur during its applications to fruit crops (up to 29.2%), vineyards and vegetables (up to 8.02%) and field crops (up to 2.77%). Drift values should be considered the rate received by neighbouring fields, expressed as a percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. buffer zones or spray drift-reducing nozzles).

If organic crops are present adjacent to the conventional crops treated, measurable residues of cyprodinil in the untreated crop cannot be excluded (above all if the treated crops are fruit trees). Dust drift is also a possibility during the drilling of treated seed. Deposition percentile values were considered for neighbouring fields, up to 17% for different crops and techniques (EFSA, 2013b). According to Adriaanse et al. (2022), the use of techniques (deflectors), size of the dust particles and average wind speed were the most important factors determining the amount of dust drift. However, since the nature of the potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

3.16.3.5 Accumulated/historical residue levels in soil

- What is the persistence of cyprodinil and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

According to available data (EFSA, 2013j, 2025b), the DT₉₀ of cyprodinil in soil has a worst-case field value of 944 days, indicating a potential for accumulation in soil and continued presence after discontinued use of the substance.

To investigate the potential uptake of residues of cyprodinil by plants field rotational crop studies were carried out with root and tuber vegetables, leafy vegetables and cereals with applications of cyprodinil following different plant-back intervals. No significant residues above the LOQ of 0.01 mg/kg were quantified in these studies (EFSA, 2013j). Therefore, residues of cyprodinil are not expected in rotational crops.

Based on the above, transfer of cyprodinil in plants planted or sown in soil previously treated with cyprodinil is considered unlikely. This is also valid for organic crops, when they are planted 2 years after the last chemical treatment, as required by the regulatory provisions for organic agriculture².

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Monitoring data for cyprodinil in soil are available from the LUCAS pesticides 2018 (JRC, 2023) on IPCHEM¹². The data show background levels of the substance in soil samples from 11 EU countries: Belgium (1 sample), Denmark (1 sample), Finland (6 samples), France (49 samples), Germany (2 samples), Greece (2 samples), Italy (6 samples), Lithuania (1 sample), Poland (11 samples), Spain (1 sample) and Sweden (4 samples). The reported residue levels ranged from 0.0011 mg/kg to 0.095 mg/kg. In LUCAS soil, the lack of information on the agricultural use history of the sites where soil was sampled precluded knowing whether the reported quantified findings were related to recent active use or historical levels in soil for cyprodinil.



Evidence on the occurrence of cyprodinil residues in soil is provided by Chiaia-Hernandez et al. (2017), who analysed 29 archived agricultural soil samples collected from 1995 to 2008 from 14 monitoring sites in Switzerland. The sites were chosen from monitoring sites where crops received regular pesticide treatment, considering land use and the long-term pesticide use pattern was recorded. Cyprodinil was one of the 20 most frequently quantified pesticides, found in 14 soil samples (48%) from cropland, orchard and viticulture land use sites, with levels ranging from 0.001 to 0.030 mg/kg. Cyprodinil was both applied and detected in 24% of cases. In an additional 24% of cases, it was detected despite not having been applied.

In a study by Riedo et al. (2021) the presence of cyprodinil was analysed in soil samples from 60 agricultural sites with different management systems (conventional tillage, conventional without soil tillage, and organic) sampled in May 2016 for an on-farm study throughout Switzerland. Results showed the presence of cyprodinil in 22% of the samples at concentrations ranging from 0.00068 to 0.33 mg/kg in all types of soil, with the higher levels reported from conventional arable farming. The concentrations in soil under organic farming systems were reported to be <0.05 mg/kg in a total of three out of 40 samples (7.5%).

Additional evidence on the occurrence of cyprodinil in soil is provided by Silva et al. (2023) in a study carried out in the framework of the EU SPRINT project. The study assessed the presence of 209 pesticide residues in 100 soil samples from conventional agriculture and 63 soil samples from organic agriculture collected during the 2021 growing season across 10 study sites in Europe: Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark. Cyprodinil was quantified in four conventional soil samples (4%) from Italy and Portugal at concentrations ranging from 0.0068 to 0.2078 mg/kg. The highest concentration was found in Portugal.

Considering the available evidence, plant uptake of cyprodinil from soil under organic farming systems is unlikely.

3.16.3.6 Residues from water used for irrigation

- Is there evidence that residues of cyprodinil present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹²¹² the following databases providing occurrence data for cyprodinil in water samples were considered:

- The EEA-WATERQUALITY³⁹ database (data retrieved on 10 April 2024) reports 188 analytical results from water samples collected in France (4 samples), Italy (103 samples) and the Netherlands (81 samples) between 2018 and 2020.
- The EMPODAT database (data retrieved on 25 March 2024) reports 2,262 analytical results from surface water samples collected in the Netherlands (2,261 samples) and Romania (1 sample) between 2017 and 2019; 18 analytical results from groundwater samples collected in 2019 in Austria (3 samples), Bulgaria (3 samples), Croatia (3 samples), Hungary (3 samples), Romania (3 samples) and Slovakia (3 samples);
- The NAIADES database (data retrieved on 2 April 2024) reports 54,366 analytical results from surface water samples collected in France from 2020 to 2022.

Among the 56,834 analytical results for cyprodinil, 960 were disregarded as found to report quantitative values below the analytical LOQ. Therefore, the number of water samples considered is 55,874.



Based on the screening process described in section 'Data and methodologies', for 99.7% of water samples analysed and reported in the above-mentioned databases (55,696 samples), the residue concentrations in these waters were below the screening Cw of 0.15 µg/L and, therefore, transfer of residues from water sources to plant commodities is unlikely.

For 0.3% of samples (178 out of 55,874 samples), the residue concentrations were or above the screening Cw of 0.15 µg/L and the potential transfer of residues to plant commodities if water containing residues at these levels is used for irrigation cannot be excluded.

Overall, considering that for 99.7% of water samples analysed and reported for cyprodinil in EEA-WATERQUALITY, EMPODAT and NAIADDES (55,874 samples), the residue concentrations were below the screening Cw of 0.15 µg/L, it can be concluded that the transfer of cyprodinil residues from water to plant commodities when this water is used to irrigate plants is unlikely.

3.16.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *cyprodinil*, *industry/industrial*, and *air/atmosphere*) identified only one European study, which was considered irrelevant for this section.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water. Based on conservative estimations of the possible transfer of residues from water used for irrigation to plant commodities, the transfer of residues of cyprodinil from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 7, 2025, using the keywords *cyprodinil*, *industry/industrial*, and *water*) did not identify any relevant European study.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Based on information on the possible plant uptake of cyprodinil from EU soil, the transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 17, 2025, using the keywords *cyprodinil*, *industry/industrial*, and *soil/sediment*) did not identify any relevant European study.

3.16.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?



Medium and long-range aerial transport of residues

Silva et al. (2023) investigated the presence of cyprodinil in 20 outdoor air samples collected during the 2021 growing season across 10 study sites in Europe of organic and conventional agriculture (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). The study was carried out under the framework of the EU SPRINT project. Organic fields had not been treated for 5 consecutive years. Cyprodinil was quantified in three out of 20 targeted samples from France, Portugal and Slovenia at a maximum concentration of 1795 ng m⁻³ found in Portugal. Two out of these three samples were collected from the surrounding areas of organic fields in Portugal (1795 ng m⁻³) and Slovenia (21.4 ng m⁻³). The results from this study suggest that medium to long-range aerial transfer of residues of cyprodinil to plants cannot be excluded.

In a study by Mayer et al. (2024) residues of cyprodinil were quantified in air samples from 29 sampling sites classified as rural, coastal, mountain and polar. The samples were collected from 15 EU countries i.e. Austria, Czechia, Estonia, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Poland, Slovakia, Spain and Sweden, Switzerland and the United Kingdom during the main pesticide application period in spring 2020. To investigate aerial transport in polar sites, air samples from the European Arctic were also collected. Results showed the presence of cyprodinil at levels from 0.5 to 10,000 pg m⁻³ in the rural sites, from 0.01 to 10 pg m⁻³ in the coastal sites and at 100 pg m⁻³ in one sample from a mountain site in Greece (the exact concentration ranges are not reported in the paper). For the rural area, the maximum concentration was quantified in Germany, whilst in the coastal area, the maximum concentration was reported in the United Kingdom. Cyprodinil was quantified in one Arctic site from Finland at 50 pg m⁻³ (the exact concentration is not reported). The total frequency of findings for all areas was above 50% (the exact % detection frequency is not reported in the paper).

The results from these studies suggest that medium-range aerial transfer of residues of cyprodinil to plants cannot be excluded.

Uptake from organic fertilisers

In a study investigating pesticide residues in organic fertilisers, residues of cyprodinil and other pesticides were quantified (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). The authors attributed the origin of the residues to the presence of plant protection products in the composted crop or in composted manure due to transfer from animal feed after digestion, or in straw used in stables. Analysis of solid organic fertilisers gave an average concentration of 0.874 mg/kg for cyprodinil in nine out of 147 samples. Considering that (according to the authors) the use of completely free from residues organic fertilisers is currently unsustainable, transfer of cyprodinil residues from fertilisers used in organic production to organic products cannot be excluded. On the other hand, no residues of cyprodinil were found in any of the products of the crops discussed in the study (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). This outcome is supported by studies in rotational crops indicating that plant uptake from soil that contains residues is unlikely (see Section 3.16.3.5).

Other sources of residues (not mentioned above)

In a study by Calliera et al. (2025), cyprodinil occurrence was monitored in wash water samples for the internal and external washing of sprayers used for pesticide applications in three vineyard areas located in Colli Tortonesi in the Piedmont Region (NW Italy). Cyprodinil was quantified in



washing water samples of two of the three areas at concentrations up to 9.9 mg/L (internal washing) and up to 369 0.8 mg/L (external washing).

3.16.4 Conclusions on cyprodinil

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use.
- Residue trials carried out to support the critical GAPs⁴ for cyprodinil, gave residue concentrations up to 8.9 mg/kg in leaf vegetables, herbs and edible flowers and up to 5.8 mg/kg in cereal straw. Concentrations in the ranges reported in Table 3.16.3.2-1 might be associated with active use of cyprodinil according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.
- Cyprodinil was quantified in the context of residue trials in several European countries in untreated (control) samples with the highest concentrations observed for one sample of barley grain and barley straw from Northern France (0.04 and 0.16 mg/kg, respectively).
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for cyprodinil in unprocessed commodities with authorised uses ranged from 0.009 mg/kg in cereals to 0.082 mg/kg in berries and small fruits.
- In organic commodities that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for cyprodinil in unprocessed commodities with authorised uses ranged from 0.012 mg/kg in stone fruits to 0.052 mg/kg in berries and small fruits.
- In organic processed commodities, residues of cyprodinil were quantified in two of the samples analysed. In samples from processed products not labelled as organic with five or more quantified findings, residues were quantified in berries and small fruits (median concentration at 0.019 mg/kg) and in fruiting vegetables (median concentration 0.16 mg/kg). Considering that the substance is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.
- Overall, in commodities labelled as organic, cyprodinil was quantified in 0.18% of samples (18 out of 10,280 samples). This percentage is more than 30 times lower than the percentage reflecting the number of findings in samples not labelled as organic (5.74%) (see Appendix B, Tables B-16.1 and B-16.2). These results suggest that the occurrence of residues of cyprodinil in organic products is less likely when compared with the conventional commodities.

- Potential sources of the unintentional presence of residues of cyprodinil in commodities of plant origin are drift from conventional crops grown in the vicinity or from transfer of residues in the medium range through aerosol transport.
- Cyprodinil is persistent in soil, however, not all substances accumulating in soil are taken up by plants. Studies assessed by EFSA on crops growing in rotation showed that plant uptake of residues of cyprodinil from soil containing residues or transfer from EU water sources used for irrigation to plant commodities is unlikely. Plant uptake of residues of cyprodinil from organic fertilisers is also unlikely.
- Transfer of cyprodinil residues from EU water sources used for irrigation to plant commodities is unlikely.
- Conservative estimates of the possible transfer of residues of cyprodinil from water used for irrigation to plant commodities and information on the possible plant uptake of residues of cyprodinil from EU soil suggest that the transfer of residues from industrial emissions to the environment and from the environment to plants and plant commodities is less likely.

The pathways of residues of cyprodinil to plants and plant commodities are summarised in Figure 16.

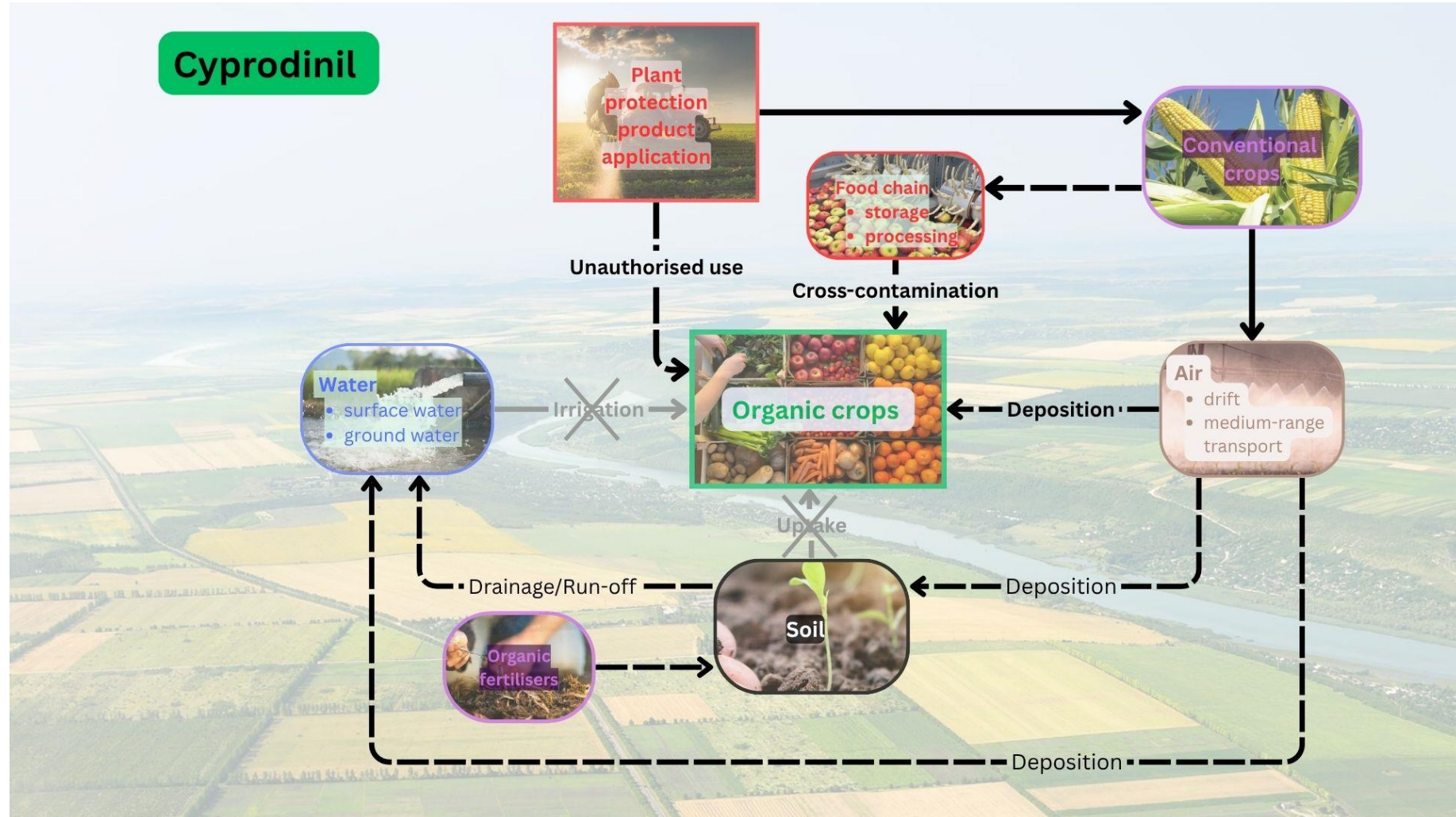


Figure 16: Pathways of residues of cyprodinil to plants and plant commodities

Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded

3.17 Chloridazon

3.17.1 Method(s)

- What is/are the residues to be monitored for the active substance chloridazon according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

For the active substance chloridazon, the residue definition for enforcement in food and feed of plant origin has been proposed as 'chloridazon (sum of chloridazon and chloridazon-desphenyl, expressed as chloridazon)⁸⁰ (R)' in the EFSA peer review conclusion (EFSA, 2007a). This residue definition is applicable to primary, rotational crops and processed products. This residue definition for enforcement is implemented in Regulation (EC) No 396/2005³. The same residue definition is implemented in Reg. (EC) 396/2005³ for honey and other apiculture products.

Based on the above residues of chloridazon and chloridazon-desphenyl are to be monitored in foods of plant origin, honey and other apiculture products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

Analytical methods based on HPLC-MS/MS have been validated for the determination of chloridazon and chloridazon-desphenyl in high water content, acidic, high oil content, and dry commodities. They are based on simple extractions in the presence of methanol and are not expected to hydrolyse conjugates of chloridazon (EFSA, 2015k). These single residue methods have an LOQ of 0.05 mg/kg for each compound, resulting in a combined LOQ of 0.1 mg/kg, and have been supported by an independent laboratory validation (ILV) and confirmatory methods (EFSA, 2007a, 2015k; Germany, 2024 under 'Documentation as provided to EFSA'). The EURL⁸¹ for Residues of Pesticides reports multi-residue methods for analysing parent chloridazon in dry commodities and single residue methods for the analysis of chloridazon-desphenyl residues in all commodity groups except for those with high oil content.

According to literature, multi-residue methods are available for the monitoring of parent chloridazon across all food and feed matrices of plant origin. A multi-residue acetate buffered QuEChERS method based on LC-MS/MS, validated along with its ILV, is available for analysing parent chloridazon in high water, high acid, high oil content matrices as well as in dry and difficult plant commodities, at an LOQ of 0.01 mg/kg (Mastovska et al., 2017). Fera Science Ltd⁸² reports a multi-residue LC-MS/MS method available for analysing parent chloridazon in all commodities of food of plant origin at the LOQ of 0.01 mg/kg. EURLs⁸¹ report a multi-residue LC-MS/MS method for the monitoring of parent chloridazon in olive oil samples at an LOQ of 0.05 mg/kg. Another multi-residue acetate buffered QuEChERS method based on LC-MS/MS is available for the monitoring of parent chloridazon in dried hops, with an LOQ of 0.05 mg/kg (Gruba et al., 2023). Additionally, a multi-residue GC-MS/MS method is validated for the analysis of parent chloridazon in dried herbs at an LOQ of 0.01 mg/kg (Rutkowska et al., 2017).

According to the EURL for Residues of Pesticides (EURL, 2024, under 'Documentation as provided to EFSA'), a single residue citrate-buffered QuEChERS method based on LC-MS/MS is validated

⁸⁰ Chloridazon-desphenyl (also called metabolite B) is reported as 5-amino-4-chloropyridazin-3(2H)-one in the EFSA peer review (EFSA, 2007a).

⁸¹ <https://www.eurl-pesticides.eu/>

⁸² <https://www.fera.co.uk/>

for monitoring chloridazon residues in honey at an LOQ of 0.002 mg/kg and chloridazon-desphenyl residues in honey using the QuPPE method at an LOQ of 0.01 mg/kg. For enforcement purposes, the sum LOQ of 0.09 mg/kg is validated for the analysis of chloridazon in honey and other apiculture products. Kujawski et al. (2014) report a multi-residue modified QuEChERS method validated for analysis of parent chloridazon residues based on LC-MS/MS in honey samples at an LOQ of 0.0375 mg/kg.

Overall, single residue methods are available for the analysis of the residue definition of chloridazon in high water, high acid, high oil content and dry commodities of plant origin, as well as in honey and other apiculture products. In the literature, multi-residue methods have been reported for the analysis of parent chloridazon, but it is not clear whether chloridazon-desphenyl is also analysed. Individual LOQs of these methods range from range from 0.002 mg/kg to 0.05 mg/kg, and the sum LOQ ranges from 0.09 mg/kg to 0.1 mg/kg.

3.17.2 Authorisation status and use

- Is chloridazon currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has chloridazon ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

a) Authorisations for plant protection use in conventional agriculture

Based on information from the EU Pesticides Database⁵ (accessed 6 May 2024), chloridazon is not currently approved for plant protection purposes in the EU. The expiry date of the approval of the active substance was on 31 December 2018. Following the decision for its non-approval, all authorisations for chloridazon at Member State level have been withdrawn. Emergency authorisations have not been granted for chloridazon.

b) Authorisations for purposes other than plant protection

Biocidal use

According to the ECHA website⁶ (accessed 6 June 2024), chloridazon and chloridazon-desphenyl have not been approved for use in biocidal products in the EU.

Other uses

According to the search carried out on the ECHA website⁹ (accessed 6 June 2024), neither chloridazon nor chloridazon-desphenyl is currently registered under REACH.

- What is/was the actual use of chloridazon? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of chloridazon

Chloridazon belongs to the class of pyridazinones. It is a systemic herbicide, targeting both soil and leaf, by inhibiting photosynthesis (EFSA, 2015k).

The phytotoxic effects of chloridazon on commodities with authorised uses were investigated⁸³. The available studies were limited and indicate that only high doses of chloridazon, above the recommended rates, and specific soil conditions may affect the growth and development of some sensitive crops (Roseberg RJ, 2016; Koray, 2020; Allegri et al., 2012). Although these studies suggest that the use of chloridazon is restricted by its phytotoxic effects, they do not give any quantitative information on the levels inducing phytotoxicity.

Conditions of use and applicable crops

The uses reported in the EFSA MRL review at the time the active substance was still approved and products containing the substance were still authorised, included applications in northern and southern Europe in food and feed commodities belonging to the following crop groups: root and tuber vegetables, bulb vegetables, leaf vegetables, herbs and edible flowers, sugar plants and fodder beet (EFSA, 2015k).

Chloridazon treatment included outdoor foliar applications and outdoor soil applications.

Outdoor foliar applications for weed control were reported for root and tuber vegetables, bulb vegetables, and sugar plants (EFSA, 2015k). Application rates range from 0.91 kg a.s./ha to 2.60 kg a.s./ha for food commodities and from 1.95 kg a.s./ha to 2.60 kg for feed commodities.

Outdoor soil treatments were reported for weed control for leaf vegetables, herbs and edible flowers with application rates ranging from 0.98 kg a.s./ha to 2.60 kg a.s./ha (EFSA, 2015k).

b) Uses for purposes other than plant protection

Biocidal use

Chloridazon and chloridazon-desphenyl are not approved for biocidal use, therefore, their use in biocidal products is not expected (see also 'authorisations for purposes other than plant protection/biocidal use').

Other use

Search on the ECHA website⁹ for registrations under REACH did not give any results for chloridazon or chloridazon-desphenyl.

3.17.3 Sources of residues in plants

3.17.3.1 Natural occurrence

- Is there evidence that chloridazon occurs naturally? What is known about the natural origin of this substance?

Chloridazon is a synthetic herbicide produced industrially through chemical processes (Lewis et al., 2016). No information on the potential natural presence of chloridazon was found in the literature²².

⁸³ A literature search was performed on Web of Science using terms 'chloridazon AND phytotoxic*' for the timeframe 2010-2024.

3.17.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of chloridazon per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of chloridazon in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.17.3.2-1 to 3.17.3.2-4. The possible presence of residues in control (untreated) samples is also discussed in this section.

In all matrices and for both residue trials and results from monitoring, chloridazon residue concentrations refer to the residue definition for enforcement (i.e. the sum of chloridazon and chloridazon-desphenyl, expressed as chloridazon).

Occurrence of chloridazon from residue trials carried out for the critical GAP per crop

Following product applications based on the critical GAPs⁴ reported to EFSA, quantified residues for the sum of chloridazon and chloridazon-desphenyl (metabolite B), expressed as chloridazon were found in root and tuber vegetables, bulb vegetables, leaf vegetables, herbs and edible flowers and sugar plants (EFSA, 2015k). Regarding feed commodities, quantified residues occurred in fodder beet (EFSA, 2015k).

The residue trials also allowed studying the occurrence of the individual substances, chloridazon and chloridazon-desphenyl. These results are reported below.

Residues of chloridazon and its glycoside (metabolite A) were below LOQ in root and tuber vegetables (EFSA, 2015k; Germany, 2015c) and bulb vegetables (EFSA, 2015k; Germany, 2007). Quantified residues of chloridazon and its glycoside were found in leaf vegetables, herbs and edible flowers (EFSA, 2015k; Germany, 2007; United Kingdom³⁵, 2015) and sugar plants (EFSA, 2015k, Germany 2007, 2015). Regarding feed commodities, quantified residues occurred in fodder beet (EFSA, 2015k; Germany 2007, 2015).

For chloridazon-desphenyl (metabolite B), residues were found in root and tuber vegetables (EFSA, 2015k; Germany, 2015c), bulb vegetables (EFSA, 2015k; Germany, 2007), leaf vegetables, herbs and edible flowers (EFSA, 2015k; Germany, 2007; United Kingdom³⁵, 2015) and sugar plants (EFSA, 2015k; Germany 2007, 2015b). Regarding feed commodities, quantified residues occurred in fodder beet (EFSA, 2015k; Germany, 2007, 2015).

The results from residue trials carried out for the critical GAP per crop for chloridazon in commodities for which uses were submitted to EFSA are summarised in Table 3.17.3.2-1 'Occurrence of chloridazon from residue trials carried out for the critical GAP per crop'.

Table 3.17.3.2-1: Occurrence of chloridazon from residue trials carried out for the critical GAP per crop

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Chloridazon (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop							
			Sum of chloridazon and chloridazon-desphenyl (metabolite B), expressed as chloridazon		Chloridazon and its glycoside (metabolite A) ^{c)}		Chloridazon-desphenyl (metabolite B)		Chloridazon-desphenyl (metabolite B), expressed as chloridazon	
			Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)	Range (mg/kg)	Median (mg/kg)
Food										
021000	Root and tuber vegetables	0.1*–0.5	<LOQ (0.13)–0.2	0.13	<LOQ (0.05)	<LOQ (0.05)	<LOQ (0.05)–0.09	0.07	<LOQ (0.08)–0.14	0.11
022000	Bulb vegetables	0.1*–0.3	<LOQ (0.1)–0.14	0.12	<LOQ (0.05)	<LOQ (0.05)	<LOQ (0.05)–0.06	0.05	<LOQ (0.08)–0.09	0.08
025000	Leaf vegetables, herbs and edible flowers	0.1*–5	0.13–1.79	1.36	<LOQ (0.05)–0.47	0.27	<LOQ (0.05)–0.93	0.65	<LOQ (0.08)–1.41	0.98
090000	Sugar plants	0.1*–0.3	<LOQ (0.025)–0.2	0.13	<LOQ (0.01)–0.06	0.05	<LOQ (0.05)–0.1	0.05	<LOQ (0.015)–0.15	0.08
Feed										
120000	Fodder beet	NA	<LOQ (0.025)–0.84	0.14	<LOQ (0.01)–0.08	0.05	<LOQ (0.05)–0.52	0.065	<LOQ (0.015)–0.79	0.08

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable.

a) Maximum Residue Level in Reg. (EU) No 2023/710 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA, 2015k; c) The results include the glycoside of chloridazon, therefore the value for chloridazon alone may be lower.

Occurrence of chloridazon under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to chloridazon are given by Regulation (EU) 2016/1015⁸⁴ for the years 2020–2022. Regarding commodities not labelled as organic, 38,611 samples were collected and analysed for chloridazon in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 36,621 (94.85%) were unprocessed and 1990 (5.15%) processed commodities. No residues were quantified in 38,540 samples out of the 38,611 samples (99.82%). In 69 samples out of the 38,611 samples (0.18%) chloridazon was found at or above the analytical LOQ but below or at the applicable MRL. These findings are summarised in Appendix B, Table B-17.1. MRLs were exceeded in two samples out of the 38,611 samples (0.01%) with quantified concentrations of 0.19 mg/kg and 0.12 mg/kg in Brassica vegetables (excluding brassica roots and brassica baby leaf crops) (head brassica and leafy brassica).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of chloridazon are summarised in Table 3.17.3.2-2a for unprocessed, and in Table 3.17.3.2-2b for processed plant commodities, honey and other

⁸⁴ Commission Regulation (EU) 2016/1015 of 17 June 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1-naphthylacetamide, 1-naphthylacetic acid, chloridazon, fluzafop-P, fluberidazole, mequiquat and tralkoxydim in or on certain products. OJ L 172, 29.6.2016, p. 1–21.

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apiculture products not labelled as organic. No monitoring data on chloridazon in feed not labelled as organic were submitted to EFSA.

Table 3.17.3.2-2a: Occurrence of chloridazon from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Chloridazon (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0210000	Root and tuber vegetables	0.1*-0.5	0.001	0.017-0.042	6	0.02
0220000	Bulb vegetables	0.1*-0.3	0.001	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.1*-5	0.001	0.003-0.2	39	0.018
0900000	Sugar plants	0.1*-0.3	0.01	<LOQ	0	<LOQ
Feed						
1200000	Fodder beet	NA	ND	ND	ND	ND
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of chloridazon is not expected)						
0110000	Citrus fruits	0.1*	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.1*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.1*	0.001	0.02	1	0.02
0140000	Stone fruits	0.1*	0.001	0.009	1	0.009
0150000	Berries and small fruits	0.1*	0.001	0.017-0.019	2	0.018
0160000	Miscellaneous fruits	0.1*	0.001	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.1*	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.1*	0.001	0.015-0.19	15	0.037
0260000	Legume vegetables	0.1*	0.001	0.011-0.03	4	0.018
0270000	Stem vegetables	0.1*-5	0.001	0.008-0.012	2	0.01
0280000	Fungi, mosses and lichens	0.1*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.1*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.1*	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.1*	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.1*	0.002	0.022	1	0.022
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*-5	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	0.1*	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.1*-5	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for unprocessed commodities in Reg. (EU) No 2023/710 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.17.3.2-2b: Occurrence of chloridazon from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Chloridazon (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0210000	Root and tuber vegetables	0.1*–0.5	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.1*–0.3	ND	ND	ND	ND
0250000	Leaf vegetables, herbs and edible flowers	0.1*–5	0.002	<LOQ	0	<LOQ
0900000	Sugar plants	0.1*–0.3	0.01	<LOQ	0	<LOQ
Feed						
1200000	Fodder beet	NA	ND	ND	ND	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of chloridazon is not expected)						
Food						
0110000	Citrus fruits	0.1*	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.1*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.1*	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.1*	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.1*	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.1*	0.01	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.1*	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.1*	0.01	<LOQ	0	<LOQ
0260000	Legume vegetables	0.1*	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.1*–5	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.1*	0.01	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.1*	ND	ND	ND	ND
0300000	Pulses (dried)	0.1*	0.01	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.1*	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.1*	0.001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*–5	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	0.1*	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.1*–5	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2019/552, 2021/1807, 2022/93 and 2022/1324 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'). c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of chloridazon in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 4,616 samples were collected and analysed for chloridazon from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 3,842 (83.2%) were unprocessed and 774 (16.8%) processed commodities. No residues were quantified in 4,613 samples out of the 4,616 samples (99.94%). In three samples out of the 4,616 samples (0.06%) chloridazon was found at or above the analytical LOQ but below or at

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the MRL. No samples labelled as organic were above MRLs. These findings are summarised in Appendix B, Table B-17.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.17.3.2-3a for unprocessed and in Table 3.17.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on chloridazon in feed labelled as organic were submitted to EFSA.

Table 3.17.3.2-3a: Occurrence of chloridazon from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Chloridazon (RD) occurrence results from the unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.1*	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.1*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.1*	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.1*	0.001	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.1*	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.1*	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.1*-0.5	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.1*-0.3	0.001	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.1*	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.1*	0.001	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.1*-5	0.001	0.008-0.054	2	0.031
0260000	Legume vegetables	0.1*	0.001	0.009	1	0.009
0270000	Stem vegetables	0.1*-5	0.001	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.1*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.1*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.1*	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.1*	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.1*	0.001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*-5	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	0.1*	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.1*-5	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.1*-0.3	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2023/710 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'). c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.17.3.2-3b: Occurrence of chloridazon from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Chloridazon (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.1*	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.1*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.1*	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.1*	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.1*	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.1*	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.1*-0.5	0.005	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.1*-0.3	ND	ND	ND	ND
0230000	Fruiting vegetables	0.1*	0.01	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.1*	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.1*-5	0.01	<LOQ	0	<LOQ
0260000	Legume vegetables	0.1*	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.1*-5	ND	ND	ND	ND
0280000	Fungi, mosses and lichens	0.1*	0.01	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.1*	ND	ND	ND	ND
0300000	Pulses (dried)	0.1*	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.1*	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.1*	0.001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.1*-5	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	0.1*	ND	ND	ND	ND
0800000	Spices (dried)	0.1*-5	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.1*-0.3	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	ND	ND	ND	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2023/710 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of chloridazon in the EU Organic Farming Information System

The EU OFIS reported five findings for chloridazon and two findings for chloridazon-desphenyl in 2021 and 2022. All the quantified results were from EU origin. Residues of chloridazon were found in one sample of fruiting vegetables (tomatoes) and four samples of leaf vegetables, herbs and edible flowers (parsley). Residues of chloridazon-desphenyl were found in one sample of fruiting vegetables (tomatoes) and one sample of spices – seed spices (fenugreek). The concentrations of chloridazon residues were below the LOQ in all five samples. The highest concentration was reported for a sample of parsley of EU origin, with the quantified level of 0.064 mg/kg. No samples labelled as organic were above MRLs. These findings are summarised in Table 3.17.3.2-4.

Table 3.17.3.2-4: Occurrence of acetamiprid from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
Chloridazon (sum of chloridazon and chloridazon-desphenyl, expressed as chloridazon)				
0231010	Tomatoes	0.1*	ND	0.023 – Tomatoes (juice)
0256040	Parsley	5	0.026; 0.026; 0.049; 0.064 – Parsley	ND
Chloridazon-desphenyl				
0231010	Tomatoes	0.1*	ND	0.015 – Tomatoes (juice)
0810080	Fenugreek	0.1*	0.035 – Fenugreek	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2023/710 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of chloridazon in untreated samples (control samples) from residue trials

No quantified findings of chloridazon were observed in control (untreated) samples from residue trials carried out for the critical GAP⁴ per crop according to all EFSA outputs.

- Could the presence of the chloridazon and/or its residues be due to biocide use?

Chloridazon is not authorised for use as a biocide, therefore, residues due to biocidal use are not expected for chloridazon.

3.17.3.3 Behaviour in food and feed products

- What key physico-chemical properties of chloridazon are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of **chloridazon** are reported in Table 3.17.3.3a.

Chloridazon has a worst-case DT₉₀ from field trials of 230 days, indicating a medium persistence in soil (see also Section 3.17.3.5). Regarding sorption to soil, the range of K_{FOC} in Table 3.17.3.3a indicates that the substance has medium mobility in soil (EFSA, 2007a).

The maximum calculated PEC_w for chloridazon for the representative uses was 125.95 µg/L (pre-emergence spray application to sugar beets; 1 × 2.6 kg a.s./ha).

Chloridazon is hydrolytically stable within a range of pH, temperatures and under standard conditions of pasteurisation, baking, brewing, boiling and sterilisation (EFSA, 2007a, 2015k). Considering that chloridazon is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Table 3.17.3.3a: Physico-chemical properties of chloridazon (EFSA, 2007a)

Structural formula	
Appearance (state purity)	Crystalline, colourless solid (99.9 %) light yellow-brown solid (93.0 %)
Melting point (state purity)	205.9–206.8°C (99.9 %)
Boiling point	No boiling point observed before decomposition (99.9%)
Temperature of decomposition	> 360°C (99.9 %)
Vapour pressure (state temperature, state purity)	1×10^{-9} Pa at 20°C calculated
Henry's law constant (state temperature)	5.3×10^{-10} Pa m ³ mol ⁻¹ (25°C)
Solubility in water (state temperature, state purity and pH)	PH 4: 0.41 g/L at 20°C (99.9%) pH 7: 0.42 g/L at 20°C (99.9%)
Partition coefficient (state temperature, pH and purity)	log Pow = 1.2 at 25°C (pH 7) (98.8%)
Partition coefficient (octanol/air)	Log Poa = 9.0 (EPISuite KOAWIN v1.10) (Debler et al. 2024)
Atmospheric half-life	DT ₅₀ < 7 hours derived by the Atkinson model. OH (12 h) concentration assumed = 1.5×10^6 mol cm ⁻³
Dissociation constant (state purity)	No dissociation takes place in water
Soil adsorption (geometric mean)	K _{Foc} = 180 mL/g
Hydrolytic degradation (>10%)	Stable over a study duration of 30 days at pH range 4–9 (25°C)

DT₅₀ – Disappearance time of 50% of the substance in field studies; pH – Potential of Hydrogen; P_{ow} – Octanol/water Partition Coefficient; P_{oa} – Octanol/air Partition Coefficient

The physico-chemical properties of **chloridazon-desphenyl** are reported in Table 3.17.3.3b.

Chloridazon-desphenyl has a worst-case DT₉₀ from estimated from laboratory incubations of 438 days (extrapolated beyond the study duration), indicating a high persistence in soil (EFSA, 2007a). Regarding sorption to soil, the range of K_{Foc} in Table 3.17.3.3b indicates that the substance has a very high mobility in soil (EFSA, 2007a).

The maximum PEC_w of the chloridazon-desphenyl was 35.23 µg/L (sugar beets, pre-emergence, 1 × 2.6 kg a.s./ha) (EFSA, 2007a).

Chloridazon-desphenyl is hydrolytically stable under the typical food/feed processing conditions like sterilisation, boiling and pasteurisation (EFSA, 2007a, 2015k). Considering that chloridazon-desphenyl is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Table 3.17.3.3b: Physico-chemical properties of chloridazon-desphenyl (EFSA, 2007a)

Structural formula	

Appearance (state purity)	Light brown solid
Melting point (state purity)	300–340°C (98%)
Boiling point	NA
Temperature of decomposition	NA
Vapour pressure (state temperature, state purity)	NA
Henry's law constant (state temperature)	NA
Solubility in water (state temperature, state purity and pH)	422 mg/L at 20°C (98%) no pH specified
Partition coefficient (state temperature, pH and purity)	NA
Partition coefficient (octanol/air)	NA
Atmospheric half-life	NA
Dissociation constant (state purity)	NA
Soil adsorption (geometric mean)	$K_{\text{Foc}} = 47 \text{ mL/g}$
Hydrolytic degradation (>10%)	Stable at pH range 4–9 (25°C)

NA – not applicable; pH – Potential of Hydrogen

3.17.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

Chloridazon is not approved since 1 January 2019, therefore, drift from conventional to organic agriculture should not be expected for chloridazon. Member States withdrew the corresponding product authorisations, and possibly granted grace periods allowing the use of products until 2021, therefore, potential drift from uses of the substance in conventional agriculture was considered.

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from soil surface at which it is applied).

The highest drift of chloridazon to neighbouring fields may occur during its applications to vegetables (up to 8.02 %) and field crops (up to 2.77 %). Drift values should be considered the rate received by neighbouring fields, expressed as a percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. buffer zones or spray drift-reducing nozzles).

If organic crops were present adjacent to the conventional crops treated when the substance was still in use, measurable residues of chloridazon in untreated crops cannot be excluded. However, since the nature of the potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

3.17.3.5 Accumulated/historical residue levels in soil

- What is the persistence of chloridazon and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

According to available data (EFSA, 2007a), the DT₉₀ of chloridazon in field trials (carried out in eight different European sites) has a worst-case non-normalised field value of 230 days, indicating there is limited potential for accumulation in soil of the parent chloridazon. However, its transformation product chloridazon-desphenyl (metabolite B) (part of the residue definition in plants) is in equilibrium with its methylated derivative in soil (metabolite B1). Based on the EFSA conclusion, chloridazon-desphenyl accumulates in soil and could be taken up by crops sown or planted 1 year after the application of chloridazon.

In succeeding crops, the major residues in plants were the parent chloridazon and soil transformation product chloridazon-desphenyl suggesting a similar metabolic pattern in rotational crops, as in primary crops. Available field rotational crop studies showed residues of chloridazon and/or chloridazon-desphenyl above the LOQ (0.05 mg/kg) in spinach, carrot tops, cauliflower (whole plant) and wheat straw and below the LOQ in potatoes, carrot roots, cauliflower head and cereal grains. Therefore, no significant residues from rotational crops are expected in root/tuber vegetables and cereal grains. For leafy vegetables and cereal straw, however, residues were quantified 365 days after treatment (EFSA, 2015k).

The above information suggests that the presence of chloridazon residues in untreated leafy crops may eventually be associated with plant uptake from soil previously treated. However, taking into account that the authorisation of the substance expired in 2018 the remaining residues in soil for sampling years between 2020 and 2022 should have been low and transfer of these residues to the plants is unlikely. This is particularly valid for organic leafy crops planted in fields that were previously used for conventional agriculture, considering that it requires at least 2 years after the last chemical treatment in order for organic crops to be planted in such area².

With Reg. (EU) 2023/710, all existing product authorisations were revoked and the MRLs for chloridazon were set at the LOQ for all commodities⁸⁵. This suggests that residues of chloridazon are no longer expected to be found in succeeding crops.

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Monitoring data for chloridazon in soil are available from the LUCAS pesticides 2018 (JRC, 2023) on IPCHEM¹². The data show background levels of the substance in soil samples from 18 EU countries: Austria (2 samples), Belgium (4 samples), Bulgaria (1 sample), Czechia (26 samples), Denmark (3 samples), France (73 samples), Germany (15 samples), Greece (2 samples), Hungary (16 samples), Italy (12 samples), Latvia (2 samples), Lithuania (1 sample), the Netherlands (10 samples), Poland (34 samples), Slovakia (5 samples), Slovenia (1 sample), Spain (17 samples) and Sweden (1 sample). The reported residue levels ranged from 0.0011

⁸⁵ Commission Regulation (EU) 2023/710 of 30 March 2023 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bromopropylate, chloridazon, fenpropimorph, imazaquin and tralkoxydim in or on certain products. OJ L 93, 31.3.2023, p. 57–83

mg/kg to 0.22 mg/kg. In LUCAS soil, the lack of information on the agricultural use history of the sites where soil was sampled precluded knowing whether the reported quantified findings were related to recent active use or historical levels in soil for chloridazon.

Plants exposed to the worst-case accumulated concentration of 0.22 mg/kg would be exposed to a level in soil equivalent to the one resulting from an application rate of 165 to 260 g/ha. This is within the range of application rates employed in active uses of chloridazon. If organic crops were planted in fields containing these levels of chloridazon, unintended residues in plants, within the range observed as resulting from active use, cannot be excluded. Nevertheless, it is noted that this monitoring data were collected before the expiry date of the approval of chloridazon in the European Union and it may be expected that current levels in soil should have significantly decreased since then. Product authorisations at Member State level may still not have been withdrawn between 2020 and 2022, but for a field to be used for organic farming a waiting period of 2 years since the last chemical pesticide treatment should have been respected².

More evidence on the occurrence of chloridazon residues in soil is provided by Chiaia-Hernandez et al. (2017), who analysed 29 archived agricultural soil samples collected from 14 monitoring sites from 1995 to 2008 in Switzerland. The sites were selected from locations where crops had been regularly treated with pesticides. Selection was based on land use characteristics and long-term patterns of pesticide application. Chloridazon was detected in five samples (17%) from cropland land use sites, with levels ranging from 0.002 to 0.011 mg/kg. Chloridazon was not applied but detected in 17% of cases. Additionally, a minor transformation product of chloridazon was detected in four samples (14%) from cropland land use sites, in concentrations ranging from 0.002 to 0.004 mg/kg.

In a study by Riedo et al. (2021) the presence of chloridazon was analysed in soil samples from 60 agricultural sites with different management systems (conventional tillage, conventional without soil tillage, and organic) sampled in May 2016 for an on-farm study throughout Switzerland. Results showed the presence of chloridazon in 59% of the samples at concentrations ranging from 0.00014 to 0.034 mg/kg in all types of soil, with higher levels in soil from conventional arable farming. The concentrations in soil under organic farming systems were reported to be <0.05 mg/kg in a total of 19 out of 40 samples (47.5%).

Additional evidence on the occurrence of chloridazon in soil is provided by Silva et al. (2023) in a study carried out in the framework of the EU SPRINT project. The study assessed the presence of chloridazon in 100 soil samples from conventional agriculture and 63 soil samples from organic agriculture collected during the 2021 growing season across 10 study sites in Europe: Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark. Chloridazon was quantified in two conventional soil samples (2%) at concentrations of 0.0029 and 0.0039 mg/kg in Czechia.

Considering the available evidence, plant uptake of chloridazon from soil under organic farming systems is concluded as unlikely.

3.17.3.6 Residues from water used for irrigation

- Is there evidence that residues of chloridazon present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for chloridazon in water samples were considered:

- The EEA-WATERQUALITY³⁹ database (data retrieved on 10 April 2024) reports data on chloridazon concentrations measured in 61,346 water samples collected from 13 European countries between 2018 and 2020: Belgium (2036 samples), Czechia (3,779 samples), Denmark (316 samples), Estonia (272 samples), Finland (66 samples), France (31,181 samples), Germany (943 samples), Italy (17,766 samples), Lithuania (33 samples), the Netherlands (3,986 samples), Slovakia (810 samples), Slovenia (104 samples) and Sweden (54 samples);
- The EMPODAT database (data retrieved on 25 March 2024) reports 15,688 analytical results in surface water samples from 2018 and 2020 in nine EU countries: Austria (15 samples), Bulgaria (28 samples), Croatia (8 samples), Czechia (8 samples), Germany (24 samples), Hungary (40 samples), the Netherlands (15,525 samples), Romania (4 samples) and Slovakia (36 samples);
- The NAIADES database (data retrieved on 2 April 2024) reports 50,904 surface water samples collected in France from 2020 to 2022.

Among the 127,938 analytical results for chloridazon, 1,057 were disregarded as found to report quantitative values below the analytical LOQ and 3,807 were disregarded as found to report quantified residues equal to LOQs as high as 1 µg/L and above. Therefore, the number of water samples considered is 123,074.

Based on the screening process described in section 'Data and methodologies', for 100% of water samples analysed for chloridazon and reported in EEA-WATERQUALITY, EMPODAT and NAIADES (123,074 samples), the residue concentrations were below the screening Cw of 45.52 µg/L.

Therefore, it can be concluded that transfer of chloridazon residues from EU water sources to plant commodities when this water is used for irrigation in the EU is unlikely.

Residues of chloridazon-desphenyl in water (originating from the use of chloridazon) can also contribute to the apparent residues of chloridazon.

- The EEA-WATERQUALITY³⁹ database (data retrieved on 10 April 2024) reports data on chloridazon-desphenyl concentrations measured in 12,287 water samples collected from seven European countries between 2018 and 2020: Belgium (823 samples), Czechia (3,779 samples), Denmark (1,375 samples), Estonia (304 samples), Finland (45 samples), France (5,889 samples) and the Netherlands (72 samples);
- The EMPODAT database (data retrieved on 4 April 2024) reports 491 analytical results from surface water samples between 2017 and 2019 in the Netherlands (490 samples) and Slovakia (1 sample);
- The NAIADES database (data retrieved on 4 April 2024) reports 3,863 analytical results from surface water samples collected in France between 2020 and 2022.

Among the 16,641 analytical results for chloridazon-desphenyl, four were disregarded as found to report quantitative values below the analytical LOQ. Therefore, the number of water samples considered is 16,637.

Based on the screening process described in section 'Data and methodologies', for 99.6% of water samples analysed for chloridazon-desphenyl and reported in the above-mentioned databases (16,630 samples), the residue concentrations in these waters were below the screening Cw of 23.00 µg/L and, therefore, transfer of residues from water sources to plant commodities if water containing residues at these levels is used for irrigation is unlikely.

For 0.4% of samples (7 out of 16,637 samples), the residue concentrations were or above the screening Cw of 23.00 µg/L and the potential transfer of residues to plant commodities cannot be excluded.

It should be noted that although monitoring data for chloridazon and chloridazon-desphenyl were collected after the expiry of the approval of chloridazon in the EU, product authorisations at Member State level may not have been withdrawn between 2020 and 2022. Following the withdrawal of product authorisations, it may be expected that current levels in surface water should have significantly decreased since then.

Based on the above evidence and taking into account the limitations of the data, it can be concluded that the transfer of chloridazon residues from water to plant commodities when this water is used to irrigate plants is unlikely.

3.17.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *chloridazon*, *industry/industrial*, and *air/atmosphere*) did not identify any relevant European studies.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water. Based on conservative estimations of the possible transfer of residues from water used for irrigation to plant commodities, the transfer of residues of chloridazon from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 7, 2025, using the keywords *chloridazon*, *industry/industrial*, and *water*) identified one European study, which was considered irrelevant for this section.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Based on information on the possible plant uptake of chloridazon from EU soil, the transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 17, 2025, using the keywords *chloridazon*, *industry/industrial*, and *soil/sediment*) did not identify any relevant European study.

3.17.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Medium and long-range aerial transport of residues

In a study published under the EU SPRINT project that investigated the presence of chloridazon in air samples collected between April 2021 and June 2022 from one agricultural area of conventional farming in the Netherlands (potatoes, onions and sugar beet) (Debler et al., 2024), chloridazon was detected in 5% of air samples. Only qualitative information was available in the study for chloridazon. Note was taken that the field had not undergone chloridazon treatment before the sample collection from the surrounding area and measurement. The limited detection frequencies suggest that the medium and long-range aerial transport of residues from treated crops to plants that have not been treated with chloridazon is not expected. In the absence of other studies, however, these results on their own do not allow a conclusion on the potential aerial transport of residues of chloridazon in the medium range from the treated areas. Since chloridazon is no longer approved for plant protection purposes in the EU, following the end of the grace period, transfer of chloridazon residues to plants from medium to long-range aerial transport is unlikely.

3.17.4 Conclusions on chloridazon

Considering that chloridazon is a non-approved active substance since January 2019 and that it does not occur naturally, quantified residues of chloridazon are generally not expected to be found in food and feed of plant origin. In the years 2020 to 2022, however, products with chloridazon may have still been on the EU market and used in conventional agriculture.

- Residue trials carried out to support the critical GAPs⁴ before the expiry date of the approval of chloridazon, gave residue concentrations of up to 1.79 mg/kg for the sum of chloridazon and chloridazon-desphenyl expressed as chloridazon, of up to 0.47 mg/kg for chloridazon and its glycoside and of up to 0.93 mg/kg for chloridazon-desphenyl. Concentrations in the ranges reported in Table 3.17.3.2-1 might be associated with active use of chloridazon according to the critical GAPs. For less critical GAPs, lower concentrations may also be associated with active use.
- Analysis of untreated commodities (control samples) in the context of residue trials carried out for chloridazon did not give quantified results.
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for chloridazon in unprocessed commodities with authorised uses ranged from 0.018 mg/kg in leaf vegetables, herbs and edible flowers to 0.02 mg/kg in root and tuber vegetables.
- In organic commodities that were analysed under the pesticide residues monitoring programme between 2020 and 2022 there were no commodity groups with five or more quantified findings.
- No residues of chloridazon were quantified in any of the processed commodities sampled under the EU monitoring programmes from 2020 to 2022. Considering that chloridazon

and chloridazon-desphenyl are stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

- Overall, residues of chloridazon were not quantified in more than 99% of samples collected and analysed between 2020 and 2022 from both labelled and not labelled as organic crops.
- During the transitional period for the withdrawal of authorisations of products containing chloridazon, transfer of residues due to drift from conventional crops grown in the vicinity of organic crops cannot be excluded. Following the end of the grace period, transfer of residues from drift is unlikely.
- The available evidence is insufficient to conclude on the potential aerial transport of residues of chloridazon in aerosols in the medium range from the treated areas. Considering, however, that chloridazon is no longer approved, medium to long-range aerial transport of chloridazon residues to plants is unlikely following the end of the grace period.
- Note was taken that from the 71 samples not labelled as organic that gave quantified results for chloridazon (0.18% of quantified findings), 39 were leafy vegetables. Data on succeeding crops suggest that the presence of chloridazon in untreated leafy crops is likely to be associated with plant uptake from soil containing chloridazon residues. Although this cannot be excluded for crops planted between 2020 and 2022 in soil treated at that time, it is unlikely for organic crops (for which a waiting period of 2 years is mandatory) and crops planted in the more recent years.
- Transfer of chloridazon and chloridazon-desphenyl residues from EU water sources used for irrigation to plant commodities is unlikely.
- Conservative estimates of the possible transfer of residues of chloridazon from water used for irrigation to plant commodities suggest that the transfer of residues from industrial emissions to water and from water to plants and plant commodities is less likely.

The pathways of residues of chloridazon to plants and plant commodities are summarised in Figure 17.



Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded

3.18 Pyriproxyfen

3.18.1 Method(s)

- What is/are the residues to be monitored for the active substance pyriproxyfen according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

For the active substance pyriproxyfen, the residue definition for enforcement in food and feed of plant origin has been proposed as 'pyriproxyfen (F)⁸⁶' in the EFSA peer review conclusion and the EFSA MRL review (EFSA, 2019g, 2022i). This residue definition is applicable to primary, rotational crops and processed products. This residue definition for enforcement is implemented in Regulation (EC) No 396/2005³ and is also applicable to honey and apiculture products.

Based on the above only residues of pyriproxyfen are to be monitored in foods of plant origin, honey and other apiculture products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

A multi-residue QuEChERS analytical method based on HPLC-MS/MS is considered suitable for the enforcement of pyriproxyfen in high water, high acid, and high oil content, as well as dry commodities and difficult matrices (e.g. black tea) with an LOQ of 0.01 mg/kg (EFSA, 2019g, 2022i). Another multi-residue QuEChERS method followed by LC-MS/MS can be used for the monitoring of pyriproxyfen in honey with a screening detection limit of 0.01 mg/kg (EFSA, 2022i).

EURLs have also developed multi-residue QuEChERS methods using both GC-MS/MS and LC-MS/MS for pyriproxyfen enforcement. The LOQ achieved with these methods is 0.01 mg/kg in high water, high acid, high oil content and dry commodities of plant origin. Note was taken that the commercially available analytical standard of pyriproxyfen is a racemate (EURLs, 2021).

Another analytical multi-residue method (DFG S19) has been developed based on GC-MS for the group of high water and high oil content matrices and has been considered sufficiently validated at the LOQ of 0.01 mg/kg (EFSA, 2016h).

According to EURL for Residues of Pesticides (EURL, 2024, under 'Documentation as provided to EFSA'), a multi-residue citrate-buffered QuEChERS method based on GC-MS/MS is validated to monitor pyriproxyfen residues in honey samples at an LOQ of 0.002 mg/kg. Higher sensitivities are achieved by utilising a multi-residue method based on LC-Q-TOF (LOQ: 0.001 mg/kg).

Overall, there are multi-residue methods available for the monitoring of residues of pyriproxyfen in high water, high acid, high oil content, dry and complex plant commodities, as well as in honey and other apiculture products, with LOQs ranging from 0.001 mg/kg to 0.01 mg/kg.

3.18.2 Authorisation status and use

- Is pyriproxyfen currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not,

⁸⁶ (F) indicates that the residue definition is fat soluble

has pyriproxyfen ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

a) Authorisations for plant protection use in conventional agriculture

Pyriproxyfen has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of its approval is on 31 July 2035 as indicated by the EU Pesticides Database⁵ (accessed 8 January 2024).

According to the EU Pesticides Database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Greece, Spain, France, Croatia, Hungary, Ireland, Italy, the Netherlands, Poland, Portugal, Romania, Sweden, Slovenia, and Slovakia.

b) Authorisations for purposes other than plant protection

Biocidal use

Pyriproxyfen has been approved for biocidal use in the EU Member States, Iceland, Liechtenstein and Norway in accordance with Regulation (EU) No 528/2012⁷ since 1 February 2015. The expiry date of approval of the active substance is on 31 July 2027, as indicated by the ECHA website⁶ (accessed 26 March 2025).

According to the ECHA website⁶, at national level, pyriproxyfen has been authorised in biocidal product formulations in Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

Other uses

A search carried out on the ECHA website⁹ (accessed 6 June 2024) showed that pyriproxyfen had one registration under REACH, which was active in the period 2020–2022, but became inactive in October 2022. Information on the manufacture, use and exposure to pyriproxyfen related to this registration is not available on the ECHA website.

According to the EU Veterinary Medicine Database²⁴, pyriproxyfen is authorised as veterinary medicine in cats and dogs.

- What is/was the actual use of pyriproxyfen? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of pyriproxyfen

According to EFSA (2013k), pyriproxyfen is an insecticide that belongs to the class of juvenile hormone mimics. Its mode of action is suppression of embryogenesis and inhibition of metamorphosis and reproduction in insects.

Conditions of use and applicable crops

The uses reported in the EFSA MRL review included a foliar application (outdoor and indoor) in both northern and southern Europe (EFSA, 2022i). Uses were reported for food and feed commodities belonging to the following crop groups: citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, oilseeds and oil fruits. Application rates range up from 21 g a.s./ha to 230 g a.s./ha (EFSA, 2022i,j).

Note was taken that the food uses of root and tuber vegetables, bulb vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables and stem vegetables and the feed uses of turnip tops were not supported by data (see Section 3.18.3.2 'Active use (all legitimate uses of the substance)').

b) Uses for purposes other than plant protection

Biocidal use

Biocidal products containing pyriproxyfen are used for indoor and/or outdoor insect pest control in livestock installations and in residential and commercial buildings (Netherlands, 2012). The products are applied as granular, aerosol or ready-to-use bait formulations and can be used by professionals and non-professionals (see also 'authorisations for purposes other than plant protection/biocidal use').

Other uses

There was one active REACH⁹ registration dossier for pyriproxyfen in the period 2020–2022, but it is no longer valid (see also 'authorisations for purposes other than plant protection/other uses').

Pyriproxyfen is a veterinary medicine²⁴ used in cats and dogs (see previous section).

3.18.3 Sources of residues in plants

3.18.3.1 Natural occurrence

- Is there evidence that pyriproxyfen occurs naturally? What is known about the natural origin of this substance?

Pyriproxyfen is a synthetic chemical produced industrially through chemical processes (Lewis et al., 2016). No information on the potential natural presence of pyriproxyfen was found in the literature²².

3.18.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of pyriproxyfen per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of pyriproxyfen in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.18.3.2-1 to 3.18.3.2-4. The possible presence of residues in control (untreated) samples is also discussed in this section.

For both residue trials and results from monitoring, residue concentrations refer to the residue definition for enforcement (i.e. pyriproxyfen).

Occurrence of pyriproxyfen from residue trials carried out for the critical GAP per crop

When applied at the critical GAPs⁴ reported to EFSA, residue levels of pyriproxyfen were below LOQ in tree nuts, berries and small fruits and oilseeds and oil fruits (EFSA, 2022i). Quantified residues of pyriproxyfen were found in citrus fruits, pome fruits, stone fruits, miscellaneous fruits, and fruiting vegetables (EFSA, 2022i,j).

Although EU GAPs were reported for all uses indicated under 3.18.2 'Conditions of use and applicable crops', for the following food commodities results from residue trials were not submitted and, therefore, were not assessed in the context of the EFSA MRL review (EFSA, 2022i): root and tuber vegetables, bulb vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables and stem vegetables. Similarly, results from residue trials were not submitted for the feed commodity turnip tops.

These findings are summarised in Table 3.18.3.2-1 'Occurrence of pyriproxyfen from residue trials carried out for the critical GAP per crop'.

Table 3.18.3.2-1: Occurrence of pyriproxyfen from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pyriproxyfen (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
Food				
0110000	Citrus fruits	0.7	0.1–0.47	0.19
0120000	Tree nuts ^{c)}	0.01*	<LOQ (0.01)	<LOQ (0.01)
0130000	Pome fruits	0.01*–0.05	<LOQ (0.01)–0.03	0.01
0140000	Stone fruits	0.01*–1.5	<LOQ (0.01)–0.24	0.017
0150000	Berries and small fruits	0.01*–0.05	<LOQ (0.01) – <LOQ (0.05)	<LOQ (0.05)
0160000	Miscellaneous fruits	0.01*–0.7	<LOQ (0.01)–0.24	0.01
0210000	Root and tuber vegetables ^{d)}	0.01*	NR	-
0220000	Bulb vegetables ^{d)}	0.01*	NR	-
0230000	Fruiting vegetables	0.01*–0.7	<LOQ (0.005)–0.38	0.11
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops) ^{d)}	0.01*	NR	-
0250000	Leaf vegetables, herbs and edible flowers ^{d)}	0.01*	NR	-
0260000	Legume vegetables ^{d)}	0.01*	NR	-
0270000	Stem vegetables ^{d)}	0.01*	NR	-
0400000	Oilseeds and oil fruits	0.01*–0.05	<LOQ (0.01)	<LOQ (0.01)
Feed				
1200000	Turnip tops	NA	NR	-

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; NR – no residue trials data are available; '-': not estimated due to lack of data.

a) Maximum Residue Level in Reg. (EU) No 2023/1753 mg/kg amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA, 2022i,j; c) Uses in tree nuts were supported from residue trials in pome fruits and stone fruits (apples and apricots) (EFSA, 2022i); d) For uses not supported by data, the MRLs were lowered to the LOQ (EFSA, 2022i).

Occurrence of pyriproxyfen under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to pyriproxyfen are given in Regulation (EU) 2020/856⁷⁷ for the years 2020–2022.

Regarding commodities non-labelled as organic, 114,694 samples were collected and analysed for pyriproxyfen in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 105,563 (92.04%) were unprocessed and 9,131 (7.96%) processed commodities. No residues were quantified in 112,886 samples out of the 114,694 samples (98.42%). In 1802 samples out of the 114,694 samples (1.57%) pyriproxyfen was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-18.1. MRLs were exceeded in six samples out of the 114,694 samples (0.01%). The highest concentration for samples exceeding the MRLs was 3.1 mg/kg in leaf vegetables, herbs and edible flowers (thyme).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.18.3.2-2a for unprocessed and in Table 3.18.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on pyriproxyfen in feed not labelled as organic were submitted to EFSA.

Table 3.18.3.2-2a: Occurrence of pyriproxyfen from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pyriproxyfen (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0110000	Citrus fruits	0.7	0.001	0.001–0.84	1399	0.019
0120000	Tree nuts	0.01*	0.005	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*–0.05	0.001	0.001–0.206	32	0.015
0140000	Stone fruits	0.01*–1.5	0.001	0.003–0.107	31	0.018
0150000	Berries and small fruits	0.01*–0.05	0.001	0.007–0.049	7	0.03
0160000	Miscellaneous fruits	0.01*–0.7	0.001	0.005–0.25	29	0.038
0210000	Root and tuber vegetables	0.01*	0.001	0.056	1	0.056
0220000	Bulb vegetables	0.01*	0.001	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*–0.7	0.001	0.001–0.944	259	0.021
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	0.001	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*	0.001	0.001–3.1	8	0.004
0260000	Legume vegetables	0.01*	0.001	0.0081	1	0.008
0270000	Stem vegetables	0.01*	0.001	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–0.05	0.005	0.19	1	0.19
Feed						
1200000	Turnip tops	NA	ND	ND	ND	ND
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of pyriproxyfen is not expected)						
0280000	Fungi, mosses and lichens	0.01*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.01*	0.002	<LOQ	0	<LOQ

Findings of not authorised substances in organic products

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pyriproxyfen (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0500000	Cereals	0.01*	0.002	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*–15	0.005	0.005–0.38	4	0.056
0700000	Hops	0.05*	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*	0.005	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.005	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2023/1753 mg/kg amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.18.3.2-2b: Occurrence of pyriproxyfen from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pyriproxyfen (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0110000	Citrus fruits	0.7	0.001	0.003–0.13	31	0.024
0120000	Tree nuts	0.05*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*–0.05	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*–1.5	0.002	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.01*–0.05	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*–0.7	0.002	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.05*	0.01	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.05*–1	0.001	0.005–0.096	2	0.051
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.05*	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.05*	0.002	<LOQ	0	<LOQ
0260000	Legume vegetables	0.05*	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.05*	0.01	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.05*	0.002	0.02–0.1	3	0.07
Feed						
1200000	Turnip tops	NA	ND	ND	ND	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of pyriproxyfen is not expected)						
0280000	Fungi, mosses and lichens	0.05*	0.005	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.05*	ND	ND	ND	ND
0300000	Pulses (dried)	0.05*	0.002	<LOQ	0	<LOQ
0500000	Cereals	0.05*	0.002	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*	0.005	<LOQ	0	<LOQ
0700000	Hops	0.05*	0.05	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*	0.005	<LOQ	0	<LOQ

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pyriproxyfen (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0900000	Sugar plants	0.05*	0.002	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2023/1753 mg/kg amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of pyriproxyfen in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 9,874 samples were collected and analysed for pyriproxyfen from plant commodities, honey and other apiculture under a monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 8,193 (82,98%) were unprocessed and 1,681 (17.02%) processed commodities. No residues were quantified in 9,867 samples out of the 9,874 samples (99.93%). In seven samples out of the 9,874 samples (0.07%) pyriproxyfen was found at or above the analytical LOQ but below or at the MRL. No samples labelled as organic were above MRLs.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.18.3.2-3a for unprocessed and in Table 3.18.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on pyriproxyfen in feed not labelled as organic were submitted to EFSA.

Table 3.18.3.2-3a: Occurrence of pyriproxyfen from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pyriproxyfen (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.7	0.001	0.001–0.25	6	0.053
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*–0.05	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*–1.5	0.001	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.01*–0.05	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*–0.7	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*	0.001	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*–0.7	0.001	0.038	1	0.038
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	0.001	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*	0.001	<LOQ	0	<LOQ
0260000	Legume vegetables	0.01*	0.001	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*	0.001	<LOQ	0	<LOQ

Findings of not authorised substances in organic products

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pyriproxyfen (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0280000	Fungi, mosses and lichens	0.01*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.01*	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.05*	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.01*	0.001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*–15	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities.

a) Maximum Residue Level in Reg. (EU) No 2023/1753 mg/kg amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.18.3.2-3b: Occurrence of pyriproxyfen from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pyriproxyfen (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.7	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.01*–0.05	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*–1.5	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.01*–0.05	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*–0.7	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*	0.005	<LOQ	0	<LOQ
0220000	Fruiting vegetables	0.01*–0.7	0.001	<LOQ	0	<LOQ
0230000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	0.01	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*	0.005	<LOQ	0	<LOQ
0260000	Legume vegetables	0.01*	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.01	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0300000	Pulses (dried)	0.01*	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.05*	0.002	<LOQ	0	<LOQ
0500000	Cereals	0.01*	0.002	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*–15	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	ND	ND	ND	ND
0800000	Spices (dried)	0.05*	0.025	<LOQ	0	<LOQ



Findings of not authorised substances in organic products

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Pyriproxyfen (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0900000	Sugar plants	0.01*	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2023/1753 mg/kg amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of pyriproxyfen in the EU Organic Farming Information System

The EU OFIS reported nine quantified results for pyriproxyfen in 2021 and 2022. Eight of the sampled and analysed had EU origin and one was of non-EU origin. Residues were found in seven samples of citrus fruits (lemons, oranges), one sample of berries and small fruits (grapes) and one sample of fruiting vegetables (chilli peppers). The concentrations of pyriproxyfen residues were above LOQ but below MRL in all nine samples. The highest concentration was reported for lemon samples of EU origin, with quantified levels of 0.092 mg/kg. No samples labelled as organic were above MRLs. These findings are summarised in Table 3.18.3.2-4.

Table 3.18.3.2-4: Occurrence of pyriproxyfen from the EU OFIS in the years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
0110020	Oranges	0.7	0.01; 0.034; 0.049 – Oranges	ND
0110030	Lemons	0.7	0.092; 0.092; 0.031 – Lemons	0.029 – Lemons (oil)
0231020	Sweet peppers/bell peppers	1	0.007 – Chilli	ND
Samples of non-EU origin				
0151010	Table grapes	0.05*	ND	0.012 – Sultanas (drying)

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2023/1753 mg/kg amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of pyriproxyfen in untreated samples (control samples) from residue trials

No quantified findings of pyriproxyfen were observed in control (untreated) samples during residue trials carried out for the critical GAP⁴ per crop (Greece, 2022; the Netherlands, 2019, 2022a).

- Could the presence of pyriproxyfen and/or its residues be due to biocide use?

Products containing pyriproxyfen are utilised for controlling insect pests both indoors and outdoors, including on surfaces plagued by lice, in animal housing and in waste treatment facilities to combat fly populations. Mitigation measures were proposed to prevent environmental exposure to pyriproxyfen (Netherlands, 2012). These measures include proposals to prevent adverse effects due to drift, restrictions on use near bodies of water, and avoidance of application on surfaces or materials that can be easily washed. PEC values have been calculated to predict the potential contamination of water and soil for different scenarios (e.g. application of manure to arable land or emissions from sewage treatment plant treating wastewater carried out by the

Evaluation Member- State). These PECs are covered by those estimated for agricultural uses of the substance (see Section 3.18.3.6).

Based on the above, it can be concluded that the release of residues of pyriproxyfen in the water and/or soil after biocidal use cannot be excluded.

3.18.3.3 Behaviour in food and feed products

- What key physico-chemical properties of pyriproxyfen are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of pyriproxyfen are reported in Table 3.18.3.3.

Pyriproxyfen exists as a racemic mixture. There is currently no knowledge regarding any potential conversion or preferential degradation of its isomers in soil or water (EFSA, 2019g).

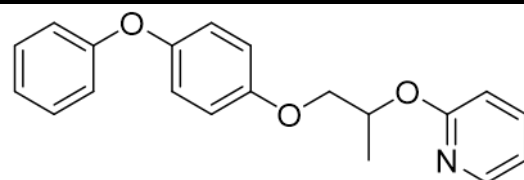
Pyriproxyfen has a $\log P_{ow}$ of 4.86 and it is considered a fat-soluble compound. The substance has low to moderate persistence in soil (see Section 3.18.3.5). Regarding sorption to soil, the geomean K_{Foc} in Table 3.18.3.3 indicates that the substance is immobile in soil (EFSA, 2019g).

The maximum calculated PEC_w for pyriproxyfen for the representative uses was 8.25 µg/L (spray application to citrus fruits; 225 g a.s./ha) (EFSA, 2019g). In the context of the evaluation of pyriproxyfen as a biocide, the PEC_w estimated for worst-case scenarios after product application was 0.14 µg/L (Netherlands, 2012).

Pyriproxyfen is hydrolytically stable under sterile hydrolysis conditions at 50°C at pH 4, 7 and 9. Its stability was also demonstrated in a study mimicking pasteurisation, baking, brewing, boiling, and sterilisation (EFSA, 2019g). Considering that pyriproxyfen is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Pyriproxyfen exhibits a short half-life in the air in the upper atmosphere (2.5 hours) and low vapour pressure ($<1.33 \times 10^{-5}$ Pa at 23°C) (EFSA, 2009 and 2019g).

Table 3.18.3.3: Physico-chemical properties of pyriproxyfen

Structural formula	
Appearance (state purity)	Granular white solid (100%); pale yellowish white solid (95.2%)
Melting point (state purity)	48–50°C (100%)
Boiling point	318°C (99.7%)
Temperature of decomposition	No decomposition up to 318°C under a N ₂ atmosphere
Vapour pressure (state temperature, state purity)	$<1.33 \times 10^{-5}$ Pa at 23°C (purity not specified)
Henry's law constant (state temperature)	$<7.37 \times 10^{-2}$ kPa m ³ mol ⁻¹ 23°C



Solubility in water (state temperature, state purity and pH)	pH 5: 0.058 mg/L at 20°C (100%) pH 7: 0.101 mg/L at 20°C (100%) pH 9: 0.119 mg/L at 20°C (100%)
Partition coefficient (state temperature, pH and purity)	log Pow = 4.86, at 25°C pH 7 (100%)
Partition coefficient (octanol/air)	NA
Atmospheric half-life	DT ₅₀ of 2.5 hours derived by the Atkinson model (APOWIN version 1.92). OH concentration assumed = 1.5×10^6 mol cm ⁻³
Dissociation constant (state purity)	Not determined due to the low water solubility of the test substance
Soil adsorption (geometric mean)	K _{Foc} = 20030 mL/g
Hydrolytic degradation (>10%)	Hydrolytically stable (pH 4–9 up to 50°C)

DT₅₀ – Disappearance time of 50% of the substance in field studies; NA – not applicable; pH – Potential of Hydrogen; P_{ow} – Octanol/water Partition Coefficient

3.18.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The spray drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be loaded over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from the soil surface at which it is applied).

The highest drift of pyriproxyfen to neighbouring fields may occur during its applications to fruit crops (up to 29.2%), hops (19.33%), vineyards and vegetables (up to 8.02%) and field crops (up to 2.77%). Drift values should be considered the rate received by neighbouring fields, expressed as a percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. buffer zones or spray drift-reducing nozzles).

If organic crops are present adjacent to the conventional crops treated, quantifiable residues of pyriproxyfen in the untreated crop cannot be excluded (above all if the treated crops are fruit trees). However, since the nature of the potential adjacent crops and their possible growing stage is not known, no quantitative estimation of the likelihood and levels of residues that will result from this scenario is possible.

3.18.3.5 Accumulated/historical residue levels in soil

- What is the persistence of pyriproxyfen and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

Since, according to available data DT₉₀ of pyriproxyfen in laboratory and field trials is < 1 year (worst-case laboratory DT₉₀=135 days; worst-case North American field DT₉₀=31.5 days), pyriproxyfen is not expected to accumulate in soil over successive seasons (EFSA, 2019g). The available confined rotational crop study with radiolabelled pyriproxyfen carried out on the relevant crop categories, i.e. cereals, leafy and root crops indicated that it is unlikely that significant residues (>0.01 mg/kg) of pyriproxyfen or its soil transformation products would be

present in crops at plant-back intervals longer than 30 days. This conclusion is also valid for organic crops, when planted in fields that were previously used pyriproxyfen for conventional agriculture, considering that it requires at least 2 years after the last chemical treatment in order for organic crops to be planted in such area².

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Accumulation of pyriproxyfen in soil is not expected.

3.18.3.6 Residues from water used for irrigation

- Is there evidence that residues of pyriproxyfen present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for pyriproxyfen in water samples were considered:

- The EMPODAT database (data retrieved on 5 April 2024) reports 35 analytical results from surface water samples collected in the Netherlands between 2018 and 2020;
- The NAIADES database (data retrieved on 25 March 2024) reports 742 analytical results from surface water samples collected in France from 2020 to 2022.

Based on the screening process described in section 'Data and methodologies', for 100% of surface water samples analysed and reported in EMPODAT and NAIADES (777 samples), the residue concentrations were below the screening Cw of 0.79 µg/L.

Therefore, it can be concluded that transfer of pyriproxyfen residues from EU surface water sources to plant commodities when this water is used for irrigation of plants is unlikely.

3.18.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *pyriproxyfen*, *industry/industrial*, and *air/atmosphere*) did not identify any relevant European studies.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water. Based on conservative estimations of the possible transfer of residues from water used for irrigation to plant commodities, the transfer of residues of pyriproxyfen from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

A literature review was carried out to gather relevant information. A search in the Scopus database (conducted on March 4, 2025, using the keywords *pyriproxyfen*, *industry/industrial*, and *water*) identified one European article, which was considered relevant for this section.

In a study by Masiá et al. (2013), the presence of 50 pesticides was investigated in water and sediment samples from the Guadalquivir River Basin in Spain in 2010 and 2011. Pyriproxyfen was quantified only in water samples from 2010 at a maximum concentration of 3.04 ng/L (88% detection frequencies). According to the authors, urban/industrial wastewaters and runoff were among the factors contributing to these residue concentrations. However, no evidence was provided in the paper to support this argument.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Based on information on the possible plant uptake of pyriproxyfen from EU soil, the transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on March 5, 2025, using the keywords *pyriproxyfen*, *industry/industrial*, and *soil/sediment*) identified one European study which was considered irrelevant for this section.

3.18.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Uptake from organic fertilisers

In a study investigating pesticide residues in organic fertilisers, residues of pyriproxyfen and other pesticides were quantified (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). The authors attributed the origin of the residues to the use of plant protection products in the composted crop or to their presence in composted manure due to transfer from animal feed after digestion, their presence in straw used in stables or due to potential veterinary use²⁴. Analysis of solid organic fertilisers gave an average concentration of 0.119 mg/kg for pyriproxyfen in two out of 147 samples (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). Considering that (according to the authors) the use of completely free from residues organic fertilisers is currently unsustainable, transfer of pyriproxyfen residues from fertilisers used in organic production to organic products cannot be excluded. On the other hand, no residues of pyriproxyfen were found in any of the products of the crops discussed in the study (van der Blom et al., 2022, under 'Documentation as provided to EFSA'), which may indicate poor plant uptake of the pyriproxyfen residues occurring in the compost.

Use as veterinary medicine

The use of pyriproxyfen as veterinary medicine²⁴ might also result in the release of residues in the environment that could be taken up by plants. On the other hand, veterinary use of pyriproxyfen does not concern food-producing animals but only domestic animals, therefore, transfer of residues to agricultural soil and, from there, to plants is less likely. This conclusion is supported by conservative estimations of the possible transfer of residues of pyriproxyfen from

water used for irrigation to plant commodities and information on the possible plant uptake of residues of pyriproxyfen from the EU soil.

3.18.4 Conclusions on pyriproxyfen

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use.
- Residue trials carried out to support the critical GAPs⁴ for pyriproxyfen, gave residue concentrations of up to 0.47 mg/kg (highest concentration for citrus fruits). Concentrations in the ranges reported in Table 3.18.3.2-1 might be associated with active use of pyriproxyfen according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.
- Analysis of untreated commodities (control samples) in the context of residue trials carried out for pyriproxyfen did not give quantified results.
- In unprocessed products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for pyriproxyfen in unprocessed commodities with authorised uses ranged from 0.004 mg/kg in leaf vegetables, herbs and edible flowers to 0.038 mg/kg in miscellaneous fruits.
- In unprocessed organic commodities that were analysed under the pesticide residues monitoring programme between 2020 and 2022 only citrus fruits had five quantified findings ranging from 0.001 to 0.25 mg/kg with a median concentration of 0.053 mg/kg.
- In processed commodities, residues of pyriproxyfen were not quantified in any of the products labelled as organic and sampled under the EU monitoring programmes from 2020 to 2022. In samples from processed products not labelled as organic with five or more quantified findings, residues of pyriproxyfen were quantified only in citrus fruits at a median concentration of 0.024 mg/kg. Considering that pyriproxyfen is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.
- Overall, in commodities labelled as organic, pyriproxyfen was quantified in 0.07% of samples (7 out of 9,874 samples). This percentage is around 23 times lower than the percentage reflecting the number of findings in samples not labelled as organic (1.6%) (see Appendix B, Tables B-18.1 and B-18.2). These results suggest that the occurrence of residues of pyriproxyfen in organic products is significantly less likely when compared with the conventional commodities.
- Potential sources of the unintentional presence of residues of pyriproxyfen in plants are drift from conventional crops grown in the vicinity. No information was identified on the potential aerial transfer of residues of pyriproxyfen in the medium range from treated areas. The atmospheric DT₅₀ indicates long-range transport is not expected.

- Pyriproxyfen is not persistent in soil. Plant uptake of residues of pyriproxyfen from soil where pyriproxyfen has not been actively used or from organic fertilisers that contain residues is unlikely.
- Transfer of pyriproxyfen residues from EU water sources used for irrigation to plant commodities is unlikely.
- Note was taken that pyriproxyfen had an active registration under REACH⁹ between 2020 and 2022, but this became inactive in October 2022. On the other hand, information on the product, its uses and relevance to this assessment is unavailable.
- The use of pyriproxyfen as a veterinary medicine²⁴ might also result in the release of residues in the environment that could be taken up by plants. On the other hand, veterinary use of pyriproxyfen does not concern food-producing animals but only domestic animals. Therefore, the transfer of residues to agricultural soil and, from there, to plants is less likely.
- Pyriproxyfen is also used in biocidal products and applications of biocidal products containing pyriproxyfen may result in the release of residues of pyriproxyfen in the environment.
- Conservative estimates of the possible transfer of residues of pyriproxyfen from water used for irrigation to plant commodities and information on the possible plant uptake of residues of pyriproxyfen from EU soil suggest that the transfer of residues of pyriproxyfen from biocidal, veterinary and other non-pesticide uses as well as the transfer from industrial emissions to the environment and from the environment to plants and plant commodities is less likely.

The pathways of residues of pyriproxyfen to plants and plant commodities are summarised in Figure 18.



3.19 Fludioxonil

3.19.1 Method(s)

- What is/are the residues to be monitored for the active substance fludioxonil according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

For the active substance fludioxonil, the residue definition for enforcement in food and feed of plant origin has been proposed as 'fludioxonil' in the EFSA peer review conclusion and the EFSA MRL review (EFSA, 2007b, 2011e and 2024f). This residue definition is applicable to primary, rotational crops, processed products, as well as for honey. This residue definition for enforcement is implemented in Regulation (EC) No 396/2005³.

Based on the above only residues of fludioxonil are to be monitored in foods of plant origin, honey and other apiculture products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

A multi-residue QuEChERS analytical method based on HPLC-MS/MS is considered suitable for the enforcement of fludioxonil in high water, high acid, high oil, and dry commodities with an LOQ of 0.01 mg/kg (EFSA, 2010c, 2011e, 2021f).

Another multi-residue analytical method (DFG S19) using HPLC-MS/MS has been validated for analysing fludioxonil in high water, high acid, high oil content, and dry commodities with an LOQ of 0.01 mg/kg (EFSA, 2019h, 2021g, 2024f).

Additionally, an analytical method using HPLC-UV was evaluated and validated for the determination of fludioxonil with an LOQ of 0.02 mg/kg in high water, high acid content, and dry commodities, and an LOQ of 0.05 mg/kg in wine (EFSA, 2011e).

According to EURL for Residues of Pesticides (EURL, 2024, under 'Documentation as provided to EFSA'), a multi-residue citrate-buffered QuEChERS method based on GC-MS/MS is validated to monitor fludioxonil residues in honey samples at an LOQ of 0.002 mg/kg. Higher sensitivities are achieved by utilising a multi-residue method based on GC-Orbitrap (LOQ: 0.0005 mg/kg). A multi-residue QuEChERS method based on GC-MS/MS is available to monitor fludioxonil residues in pollen collected by bees at an LOQ of 0.005 mg/kg.

Overall, there are multi-residue methods available for the monitoring of residues of fludioxonil in high water, high acid, high oil content and dry commodities of plant origin, as well as in honey and other apiculture products, with LOQs ranging from 0.0005 to 0.05 mg/kg.

3.19.2 Authorisation status and use

- Is fludioxonil currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has fludioxonil ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

a) Authorisations for plant protection use in conventional agriculture

Fludioxonil has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of approval of the active substance is on 15 June 2025, as indicated by the EU Pesticides Database⁵ (accessed 27 November 2024). The application for the renewal of the approval of fludioxonil is under assessment.

According to the EU Pesticides Database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, France, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, and Slovakia.

b) Authorisations for purposes other than plant protection

Biocidal use

Fludioxonil has been approved for biocidal use in the EU Member States, Iceland, Liechtenstein and Norway in accordance with Regulation (EU) No 528/2012⁷ since 1 April 2018. The expiry date of the approval of the active substance is on 31 March 2028, as indicated by the ECHA website⁶ (accessed 12 February 2024).

Other uses

According to the search carried out on the ECHA website⁹ on 6 June 2024, fludioxonil is not currently registered under REACH.

- What is/was the actual use of fludioxonil? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of fludioxonil

Fludioxonil is a fungicide belonging to the phenylpyrrole class of compounds. It acts by inhibiting a mitogen-activated protein (MAP) kinase involved in the signal transduction pathways for osmoregulatory processes, such as glycerol synthesis. This compound is used in both foliar and seed treatments to control fungal diseases caused by *Ascomycetes*, *Basidiomycetes*, and *Deuteromycetes* (also known as *Fungi imperfecti*) (EFSA, 2011e).

Conditions of use and applicable crops

The uses reported in the EFSA MRL review for fludioxonil included applications from northern and southern Europe in food and feed commodities belonging to the following crop groups: citrus fruits, pome fruits, stone fruits, berries and small fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds, cereals, herbal infusions from roots, root and rhizome spices (dried), and sugar plants (EFSA, 2011e). Note was taken that the uses for sugar plants were not supported by data from the EU (see Section 3.19.3.2 'Active use (all legitimate uses of the substance)') (EFSA, 2011e).

After the EFSA MRL review, applications were submitted to EFSA to modify the existing MRLs for berries and small fruits, root and tuber vegetables, fruiting vegetables, leaf vegetables, herbs

and edible flowers, legume vegetables, stem vegetables, and oilseeds (EFSA, 2011f, 2012i, 2013l, 2016i, 2019h,i,j, 2020f,g, 2021g).

Fludioxonil treatment included outdoor and indoor foliar applications, outdoor seed treatments and indoor post-harvest treatments by spraying and dipping:

- Foliar applications were reported for commodities belonging to the following crop groups: pome fruits, stone fruits, berries and small fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds, herbal infusions from roots, and root and rhizome spices (dried). Application rates range from 0.037 kg a.s./ha to 0.50 kg a.s./ha for outdoor cultivation and from 0.037 kg a.s./ha to 0.29 kg a.s./ha for indoor cultivation (EFSA, 2011e, f, 2012i, 2013l, 2016i, 2019h,i,j, 2020f, g, 2021g, 2024f).
- Seed treatments were reported for root and tuber vegetables (potatoes), fruiting vegetables (sweet corn), oilseeds, cereals, and sugar plants (sugar beet). The application range ranged from 2.5 g a.s./100 kg to 16 g a.s./100 kg or at 0.01 kg a.s./unit (sugar beet) (EFSA, 2011e, 2024f).
- Post-harvest treatments (indoor) were reported for citrus fruits by spraying at 0.06 kg a.s./hL and for pome fruits by dipping at the same rate (EFSA, 2011e).

b) Uses for purposes other than plant protection

Biocidal use

Despite fludioxonil is approved for biocidal use, according to the ECHA website⁶, there are currently no products that contain fludioxonil and are authorised for use in biocidal product formulations at national level in the EU.

Other use

A search carried out on the ECHA website⁹ for REACH registrations did not give any results for fludioxonil.

3.19.3 Sources of residues in plants

3.19.3.1 Natural occurrence

- Is there evidence that fludioxonil occurs naturally? What is known about the natural origin of this substance?

Fludioxonil is a synthetic chemical, produced industrially through chemical processes (Lewis et al., 2016; Zhou et al., 2020). No information on the potential natural presence of fludioxonil was found in the literature²².

3.19.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of fludioxonil per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of fludioxonil in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.19.3.2-1 to 3.19.3.2-4. Findings relating to residues in control (untreated) samples are also discussed in this section.

In all matrices and for both residue trials and results from monitoring, fludioxonil residue concentrations refer to the residue definition for enforcement (i.e. fludioxonil).

Occurrence of fludioxonil from residue trials carried out for the critical GAP per crop

Following product applications based on the critical GAPs⁴ reported to EFSA, residue levels of fludioxonil were below the LOQ in cereals (grains and straw) (EFSA, 2011e, 2024f).

Residues of fludioxonil were quantified in citrus fruits, pome fruits, stone fruits, berries and small fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds, herbal infusions from roots, and root and rhizome spices (EFSA, 2011e,f, 2012i, 2013l, 2016i, 2019h,i,j, 2020f,g, 2021g, 2024f).

Although EU GAPs were reported for all uses indicated under 3.19.2 'Conditions of use and applicable crops', no EU residue trial data on sugar plants were submitted or evaluated in the EFSA MRL review or in subsequent Art 10 opinions (EFSA, 2011e, f, 2012i, 2013l, 2016i, 2019h,i,j, 2020f,g, 2021g).

The results from residue trials carried out for the critical GAP per crop for fludioxonil in commodities for which uses were submitted to EFSA are summarised in Table 3.19.3.2-1 'Occurrence of fludioxonil from residue trials carried out for the critical GAP per crop'.

Table 3.19.3.2-1: Occurrence of fludioxonil from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fludioxonil (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
Food				
0110000	Citrus fruits	10	1.26–2.23	1.67
0130000	Pome fruits	5	0.05–0.60	0.23
0140000	Stone fruits	0.01*–10	0.02–0.50	0.13
0150000	Berries and small fruits	0.01*–5	0.04–3.73	0.33
0210000	Root and tuber vegetables	0.01*–10	<LOQ (0.01)–5.7	0.06
0220000	Bulb vegetables	0.5–5	<LOQ (0.02)–0.47	0.02
0230000	Fruiting vegetables	0.01*–3	<LOQ (0.02)–0.93	0.10
0250000	Leaf vegetables, herbs and edible flowers	0.01*–40	<LOQ (0.02)–11.42	1.10
0260000	Legume vegetables	0.01*–1	<LOQ (0.01)–0.86	0.07
0270000	Stem vegetables	0.01*–1.5	0.02–0.62	0.24
0300000	Pulses (dried)	0.4–0.5	<LOQ (0.02)–0.31	0.02
0401000	Oilseeds	0.01*–0.3	<LOQ (0.01)–0.19	0.02
0500000	Cereals	0.01*	<LOQ (0.02) – <LOQ (0.05)	<LOQ (0.02)
0633000	Herbal infusions from roots ^{c)}	1–4	0.19–0.54	0.41
0840000	Root and rhizome spices ^{c)}	1	0.19–0.54	0.41
0900000	Sugar plants ^{d)}	0.01*–4	NR	-
Feed				
1200000	Cereal straw	NA	<LOQ (0.02) – <LOQ (0.05)	<LOQ (0.05)
	Sugar beet top ^{d)}	NA	NR	-

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; NR – no residue trials data are available; '-': not estimated due to lack of data.

a) Maximum Residue Level in Reg. (EU) No 2022/1264 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA 2011e,f, 2012i, 2013l, 2016i, 2019h,i,j, 2020f,g, 2021g, 2024f; c) Uses in herbal infusions from roots and root and rhizome spices were supported from residue trials in root and tuber vegetables (carrots) (EFSA, 2011e); d) No residue trials from the EU were submitted to EFSA.

Occurrence of fludioxonil under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to fludioxonil are given in Regulations (EU) 2019/1791⁵⁹, 2020/856⁷⁷⁷⁷ and 2020/1633⁸⁷ for the year 2020, Regulations (EU) 2020/1633⁸⁷, 2021/1098⁸⁸ and 2021/1807³³ for the year 2021 and Regulations (EU) 2021/1807³³ and 2022/1264⁸⁹ for year 2022.

Regarding commodities not labelled as organic, 108,406 samples were collected and analysed for fludioxonil in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 99,935 (92.19%) were unprocessed and 8,471 (7.81%) processed commodities. No residues were quantified in 98,591 samples out of the 108,406 samples (90.95%). In 9,792 samples out of the 108,406 samples (9.03%) fludioxonil was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-19.1. MRLs were exceeded in 23 samples out of the 108,406 samples (0.02%). The highest concentration for samples exceeding the MRLs was 25.8 mg/kg in leaf vegetables, herbs and edible flowers (lettuces and salad plants – roman rocket/rucola).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of fludioxonil are summarised in Table 3.19.3.2-2a for unprocessed and in Table 3.19.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on fludioxonil in feed not labelled as organic were submitted to EFSA.

Table 3.19.3.2-2a: Occurrence of fludioxonil monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fludioxonil (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0110000	Citrus fruits	10	0.001	0.001–8.3	409	0.171
0130000	Pome fruits	5	0.001	0.001–5.5	2,479	0.049
0140000	Stone fruits	0.01*–10	0.001	0.001–9.307	1,546	0.12
0150000	Berries and small fruits	0.01*–5	0.001	0.001–3.4	2,955	0.071
0210000	Root and tuber vegetables	0.01*–10	0.001	0.011–1	298	0.017
0220000	Bulb vegetables	0.5–5	0.001	0.002–0.427	14	0.017
0230000	Fruiting vegetables	0.01*–3	0.001	0.001–5.2	811	0.023
0250000	Leaf vegetables, herbs and edible flowers	0.01*–40	0.001	0.001–25.8	677	0.083
0260000	Legume vegetables	0.01*–1	0.001	0.001–1.3	82	0.02
0270000	Stem vegetables	0.01*–1.5	0.001	0.001–0.56	66	0.015
0300000	Pulses (dried)	0.4–0.5	0.002	0.012	1	0.012

⁸⁷ Commission Regulation (EU) 2020/1633 of 27 October 2020 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azinphos-methyl, bentazone, dimethomorph, fludioxonil, flufenoxuron, oxadiazon, phosalone, pyraclostrobin, repellants: tall oil and teflubenzuron in or on certain products. OJ L 367, 5.11.2020, p. 1–38.

⁸⁸ Commission Regulation (EU) 2021/1098 of 2 July 2021 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 24-epibrassinolide, Allium cepa L. bulb extract, cyflumetofen, fludioxonil, fluroxypyr, sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate in or on certain products. OJ L 238, 6.7.2021, p. 5–28.

⁸⁹ Commission Regulation (EU) 2022/1264 of 20 July 2022 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fludioxonil in or on certain products. OJ L 192, 21.7.2022, p. 1–13.

Findings of not authorised substances in organic products

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fludioxonil (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0401000	Oilseeds ^{d)}	0.01*-0.3	0.005	0.02	1	0.02
0500000	Cereals	0.01*	0.001	0.013-0.027	4	0.019
0633000	Herbal infusions from roots ^{d)}	1-4	ND	ND	ND	ND
0840000	Root and rhizome spices ^{d)}	1	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*-4	0.005	<LOQ	0	<LOQ
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
	Sugar beet top	NA	ND	ND	ND	ND
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of fludioxonil is not expected)						
0120000	Tree nuts	0.01*-0.2	0.005	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*-15	0.001	0.001-4.8	341	0.13
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*-10	0.001	0.002-0.688	19	0.023
0280000	Fungi, mosses and lichens	0.01*	0.001	0.002	1	0.002
0290000	Algae and prokaryotes organisms	0.01*	0.01	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*-0.3	0.005	0.02	1	0.02
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*-4	0.003	0.012-0.06	4	0.024
0700000	Hops (dried)	0.05*	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*-1	0.005	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.005	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2022/1264 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Oilseeds, herbal infusions and root and rhizome spices appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0401000, 0633000 and 0840000 and non-use of the substance for all other commodities '040N000' or '06N0000' or '08N0000' that are reported under the 'broader' category 0400000 or 0600000 or 0800000 on the table. This creates an inconsistency in the results indicating non-uses which are overestimated.

Table 3.19.3.2-2b: Occurrence of fludioxonil from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fludioxonil (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0110000	Citrus fruits	10	0.001	0.002–2.7	12	0.112
0130000	Pome fruits	5	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*–10	0.002	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.01*–5	0.001	0.003–0.83	82	0.021
0210000	Root and tuber vegetables	0.01*–10	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.5–5	0.01	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*–3	0.001	0.02–0.16	7	0.052
0250000	Leaf vegetables, herbs and edible flowers	0.01*–40	0.002	0.013–2.9	3	0.054
0260000	Legume vegetables	0.01*–1	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*–1.5	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.4–0.5	0.002	<LOQ	0	<LOQ
0401000	Oilseeds ^{d)}	0.01*–0.3	0.002	<LOQ	0	<LOQ
0500000	Cereals	0.01*	0.0007	<LOQ	0	<LOQ
0633000	Herbal infusions from roots ^{d)}	1–4	0.01	<LOQ	0	<LOQ

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fludioxonil (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0840000	Root and rhizome spices ^{d)}	1	ND	ND	ND	ND
0900000	Sugar plants	0.01*-4	0.002	<LOQ	0	<LOQ
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
	Sugar beet top	NA	ND	ND	ND	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of fludioxonil is not expected)						
0120000	Tree nuts	0.01*-0.2	0.01	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*-15	0.002	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*-10	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.005	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0400000	Oilseeds and oil fruits	0.01*-0.3	0.002	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*-4	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	0.05	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*-1	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.01	0.02-0.68	2	0.044

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2022/1264 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Oilseeds, herbal infusions and root and rhizome spices appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0401000, 0630000 and 0840000 and non-use of the substance for all other commodities '040N000' or '06N0000' or '08N0000' that are reported under the 'broader' category 0400000 or 0600000 or 0800000 on the table. This creates an inconsistency in the results indicating non-uses which are overestimated.

Occurrence of fludioxonil in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 9,556 samples were collected and analysed for fludioxonil from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 7,941 (83.1%) were unprocessed and 1615 (16.9%) processed commodities. No residues were quantified in 9,536 samples out of the 9,556 samples (99.79%). In 19 samples out of the 9,556 samples (0.2%) fludioxonil was found at or above the analytical LOQ but below or at the MRL. MRLs exceeded in one sample (0.01%) from organic production with the quantified level of 0.025 mg/kg in cereals (buckwheat and other pseudocereals). These findings are summarised in Appendix B, Table B-19.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.19.3.2-3a for unprocessed and in Table 3.19.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on fludioxonil in feed labelled as organic were submitted to EFSA.

Table 3.19.3.2-3a: Occurrence of fludioxonil from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fludioxonil (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	10	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.01*-0.2	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	5	0.001	0.04-0.08	3	0.066
0140000	Stone fruits	0.01*-10	0.001	0.001	1	0.001
0150000	Berries and small fruits	0.01*-5	0.001	0.057-0.06	2	0.059
0160000	Miscellaneous fruits	0.01*-15	0.001	0.012-3.7	4	0.113
0210000	Root and tuber vegetables	0.01*-10	0.001	0.011-0.064	3	0.018
0220000	Bulb vegetables	0.5-5	0.001	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*-3	0.001	0.003	1	0.003
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*-10	0.001	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*-40	0.001	0.001	4	0.001
0260000	Legume vegetables	0.01*-1	0.001	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*-1.5	0.001	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.4-0.5	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*-0.3	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.01*	0.001	0.025	1	0.025
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*-4	0.003	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*-1	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*-4	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities.

a) Maximum Residue Level in Reg. (EU) No 2022/1264 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.19.3.2-3b: Occurrence of fludioxonil from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fludioxonil (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	10	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.01*-0.2	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	5	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*-10	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.01*-5	0.001	0.013	1	0.013
0160000	Miscellaneous fruits	0.01*-15	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.01*-10	0.005	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.5-5	ND	ND	ND	ND
0230000	Fruiting vegetables	0.01*-3	0.001	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*-10	0.01	<LOQ	0	<LOQ

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Fludioxonil (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0250000	Leaf vegetables, herbs and edible flowers	0.01*-40	0.005	<LOQ	0	<LOQ
0260000	Legume vegetables	0.01*-1	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*-1.5	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*	0.005	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0300000	Pulses (dried)	0.4-0.5	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*-0.3	0.002	<LOQ	0	<LOQ
0500000	Cereals	0.01*	0.0001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*-4	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	ND	ND	ND	ND
0800000	Spices (dried)	0.05*-1	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*-4	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2022/1264 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of fludioxonil in the EU Organic Farming Information System

The EU OFIS reported 8 findings for fludioxonil in 2021 and 2022. Five of the products sampled and analysed had an EU origin and three were of non-EU origin. Residues were found in two samples of citrus fruits (lemons), 1 sample of stone fruits (plums), 3 samples of berries and small fruits (strawberries), 1 sample of miscellaneous fruits with inedible peel, large (pomegranates) and one sample of legume vegetables (peas (without pods)). The concentrations of fludioxonil residues were above LOQ but below the MRL in all eight samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005³. No samples labelled as organic were above MRLs. The highest concentration was reported in sample of citrus fruits (lemon) from non-EU origin, with the quantified level of 0.13 mg/kg. These findings are summarised in Table 3.19.3.2-4.

Table 3.19.3.2-4: Occurrence of fludioxonil from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
0110030	Lemons	10	ND	0.095 – Lemons (oil)
0152000	Strawberries	4	0.027 – Strawberries	0.005 – Strawberries (purée)
0260040	Peas (without pods)	0.3	0.014 – Peas (without pods)	ND
Samples of non-EU origin				
0110030	Lemons	10	0.13 – Lemons	ND
0140040	Plums	5	ND	0.024 – Plums (dehydrated)
0163050	Pomegranates	3	0.027 – Pomegranates	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2022/1264 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of fludioxonil in untreated samples (control samples) from residue trials

Fludioxonil residues were quantified in control (untreated) apple samples from two residue trials conducted in northern France (France, 2018c). In the trial with the highest residue levels,

fludioxonil had been applied to the orchard 1 year before the trial (France, 2018c). Additionally, residues were detected in an untreated pear sample from Spain (France, 2018c).

Additional residues were quantified in both processed and unprocessed grape control samples, including young wine and wine from Germany, fruit and must from Spain, raisins from Greece, and berries from northern France and other European countries (France, 2018c; Denmark, 2011).

Residues were also found in the control samples from other crops, including spring wheat (whole plant) from Germany, strawberries from Spain, blackcurrants and blueberries from Germany, and lettuce from northern France and Italy (Denmark, 2011; France, 2018c; Germany, 2019e; Italy, 2015).

Aside from the apple trial where fludioxonil had been applied to the orchard 1 year earlier, no other evidence-based explanations for the presence of residues in control (untreated) samples were provided in the above Member State ERs and RARs.

The summary of the quantified findings of fludioxonil in control (untreated) samples from residue trials carried out for the critical GAP⁴ per crop is given below in Table 3.19.3.2-5.

Table 3.19.3.2-5: Summary of the quantified findings of fludioxonil in control (untreated) samples from residue trials carried out for the critical GAP per crop.

Commodity	Country/Area	Result (mg/kg)
Apples	Northern France	0.017; 0.02 ^{a)}
Blackcurrants	Germany	0.02
Blueberries	Germany	0.02; 0.05
Grapes	Germany	0.01 (young wine and wine)
	Greece	0.03 (raisins)
	Northern and/or southern Europe ^{b)}	0.02–0.09 (berries); up to 0.19 (wine)
	Spain	0.03 (fruit), 0.018 (must)
Lettuce	Northern and/or southern Europe ^{b)}	0.45
	Northern France	0.01 (leafy head)
	Italy	0.022; 0.29
Pears	Spain	0.07
Spring wheat (whole plant)	Germany	0.04
Strawberries	Spain	0.10

a) Fludioxonil had been applied to the orchard 1 year before the trial; b) Country not available in the evaluation report (Denmark, 2011).

- Could the presence of fludioxonil and/or its residues be due to biocide use?

According to the ECHA website⁶, products that contain fludioxonil are not authorised for use in biocidal product formulations at national level in the EU. Therefore, the transfer of residues of fludioxonil due to its use as a biocide is unlikely.

3.19.3.3 Behaviour in food and feed products

- What key physico-chemical properties of fludioxonil are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of fludioxonil are shown in Table 3.19.3.3.

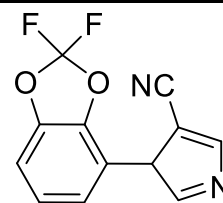
Fludioxonil exhibits high persistence in soil (see Section 3.19.3.5). Regarding sorption to soil, the range of K_{Foc} in Table 3.19.3.3 indicates that the substance has slight mobility in soil (EFSA, 2024f).

The maximum calculated PEC_w for fludioxonil for the representative uses was 8.91 µg/L (spray application to pome/stone fruits; 2 × 225 g a.s./ha) (EFSA, 2024f).

Fludioxonil was shown to be stable under the standard conditions of pasteurisation, cooking, boiling, brewing, baking and sterilisation (EFSA, 2007b). Considering that fludioxonil is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Fludioxonil has a low vapour pressure (3.9×10^{-7} Pa) and short atmospheric half-life (3.6 hours) (EFSA, 2007b).

Table 3.19.3.3: Physico-chemical properties of fludioxonil (EFSA, 2024f)

Structural formula	
Appearance (state purity)	Faintly yellow powder (99.9 %), light olive green powder (96.8 %)
Melting point (state purity)	199.8°C (99.8%)
Boiling point	Decompose before boiling
Temperature of decomposition	306°C (99.8%)
Vapour pressure (state temperature, state purity)	3.9×10^{-7} Pa at 25°C
Henry's law constant (state temperature)	5.4×10^{-5} Pa m ³ mol ⁻¹ at 25°C
Solubility in water (state temperature, state purity and pH)	1.8 mg/L (25°C, 99.8%) The solubility has not been carried out at different pHs as the molecule does not dissociate within the range pH 2 to pH 12.
Partition coefficient (state temperature, pH and purity)	log P _{ow} = 4.12 at 25°C (without pH dependence)
Partition coefficient (octanol/air)	Log P _{oa} = 11.8 (EPISuite KOAWIN v1.10) (Debler et al. 2024)
Atmospheric half-life	DT ₅₀ of 3.6 hours derived by the Atkinson model. OH (12h) radical concentration assumed = 1.5×10^6 cm ⁻³
Dissociation constant (state purity)	pKa1 <0 (basic) (99.8%) pKa2 ca. 14.1 (acidic) (99.8%)
Soil adsorption (geometric mean)	K_{Foc} = 2793 mL/g
Hydrolytic degradation (>10%)	Hydrolytically stable (pH 5–9 at 25°C)

DT₅₀ – Disappearance time of 50% of the substance in field studies; pH – Potential of Hydrogen; P_{ow} – Octanol/water Partition Coefficient; P_{oa} – Octanol/air Partition Coefficient

3.19.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from soil surface at which it is applied).

The highest drift of fludioxonil to neighbouring fields may occur during its applications to fruit crops (up to 29.2%), vineyards and vegetables (up to 8.02%) and field crops (up to 2.77%). Drift values should be considered the rate received by neighbouring fields, expressed as a percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. buffer zones or spray drift-reducing nozzles). For seed treatment uses dust drift at the time of drilling is a possibility. Deposition percentile values were considered for neighbouring fields, up to 17% for different crops and techniques (EFSA, 2013b). According to Adriaanse et al. (2022), the use of techniques (deflectors), size of the dust particles and average wind speed were the most important factors determining the amount of dust drift.

If organic crops are present adjacent to the conventional crops treated, measurable residues of fludioxonil in the untreated crop cannot be excluded. However, since the nature of the potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

3.19.3.5 Accumulated/historical residue levels in soil

- What is the persistence of fludioxonil and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

According to available data, DT₉₀ of fludioxonil in soil has a worst-case field value of 790 days, indicating a potential for accumulation in soil after discontinued use of the substance (EFSA, 2024f).

Considering the persistence of fludioxonil in soil, confined and field rotational crop studies were carried out with bare soil to investigate the potential uptake of residues of fludioxonil by the plants. The results of these studies suggested that uptake of significant residues from soil is not expected in rotational crops when the substance is applied according to the representative GAPs⁴ (EFSA, 2011e).

Therefore, the presence of fludioxonil in untreated crops is less likely to be associated with plant uptake from soil growing previously treated crops. This is also valid for organic crops, when planted in fields that were previously used for conventional agriculture, considering that it requires at least 2 years after the last chemical treatment in order for organic crops to be planted in such area².

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Monitoring data for fludioxonil in soil are available from the LUCAS pesticides 2018 (JRC, 2023) on IPCHEM¹²¹². The data show background levels of the substance in soil samples from 12 EU countries: Belgium (1 sample), Bulgaria (1 sample), Czechia (2 samples), Finland (3 samples), France (5 samples), Germany (2 samples), Greece (1 sample), Italy (6 samples), Latvia (1 sample), Lithuania (1 sample), Spain (1 sample) and Sweden (4 samples) at levels ranging from 0.0056 to 0.043 mg/kg. In LUCAS soil, the lack of information on the agricultural use history of the sites where soil was sampled precluded knowing whether the reported quantified findings were related to recent active use or historical levels in soil for fludioxonil.

Evidence on the occurrence of fludioxonil residues in soil is provided by Chiaia-Hernandez et al. (2017), who analysed 29 archived agricultural soil samples collected from 14 monitoring sites from 1995 to 2008 in Switzerland. The sites were selected from locations where crops had been regularly treated with pesticides. Selection was based on land use characteristics and long-term patterns of pesticide application. Fludioxonil was one of the 20 most frequently detected pesticides, detected in 12 samples (41%) from cropland, orchard and viticulture land use sites, with levels ranging from 0.002 to 0.330 mg/kg. Fludioxonil was applied and detected in 21% of cases, whilst it was not applied but detected in 21% of cases.

Additional evidence on the occurrence of fludioxonil in soil is provided by Silva et al. (2023) in a study carried out in the framework of the EU SPRINT project. The study assessed the presence of 209 pesticide residues in 100 soil samples from conventional agriculture and 63 soil samples from organic agriculture collected during the 2021 growing season across 10 study sites in Europe: Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark. Fludioxonil was quantified in three conventional soil samples (3%) at concentrations from 0.0081 and 0.1659 mg/kg all of them in Portugal.

Considering the available evidence, plant uptake of fludioxonil from soil under organic farming systems is less likely.

3.19.3.6 Residues from water used for irrigation

- Is there evidence that residues of fludioxonil present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for fludioxonil in water samples were considered:

- The EEA-WATERQUALITY³⁹ database (data retrieved on 10 April 2024) reports 97⁹⁰ analytical results from water samples collected in France (8 samples), Italy (71 samples) and the Netherlands (18 samples) between 2018 and 2020.
- The EMPODAT database (data retrieved on 14 March 2024) reports 415 analytical results from surface water samples collected in the Netherlands (414 samples) and Romania (1 sample) between 2017 and 2019; 6 analytical results from groundwater samples collected

⁹⁰ The total number of results in the database is 30,871. The number reported does not include outliers.

in 2019 in Austria (1 sample), Bulgaria (1 sample), Croatia (1 sample), Hungary (1 sample), Romania (1 sample) and Slovakia (1 sample);

- The NAIADES database (data retrieved on 14 March 2024) reports 52,590 analytical results from surface water samples collected in France from 2020 to 2022.

Among the 53,108 analytical results for fludioxonil, 281 were disregarded as found to report quantitative values below the analytical LOQ. Therefore, the number of water samples considered is 52,827.

Based on the screening process described in section 'Data and methodologies', for 99.7% of water samples analysed and reported in the above-mentioned databases (52,681 samples), the residue concentrations in these waters were below the screening Cw of 0.08 µg/L and, therefore, transfer of residues from water sources to plant commodities is unlikely.

For 0.3% of samples (146 out of 52,827 samples), the residue concentrations were or above the screening Cw of 0.08 µg/L and the potential transfer of residues to plant commodities if water containing residues at these levels is used for irrigation cannot be excluded.

In a study by Silva et al. (2023) carried out under the framework of the EU SPRINT project the authors assessed the presence of 209 pesticide residues in 58 surface water samples collected during the 2021 growing season across 10 study sites in Europe (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). Fludioxonil was detected in seven samples (12% detection frequency) at concentrations ranging between 0.005 and 0.14 µg/L. Only one sample from Czechia was found to contain residues above 0.1 µg/L. Despite being limited in number, these results suggest that the transfer of fludioxonil residues from EU surface water sources to plant commodities is unlikely.

Overall, considering that for 99.7% of water samples analysed and reported for fludioxonil in EEA-WATERQUALITY, EMPODAT and NAIADES (52,827 samples), the residue concentrations were below the screening Cw of 0.08 µg/L, it can be concluded that the transfer of fludioxonil residues from water to plant commodities when this water is used to irrigate plants is unlikely.

3.19.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *fludioxonil*, *industry/industrial*, and *air/atmosphere*) did not identify any relevant European study.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water. Based on conservative estimations of the possible transfer of residues from water used for irrigation to plant commodities, the transfer of residues of fludioxonil from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 7, 2025, using the keywords *fludioxonil*, *industry/industrial*, and *water*) did not identify any relevant European study.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Based on information on the possible plant uptake of fludioxonil from EU soil, the transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 17, 2025, using the keywords *fludioxonil*, *industry/industrial*, and *soil/sediment*) did not identify any relevant European study.

3.19.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Uptake from organic fertilisers

In a study investigating pesticide residues in organic fertilisers, residues of fludioxonil and other pesticides were quantified (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). The authors attributed the origin of the residues to the presence of plant protection products in the composted crop or in composted manure due to transfer from animal feed after digestion, or in straw used in stables. Analysis of solid organic fertilisers gave an average concentration of 1.75 mg/kg for fludioxonil in 12 out of 147 samples. Considering that (according to the authors) the use of completely free from residues organic fertilisers is currently unsustainable, transfer of fludioxonil residues from fertilisers used in organic production to organic products cannot be excluded. On the other hand, no residues of fludioxonil were found in any of the products of the crops discussed in the study (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). This outcome is supported by studies in rotational crops indicating that plant uptake from soil that contains residues is less likely (see 5.19.3.5).

Medium and long-range aerial transport of residues

Silva et al. (2023) investigated the presence of fludioxonil in 20 outdoor air samples collected during the 2021 growing season across 10 study sites in Europe of organic and conventional agriculture (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, the Czechia, the Netherlands, and Denmark). The study was carried out under the framework of the EU SPRINT project. Organic fields had not been treated for five consecutive years. Fludioxonil was detected in two out of 20 targeted samples (10%), one from France and one from Portugal, at the concentrations of 32.9 and 658 ng m⁻³, respectively. The sample with the quantified value from Portugal had been collected from the surrounding area of an organic field.

In a study carried out under the EU SPRINT project investigating the presence of fludioxonil in air samples collected between April 2021 and June 2022 from one agricultural area of conventional farming in Portugal (vineyard), fludioxonil was quantified exclusively in the particle phase, with no gas-phase detection in 3% of air samples at a concentration of 21 pg/m³ (Debler et al., 2024). Note was taken that the field had not undergone treatment with fludioxonil before the sample collection and measurement.

Based on the above, the medium-range transfer of fludioxonil to plants that had not been previously treated, via air cannot be excluded.

3.19.4 Conclusions on fludioxonil

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use.
- Residue trials carried out to support the critical GAPs⁴ for fludioxonil, gave residue concentrations of up to 11.42 mg/kg (highest value for leaf vegetables, herbs and edible flowers). Concentrations in the ranges reported in Table 3.19.3.2-1 might be associated with active use of fludioxonil according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.
- Fludioxonil was quantified in the context of residue trials in untreated (control) samples with the highest concentrations observed for one sample of lettuce of unknown origin (0.45 mg/kg).
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for fludioxonil in unprocessed commodities with authorised uses ranged from 0.015 mg/kg in stem vegetables, to 0.171 mg/kg in citrus fruits.
- In organic unprocessed commodities that were analysed under the pesticide residues monitoring programme between 2020 and 2022 residues of fludioxonil were not quantified or were quantified in fewer than five samples per commodity.
- Without additional information on the individual samples' history and context, it is not possible to conclude if quantified results in organic commodities are associated with active use or unintentional presence of fludioxonil.
- In organic processed commodities, residues of fludioxonil were quantified in one sample only. In samples from processed products not labelled as organic with five or more quantified findings, the median concentrations of residues of fludioxonil ranged from 0.021 mg/kg in berries and small fruits to 0.112 mg/kg in citrus fruits. Considering that fludioxonil is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.
- Overall, in commodities labelled as organic, fludioxonil was quantified in 0.21% of samples (20 out of 9,556 samples). This percentage is more than 40 times lower than the percentage reflecting the number of findings in samples not labelled as organic (9.05%) (see Appendix B, Tables B-19.1 and B-19.2). These results suggest that the occurrence of residues of fludioxonil in organic products is less likely when compared with the conventional commodities.
- Potential sources of the unintentional presence of residues of fludioxonil in commodities of plant origin are drift from conventional crops grown in the vicinity.

- The aerial transport of residues of fludioxonil over medium distances from the treated areas cannot be excluded.
- Fludioxonil is persistent in soil, however, not all substances accumulating in soil are taken up by plants. Studies assessed by EFSA on crops growing in rotation showed that plant uptake of residues of fludioxonil from soil containing residues of fludioxonil or from organic fertilisers is considered a less likely explanation for residues found in crops where fludioxonil has not been actively used.
- Transfer of fludioxonil residues from EU water sources used for irrigation to plant commodities is unlikely.
- Fludioxonil is also in biocidal products and applications of biocidal products containing fludioxonil may result in the release of residues of fludioxonil into the environment. Considering, however, that products that contain fludioxonil and are not authorised for use in biocidal product formulations at national level in the EU, the transfer of residues of fludioxonil due to its use as a biocide is unlikely.
- Conservative estimates of the possible transfer of residues of fludioxonil from water used for irrigation to plant commodities and information on the possible plant uptake of residues of fludioxonil from EU soil suggest that the transfer of residues of fludioxonil from other non-pesticide uses as well as the transfer from industrial emissions to the environment and from the environment to plants and plant commodities is less likely.

The pathways of residues of fludioxonil to plants and plant commodities are summarised in Figure 19.

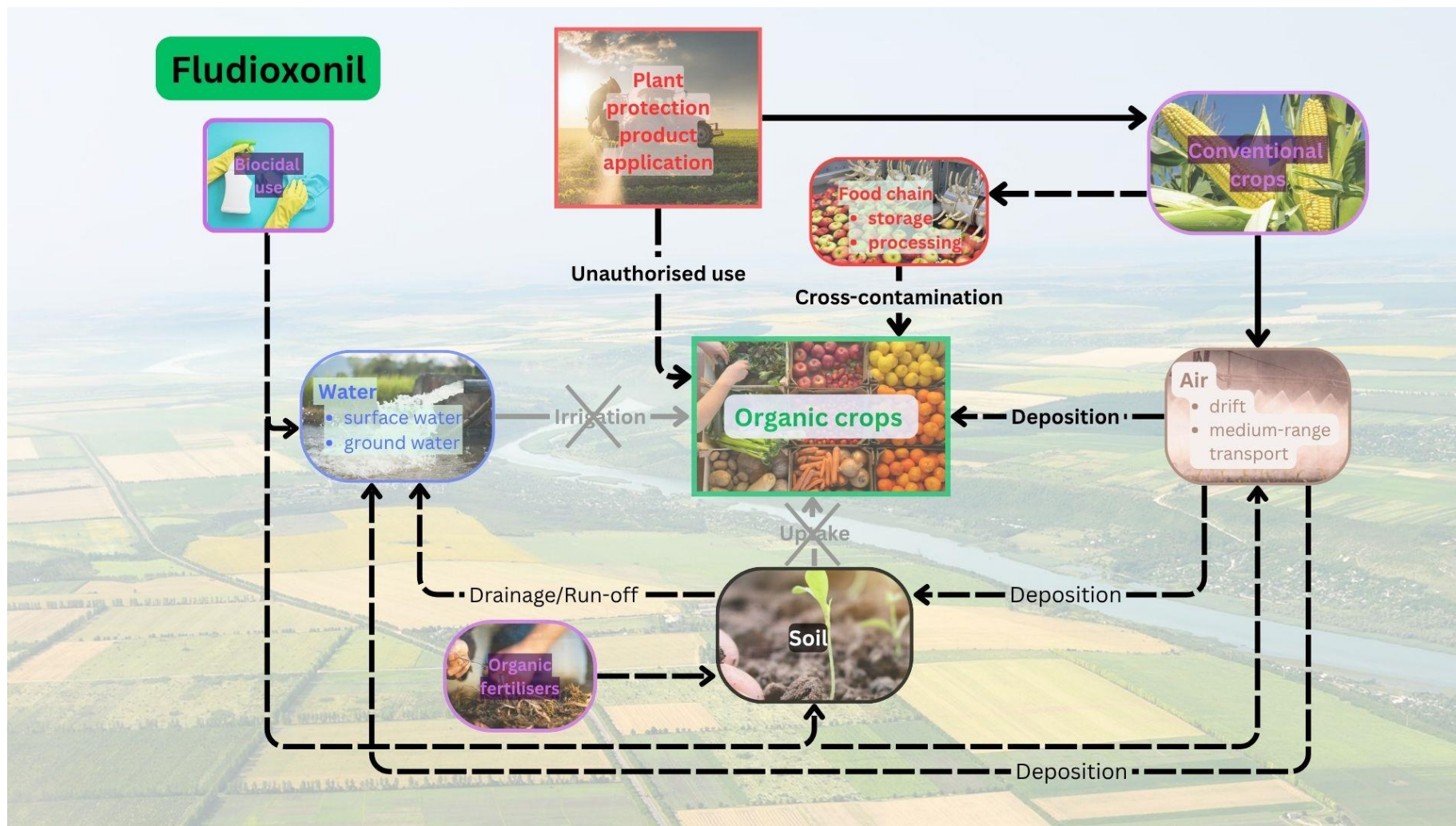


Figure 19: Pathways of residues of fludioxonil to plants and plant commodities

Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded

3.20 Difenoconazole

3.20.1 Method(s)

- What is/are the residues to be monitored for the active substance difenoconazole to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

For the active substance difenoconazole, the residue definition for monitoring in food and feed of plant origin has been proposed as 'difenoconazole' (EFSA, 2011g, 2024g). This residue definition is implemented in Reg. (EC) No 396/2005³ and is applicable to primary crops, rotational crops and processed products. The same residue definition was also implemented for honey and other apiculture products.

Note was taken that difenoconazole generates triazole metabolites (TDMs) i.e. triazole alanine, triazole lactic acid, triazole acetic acid and 1,2,4-triazole, that are common metabolites of difenoconazole and several other triazole active substances and their presence may also relate to the use of some fertilisers (EFSA, 2018d). Therefore, findings of TDMs in food and feed are not necessarily associated with the use of difenoconazole (EFSA, 2018d).

Since TDMs are not included in the residue definition for enforcement and are, therefore, not monitored, only residues of difenoconazole in food and feed of plant origin, honey and apiculture products will be considered in this technical report.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

The multi-residue QuEChERS method is validated for the monitoring of difenoconazole residues. The method is based on HPLC-MS/MS and has an LOQ of 0.01 mg/kg in high water, high acid, high oil content, dry and complex matrices of plant origin (EFSA, 2021h).

Another multi-residue method (DFG-S19) is validated for quantifying difenoconazole residues with an LOQ of 0.02 mg/kg in high water content commodities and an LOQ of 0.05 mg/kg in high oil content and dry commodities (EFSA, 2011g, 2017d).

Other validated methods based on LC-MS/MS are available with LOQs at 0.02 mg/kg in high water content matrices, and at 0.05 mg/kg in dry and high oil content commodities (EFSA, 2023k).

According to the EURL for Residues of Pesticides (EURL, 2024 under 'Documentation as provided to EFSA'), difenoconazole residues in honey can be monitored using a multi-residue citrate buffered QuEChERS method based on LC-MS/MS at an LOQ of 0.002 mg/kg. Higher sensitivities are achieved utilising a multi-residue method based on LC-Q-TOF (LOQ: 0.001 mg/kg). A multi-residue QuEChERS method based on LC-MS/MS is also available for the analysis of difenoconazole residues in pollen collected by bees at an LOQ of 0.005 mg/kg.

Overall, there are multi-residue methods available for the monitoring of difenoconazole residues in high water, high acid, high oil content, dry and complex commodities of plant origin, as well as in honey and other apiculture products with LOQs ranging from 0.001 to 0.05 mg/kg.

3.20.2 Authorisation status and use

- Is difenoconazole authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has difenoconazole ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

a) Authorisations for plant protection use in conventional agriculture

Difenoconazole has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of approval of the active substance is on 15 March 2026, as indicated by the EU Pesticides Database⁵ (accessed on 8 January 2024). The application for the renewal of the approval of difenoconazole is under assessment.

According to the EU Pesticides Database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, France, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, and Slovakia.

b) Authorisations for purposes other than plant protection

Biocidal use

Difenoconazole has not been approved for use in biocidal products in the EU Member States, Iceland, Liechtenstein and Norway, according to information from the ECHA website⁶ (accessed on 12 February 2024).

Other uses

According to the search carried out on the ECHA website⁹ on 6 June 2024, difenoconazole is not currently registered under REACH.

- What is/was the actual use of difenoconazole? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of difenoconazole

Difenoconazole is a systemic triazole fungicide that controls a broad spectrum of foliar, seed, and soilborne diseases in plants caused by *Ascomycetes*, *Basidiomycetes*, and *Deuteromycetes* fungi. Difenoconazole disrupts ergosterol biosynthesis in target fungi by inhibiting C-14-demethylation of sterols, resulting in structural and functional changes in the fungal cell membrane (EFSA, 2009e).

Conditions of use and applicable crops

The uses reported in the EFSA MRL review for difenoconazole included applications from the northern and southern EU in food and feed commodities belonging to the following crop groups: tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds and oil fruits, cereals, herbal infusions from flowers,

leaves, herbs and roots, spices (dried), sugar plants, alfalfa, clover and vetch (EFSA, 2024g). Note was taken that the food uses of tree nuts and feed uses of alfalfa, beans and peas, clover, vetch and turnips (tops) were not supported by data (see Section 3.20.3.2 'Active use (all legitimate uses of the substance)').

Difenoconazole treatment included outdoor and indoor foliar applications and seed treatments:

- Foliar applications (outdoor and indoor) were reported for commodities belonging to the following crop groups: tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds and oil fruits, cereals, herbal infusions from flowers, leaves, herbs and roots, spices, sugar plants, alfalfa, clover and vetch (EFSA, 2024g). Application rates range from 48 g a.s./ha to 200 g a.s./ha for outdoor cultivation and from 100 g a.s./ha to 7500 g a.s./ha for indoor cultivation (EFSA, 2024g).
- Seed treatments (outdoor) were reported for cereals at a rate of 60 g a.s./ton (EFSA, 2024g).

b) Uses for purposes other than plant protection

Biocidal use

Difenoconazole is not approved for biocidal use, therefore, use of the substance in biocidal products is not expected (see also 'authorisations for purposes other than plant protection/biocidal use').

Other use

A search carried out on the ECHA website⁹ for REACH registrations did not give any results for difenoconazole.

3.20.3 Sources of residues in plants

3.20.3.1 Natural occurrence

- Is there evidence that difenoconazole occurs naturally? What is known about the natural origin of this substance?

Difenoconazole is a synthetic chemical produced industrially through chemical processes (Lewis et al., 2016). No information on the potential natural presence of difenoconazole was found in the literature²².

3.20.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of difenoconazole per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of difenoconazole in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.20.3.2-1 to 3.20.3.2-4. Findings relating to residues in control (untreated) samples are also discussed in this section.

In all matrices and for both residue trials and results from monitoring, difenoconazole residue concentrations refer to the residue definition for enforcement (i.e. difenoconazole) if not otherwise specified.

Occurrence of difenoconazole from residue trials carried out for the critical GAP per crop

Following product applications based on the critical GAPs⁴ reported to EFSA, residues of difenoconazole were quantified in pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables (also for forage), stem vegetables, pulses (dried), oilseeds and oil fruits, cereals, herbal infusions from flowers, leaves, herbs and roots, spices (dried), sugar plants and fodder beets (EFSA, 2024g). Regarding feed commodities, residues of difenoconazole were quantified in cereal straw, fodder beet and sugar beet tops (EFSA, 2024g).

Although EU GAPs were reported for all uses indicated under 3.20.2 'Conditions of use and applicable crops', data on residue trials for tree nuts, alfalfa, bean and pea vines, clover and vetch forages, and turnip tops were not submitted and evaluated in the EFSA MRL review (EFSA, 2024g).

The results from residue trials carried out for the critical GAP per crop for difenoconazole in commodities for which uses were submitted to EFSA are summarised in Table 3.20.3.2-1 'Occurrence of difenoconazole from residue trials carried out for the critical GAP per crop'.

Table 3.20.3.2-1: Occurrence of difenoconazole from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Difenoconazole (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
Food				
0120000	Tree nuts ^{c)}	0.05*	NR	-
0130000	Pome fruits	0.8	0.02–0.35	0.10
0140000	Stone fruits	0.1–0.7	0.01–0.37	0.11
0150000	Berries and small fruits	0.1–4	0.02–0.77	0.13
0160000	Miscellaneous fruits	0.1–2	<LOQ (0.01)–0.11	0.03
0210000	Root and tuber vegetables	0.1–2	<LOQ (0.01)–0.30	0.01
0220000	Bulb vegetables	0.5–9	<LOQ (0.01)–0.86	0.01
0230000	Fruiting vegetables	0.05*–2	<LOQ (0.01)–1.30	0.08
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.05*–2	<LOQ (0.01)–3.07 ^{d)}	0.04
0250000	Leaf vegetables, herbs and edible flowers	0.05*–10	<LOQ (0.01)–6.60	0.29
0260000	Legume vegetables	0.05*–1	<LOQ (0.01)–0.41	0.04
0270000	Stem vegetables	0.05*–7	<LOQ (0.02)–3.4	0.21
0300000	Pulses (dried)	0.06–0.15	<LOQ (0.02)–0.03	0.02
0400000	Oilseeds and oil fruits	0.05*–0.5	<LOQ (0.01)–1.15	0.01
0500000	Cereals	0.05*–3	<LOQ (0.01)–1.40	0.02
0631000	Herbal infusions from flowers	20	1.7–12.0	4.6
0632000	Herbal infusions from leaves and herbs	20	1.7–12.0	4.6
0633000	Herbal infusions from roots	20	0.16–2.24	0.64
0800000	Spices (dried)	0.3–3	<LOQ (0.04)–0.64	0.06
0900000	Sugar plants	0.05*–0.6	<LOQ (0.01)–0.32	0.03
Feed				
1200000	Alfalfa (for forage)	NA	NR	-
	Beans (for forage)	NA	NR	-
	Cereal straw	NA	<LOQ (0.01)–4.56	0.12
	Clover (for forage)	NA	NR	-
	Fodder beets (roots and tops)	NA	<LOQ (0.01)–2.73	0.07
	Peas (for forage)	NA	NR	-

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Difenoconazole (RD) occurrence from residue trials based on the most critical GAP ^{b)} per crop	
			Range (mg/kg)	Median (mg/kg)
	Sugar beet tops	NA	0.06–3.3	0.65
	Vetch (for forage)	NA	NR	-
	Turnip tops	NA	NR	-

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; NR – no residue trials data are available; '-': not estimated due to lack of data.

a) Maximum Residue Level in Reg. (EU) No 2019/552 amending Annex II of Reg. (EC) No 396/2005; b) GAP tables per crop are available in EFSA, 2024g; c) For uses not supported by data, the MRLs were lowered to the LOQ; d) Residues quantified above the MRLs come from the EFSA MRL review for difenoconazole (EFSA, 2024g) that has not been considered by risk managers yet.

Occurrence of difenoconazole under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to difenoconazole are given in Regulation (EU) 2019/552³² for the years 2020–2022.

Regarding commodities not labelled as organic, 115,254 samples were collected and analysed for difenoconazole in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 106,106 (92.06%) were unprocessed and 9,148 (7.94%) processed commodities. No residues were quantified in 109,846 samples out of the 115,254 samples (95.31%). In 5,404 samples out of the 115,254 samples (4.69%) difenoconazole was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-20.1. MRLs were exceeded in four samples out of the 115,254 samples (0.003%). The highest concentration for samples exceeding the MRLs was 10.84 mg/kg in leaf vegetables, herbs and edible flowers (herbs and edible flowers – parsley).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of difenoconazole are summarised in Table 3.20.3.2-2a for unprocessed and in Table 3.20.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on difenoconazole in feed not labelled as organic were submitted to EFSA.

Table 3.20.3.2-2a: Occurrence of difenoconazole monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Difenoconazole (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0120000	Tree nuts	0.05*	0.005	<LOQ	0	<LOQ
0130000	Pome fruits	0.8	0.001	0.001–0.56	571	0.015
0140000	Stone fruits	0.1–0.7	0.001	0.001–0.59	447	0.014
0150000	Berries and small fruits	0.1–4	0.001	0.001–2	621	0.026
0160000	Miscellaneous fruits	0.1–2	0.001	0.001–0.089	15	0.017
0210000	Root and tuber vegetables	0.1–2	0.001	0.001–0.681	895	0.017
0220000	Bulb vegetables	0.5–9	0.001	0.002–0.486	16	0.041
0230000	Fruiting vegetables	0.05*–2	0.001	0.001–1.5	699	0.025
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.05*–2	0.001	0.001–4.41	666	0.021
0250000	Leaf vegetables, herbs and edible flowers	0.05*–10	0.001	0.001–10.84	621	0.083

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Difenoconazole (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0260000	Legume vegetables	0.05*-1	0.001	0.002-0.24	29	0.024
0270000	Stem vegetables	0.05*-7	0.001	0.001-4.25	670	0.032
0300000	Pulses (dried)	0.06-0.15	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.05*-2	0.005	0.019-0.022	2	0.021
0500000	Cereals	0.05*-3	0.001	0.006-0.3	35	0.015
0631000	Herbal infusions from flowers ^{d)}	20	0.01	<LOQ	0	<LOQ
0632000	Herbal infusions from leaves and herbs ^{d)}	20	0.005	0.022-0.045	3	0.033
0633000	Herbal infusions from roots ^{d)}	20	0.005	<LOQ	0	<LOQ
0800000	Spices (dried)	0.3-3	0.005	0.24	1	0.24
0900000	Sugar plants	0.05*-0.6	0.005	0.006-0.021	2	0.014

Feed

1200000	Alfalfa (for forage)	NA	ND	ND	ND	ND
	Beans (for forage)	NA	ND	ND	ND	ND
	Cereal straw	NA	ND	ND	ND	ND
	Clover (for forage)	NA	ND	ND	ND	ND
	Fodder beets (roots and tops)	NA	ND	ND	ND	ND
	Peas (for forage)	NA	ND	ND	ND	ND
	Sugar beet tops	NA	ND	ND	ND	ND
	Vetch (for forage)	NA	ND	ND	ND	ND
	Turnip tops	NA	ND	ND	ND	ND

Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of difenoconazole is not expected)

0110000	Citrus fruits	0.6	0.001	0.001-0.055	9	0.014
0280000	Fungi, mosses and lichens	0.05*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.05*	0.005	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*-20	0.005	0.01-0.045	5	0.022
0700000	Hops (dried)	0.05*	0.005	0.013	1	0.013
1040000	Processed apiculture products	0.05*	0.005	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2019/552 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Herbal infusions from flowers, herbal infusions from leaves and herbs and herbal infusions from roots appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0631000, 0632000 and 0633000 and non-use of the substance for all other commodities '06N0000' that are reported under the 'broader' category 0600000 on the table. This creates an inconsistency in the results indicating non-uses which are overestimated.

Table 3.20.3.2-2b: Occurrence of difenoconazole from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Difenoconazole (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0120000	Tree nuts	0.05*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.8	0.001	<LOQ	0	<LOQ
0140000	Stone fruits	0.1–0.7	0.002	0.008	1	0.008
0150000	Berries and small fruits	0.1–4	0.001	0.001–0.066	33	0.017
0160000	Miscellaneous fruits	0.1–2	0.002	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.1–2	0.001	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.5–9	0.01	<LOQ	0	<LOQ

Findings of not authorised substances in organic products

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Difenoconazole (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0230000	Fruiting vegetables	0.05*-2	0.001	0.001-0.902	32	0.039
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.05*-2	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.05*-10	0.002	0.016-4	24	0.227
0260000	Legume vegetables	0.05*-1	0.005	<LOQ	0	<LOQ
0270000	Stem vegetables	0.05*-7	0.005	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.06-0.15	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.05*-2	0.002	0.01-0.05	11	0.017
0500000	Cereals	0.05*-3	0.001	<LOQ	0	<LOQ
0631000	Herbal infusions from flowers ^{d)}	20	0.01	0.094	1	0.094
0632000	Herbal infusions from leaves and herbs ^{d)}	20	0.01	<LOQ	0	<LOQ
0633000	Herbal infusions from roots ^{d)}	20	ND	ND	ND	ND
0800000	Spices (dried)	0.3-3	0.005	0.03	1	0.03
0900000	Sugar plants	0.05*-0.6	0.002	<LOQ	0	<LOQ
Feed						
1200000	Alfalfa (for forage)	NA	ND	ND	ND	ND
	Beans (for forage)	NA	ND	ND	ND	ND
	Cereal straw	NA	ND	ND	ND	ND
	Clover (for forage)	NA	ND	ND	ND	ND
	Fodder beets (roots and tops)	NA	ND	ND	ND	ND
	Peas (for forage)	NA	ND	ND	ND	ND
	Sugar beet tops	NA	ND	ND	ND	ND
	Vetch (for forage)	NA	ND	ND	ND	ND
	Turnip tops	NA	ND	ND	ND	ND
Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of difenoconazole is not expected)						
0110000	Citrus fruits	0.6	0.001	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.05*	0.005	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.05*	ND	ND	ND	ND
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*-20	0.005	0.094	1	0.094
0700000	Hops (dried)	0.05*	0.005	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2019/552 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Herbal infusions from flowers, herbal infusions from leaves and herbs and herbal infusions from roots appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0631000, 0632000 and 0633000 and non-use of the substance for all other commodities '06N0000' that are reported under the 'broader' category 0600000 on the table. This creates an inconsistency in the results indicating non-uses which are overestimated.

Occurrence of difenoconazole in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 10,064 samples were collected and analysed for difenoconazole from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 8,364 (83.11%) were unprocessed and 1,700 (16.89%) processed commodities. No residues were quantified in 10,047 samples out of the 10,064 samples (99.83%). In 17 samples out of the 10,064 samples (0.17%) difenoconazole was found at or above the analytical LOQ but below or at the MRL. No samples labelled as organic were above MRLs. These findings are summarised in Appendix B, Table B-20.2.

Findings of not authorised substances in organic products

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.20.3.2-3a for unprocessed and in Table 3.20.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on difenoconazole in feed labelled as organic were submitted to EFSA.

Table 3.20.3.2-3a: Occurrence of difenoconazole from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Difenoconazole (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.6	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.05*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.8	0.001	0.006–0.01	2	0.008
0140000	Stone fruits	0.1–0.7	0.001	0.012–0.068	2	0.04
0150000	Berries and small fruits	0.1–4	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.1–2	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.1–2	0.001	0.002–0.007	2	0.005
0220000	Bulb vegetables	0.5–9	0.001	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.05*–2	0.001	0.13	1	0.13
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.05*–2	0.001	0.003–0.083	4	0.009
0250000	Leaf vegetables, herbs and edible flowers	0.05*–10	0.001	0.58	1	0.58
0260000	Legume vegetables	0.05*–1	0.001	<LOQ	0	<LOQ
0270000	Stem vegetables	0.05*–7	0.001	0.018–3.7	2	1.859
0280000	Fungi, mosses and lichens	0.05*	0.001	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.05*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.06–0.15	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.05*–2	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.05* 3	0.001	0.01	1	0.01
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*–20	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	0.01	<LOQ	0	<LOQ
0800000	Spices (dried)	0.3–3	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.05*–0.6	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities.

a) Maximum Residue Level in Reg. (EU) No 2019/552 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.20.3.2-3b: Occurrence of difenoconazole from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Difenoconazole (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.6	0.001	<LOQ	0	<LOQ
0120000	Tree nuts	0.05*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.8	0.001	<LOQ	0	<LOQ

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Difenoconazole (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0140000	Stone fruits	0.1–0.7	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.1–4	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.1–2	0.001	<LOQ	0	<LOQ
0210000	Root and tuber vegetables	0.1–2	0.005	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.5–9	ND	ND	ND	ND
0230000	Fruiting vegetables	0.05*–2	0.001	0.002–0.014	2	0.008
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.05*–2	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.05*–10	0.005	<LOQ	0	<LOQ
0260000	Legume vegetables	0.05*–1	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.05*–7	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.05*	0.005	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.05*	ND	ND	ND	ND
0300000	Pulses (dried)	0.06–0.15	0.002	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.05*–2	0.002	<LOQ	0	<LOQ
0500000	Cereals	0.05*–3	0.0001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*–20	0.005	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	ND	ND	ND	ND
0800000	Spices (dried)	0.3–3	0.005	<LOQ	0	<LOQ
0900000	Sugar plants	0.05*–0.6	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.01	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2019/552 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of difenoconazole in the EU Organic Farming Information System

The EU OFIS reported seven findings for difenoconazole in 2021 and 2022. Four of the products sampled and analysed had an EU origin and three were of non-EU origin. Residues were found in two samples of root and tuber vegetables (potatoes and carrots), one sample of fruiting vegetables (sweet peppers/bell peppers), 2 samples of leaf vegetables, herbs and edible flowers (spinaches and thyme) and two samples of teas, coffee, herbal infusions, cocoa and carobs (strawberry and ginseng). The concentrations of difenoconazole residues were above LOQ but below MRL in all seven samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005³. No samples labelled as organic were above MRLs. The highest concentration was reported in sample of root and tuber vegetables (dehydrated carrots) of EU origin, with the quantified level of 0.102 mg/kg. These findings are summarised in Table 3.20.3.2-4.

Table 3.20.3.2-4: Occurrence of difenoconazole from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
0211000	Potatoes	0.1	0.016 – Sweet potatoes	ND
0213020	Carrots	0.4	ND	0.102 – Carrots (dehydrated)
0231020	Sweet peppers/bell peppers	0.9	0.021 – Peppers (chilli)	ND
0252010	Spinaches	3	ND	0.01 – Spinach (powder)
Samples of non-EU origin				
0256070	Thyme	4	0.019 – Oregano	ND
0632010	Strawberry	20	0.076 – <i>Equisetum arvense</i> /horsetail herb	ND

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
0633020	Ginseng	20	<0.01 – Ginseng (white root)	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2019/552 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of difenoconazole in untreated samples (control samples) from residue trials

Difenoconazole residues were quantified in untreated (control) samples across various European regions. These included one sample of beans with pods from Italy (France, 2022b), one beet leaf sample from Germany (Germany, 2010), and two broccoli samples from Germany and Italy (United Kingdom³⁵, 2017a). Several carrot samples from Germany, Northern France, and Southern France also had quantified residues (Germany, 2022c; Spain, 2023).

Other crops with quantified residues included five chamomile samples from Germany (Spain, 2022), one celery sample from Switzerland (Netherlands, 2022b), and two cucumber samples from Germany (Spain, 2022). Residues were also found in one head cabbage sample from Germany (Germany, 2022c), one leek sample from the Netherlands (Czechia, 2022), one lettuce sample from Spain (France, 2022b), and two melon samples from Spain and Southern France (France, 2012b). Additionally, two parsley samples from Germany (Spain, 2022), several winter wheat samples from Northern France, Denmark, and the UK, and two spring wheat samples from Northern France (Czechia, 2022) contained quantified residues. Residues of difenoconazole also occurred in tomato control samples from Italy and Spain (Spain, 2022, 2023), one sugar beet sample from Spain (Spain, 2022), and several witloof samples from Northern France (United Kingdom³⁵, 2017a).

Regarding the trial on beet leaves from Germany and the trial on lettuce from Spain, it was reported that the treated and untreated specimens might have been switched (see Table 3.20.3.2-5) (France, 2022b; Germany, 2010; Portugal, 2022). Additionally, difenoconazole was used as a maintenance chemical 82 days before the first application in the sugar beet trial from Spain (Spain, 2022). No other evidence-based explanations on the causes for these occurrences in control (untreated) samples were provided in the above Member State ERs and DARs.

A summary of quantified residues in untreated (control) samples is provided in Table 3.20.3.2-5.

Table 3.20.3.2-5: Summary of the quantified findings for difenoconazole in control (untreated) samples from residue trials carried out for the critical GAP per crop.

Crop	Country/area	Result (mg/kg)
Beans with pods (portion not specified)	Italy	0.05
Beet leaves (leaf and stem)	Germany	0.09 ^{a)}
Broccoli	Germany	0.04 (whole plant)
	Italy	0.02 (inflorescence)
Carrot	Germany	0.013 (whole plant with root); 0.019 (root body); 0.048 (tops); 0.071 (tops); 0.072 (tops); 0.075 (tops); 0.10 (whole plant with root); 0.27 (tops); 0.28 (tops)
	Northern France	0.029 (root body); 0.039 (root body); 0.046 (root body); 0.25 (tops); 0.31 (tops); 0.35 (whole plant with roots); 0.53 (tops)
	Southern France	0.06 (portion not specified)
Celery (stem)	Switzerland	0.02
Chamomile (flower, dried)	Germany	0.07; 0.072; 0.076; 0.08; 0.08

Crop	Country/area	Result (mg/kg)
Cucumber (fruit)	Germany	0.013; 0.013
Head cabbage (portion not specified)	Germany	0.02
Leek (portion not specified)	The Netherlands	0.025
Lettuce (whole plant)	Spain	0.11 ^{a)}
Melon (whole fruit)	Spain	0.01
	Southern France	0.01
Parsley (leaves)	Germany	0.011; 0.027
Spring wheat (straw)	Northern France	0.04; 0.08
Sugar beet (tops with leaves)	Spain	0.02 ^{b)}
Tomato (fruit)	Italy	0.014
Winter wheat (straw)	Denmark	0.03
	Northern France	0.10
	United Kingdom ³⁵	0.02; 0.07; 0.16; 0.36; 0.40
Witloof	Northern France	Up to 0.015 (roots) and up to 0.14 (leaves); up to 0.15 (roots) and up to 0.64 (leaves)

a) Apparent (but not proven) mix-up with the treated sample. Residues in the treated sample were below the LOQ; b) Difenonazole was used as a maintenance chemical by the farmer 82 days before the first application.

- Could the presence of difenonazole and/or its residues be due to biocide use?

Difenonazole is not authorised for use as a biocide, therefore, residues due to biocidal use are not expected for difenonazole.

3.20.3.3 Behaviour in food and feed products

- What key physico-chemical properties of difenonazole are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of difenonazole are reported in Table 3.20.3.3.

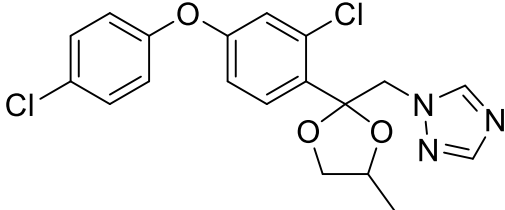
Difenonazole shows moderate to high persistence in soil (see Section 3.20.3.5). Regarding sorption to soil, the K_{Foc} in Table 3.20.3.3 indicates that the substance has slight mobility in soil (EFSA, 2011g).

The maximum calculated PEC_w for difenonazole for the representative uses was 2.76 µg/L (spray application to apples; 1 × 75 g a.s./ha) (EFSA, 2011g).

Difenonazole is hydrolytically stable under standard conditions of pasteurisation, baking/brewing/boiling and sterilisation (EFSA, 2011g). Considering that difenonazole is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.

Difenonazole has a low volatility (vapour pressure < 10⁻⁷ Pa) (EFSA, 2011g).

Table 3.20.3.3: Physico-chemical properties of difenoconazole (EFSA, 2011g)

Structural formula	
Chemical name IUPAC	3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether
Appearance (state purity)	Technical material: Off-white powder with a slightly sweetish odour, purity not stated. Purified material: White fine odourless crystalline powder (99.3%)
Melting point (state purity)	82.0–83.0°C (99.3%)
Boiling point	Not relevant at atmospheric pressure as decomposition occurs. 100.8°C at 3.7 mPa (99.3%)
Temperature of decomposition	Decomposition starts at about 337°C (99.3%)
Vapour pressure (state temperature, state purity)	3.32×10^{-8} Pa at 25°C (99.0%)
Henry's law constant (state temperature)	9.0×10^{-7} Pa m ³ mol ⁻¹ (25°C)
Solubility in water (state temperature, state purity and pH)	15 mg/L $\pm$ 1.3 mg/L at pH 7.2 and 25°C No pH effect is anticipated at environmentally relevant pH
Partition coefficient (state temperature, pH and purity)	log P _{ow} : 4.36 at 25°C (99.3%)
Partition coefficient (octanol/air)	Log P _{oa} = 13.7 (EPISuite KOAWIN v1.10) (Debler et al. 2024)
Atmospheric half-life	DT ₅₀ of 5 hours derived by the Atkinson model (AOPWIN version 1.85). OH (12 h) radical concentration assumed = 1.5×10^6 OH/cm ³
Dissociation constant (state purity)	pK _{a1} = 1.07 for the corresponding acid (i.e. the neutral species is predominantly present at pH > 1.1) (99.3%)
Soil adsorption (geometric mean)	K _{Foc} = 2943 mL/g
Hydrolytic degradation (>10%)	Hydrolytically stable (pH 5–9 at 25°C)

DT₅₀ – Disappearance time of 50% of the substance in field studies; pH – Potential of Hydrogen; P_{ow} – Octanol/water Partition Coefficient; P_{oa} – Octanol/air Partition Coefficient

3.20.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from soil surface at which it is applied).

The highest drift of difenoconazole to neighbouring fields may occur during its applications to fruit crops (up to 29.2%), hops (19.33%), vineyards and vegetables (up to 8.02%) and field crops (up to 2.77%). Drift values should be considered the rate received by neighbouring fields, expressed as a percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the

neighbouring field, the number of applications and potential managerial measures in place (e.g. buffer zones or spray drift-reducing nozzles).

Difenoconazole is used as a seed treatment, which necessitates consideration of potential dust drift. Deposition percentile values were considered for neighbouring fields, up to 17% for different crops and techniques (EFSA, 2013b). According to Adriaanse et al. (2022), the use of techniques (deflectors), size of the dust particles and average wind speed were the most important factors determining the amount of dust drift.

If organic crops are present adjacent to the conventional crops treated, measurable residues of difenoconazole in the untreated crop cannot be excluded (above all if the treated crops are fruit trees). However, since the nature of the potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

3.20.3.5 Accumulated/historical residue levels in soil

- What is the persistence of difenoconazole and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

According to available data (EFSA, 2011g), the DT₉₀ of difenoconazole in soil has a worst-case field value of 879 days, indicating a potential for accumulation in soil and for residues to remain after discontinued use of the substance.

To investigate the potential uptake of residues of difenoconazole by plants, a field rotational crop study was carried out with root crops (carrots) and leafy vegetables (spinaches) planted in bare soil previously treated with difenoconazole (750 g/ha) 30 and 31 DAT and sampled 97 and 136 DAT, respectively. Although all residues in carrots and spinaches were found below the LOQ of 0.02 mg/kg, the study did not cover the predicted plateau concentration of difenoconazole in soil for multiple years of consecutive applications for the most critical GAP⁴ (EFSA, 2024g). To cover the data gap, risk mitigation measures were recommended to the Member States to avoid the potential accumulation of residues in rotational crops (EFSA, 2024g).

Based on the above, transfer of difenoconazole in plants planted or sown in soil previously treated with difenoconazole cannot be excluded in organic crops, even if they are planted 2 years after the last chemical treatment, as required by the regulatory provisions for organic agriculture².

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Monitoring data for difenoconazole in soil are available from the LUCAS pesticides 2018 (JRC, 2023) on IPCHEM¹². The data show background levels of the substance in soil samples from 19 EU countries: Austria (3 samples), Belgium (4 samples), Bulgaria (19 samples), Czechia (30 samples), Estonia (4 samples), Finland (8 samples), France (94 samples), Germany (13 samples), Greece (6 samples), Hungary (7 samples), Italy (16 samples), Latvia (6 samples), Lithuania (9 samples), the Netherlands (7 samples), Poland (29 samples), Portugal (1 sample), Slovakia (5 samples), Spain (50 samples) and Sweden (18 samples). The reported residue levels ranged from 0.0011 mg/kg to 1.1 mg/kg. The highest concentration was found in a sample from

Finland. In LUCAS soil, the lack of information on the agricultural use history of the sites where soil was sampled precluded knowing whether the reported quantified findings were related to recent active use or historical levels in soil for difenoconazole.

Evidence on the presence of difenoconazole residues in soil is provided by Chiaia-Hernandez et al. (2017), who analysed 29 archived agricultural soil samples collected from 14 monitoring sites from 1995 to 2008 in Switzerland. The sites were selected from locations where crops had been regularly treated with pesticides. Selection was based on land use characteristics and long-term patterns of pesticide application. Difenoconazole was detected in 10 samples (34%) from cropland, orchard, vegetable and viticulture land use sites, although not quantified. There are 31% cases of detection where the substance had been applied, 14% where it was applied but not detected, and 3% where detection occurred without prior application.

Additional evidence on the occurrence of difenoconazole in soil is provided by Silva et al. (2023) in a study carried out in the framework of the EU SPRINT project. The study assessed the presence of 209 pesticide residues in 100 soil samples from conventional agriculture and 63 soil samples from organic agriculture collected during the 2021 growing season across 10 study sites in Europe: Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark. Difenoconazole was quantified in 28 conventional soil samples (28%) at concentrations from 0.0023 to 0.3093 mg/kg and one in organic soil in Italy at a concentration of 0.0089 mg/kg. The highest concentration in conventional soil was found in Spain.

Considering that difenoconazole is persistent in soil, that plant uptake of difenoconazole from soil containing residues is plausible and that difenoconazole was found in soil of organic agriculture, it can be concluded that uptake of residues of difenoconazole from organic crops planted in such soil cannot be excluded. If difenoconazole is quantified in organic crops, an analysis of the soil the plants were grown in is recommended.

3.20.3.6 Residues from water used for irrigation

- Is there evidence that residues of difenoconazole present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for difenoconazole in surface water samples were considered:

- The EMPODAT database (data retrieved on 18 March 2024) reports 817 analytical results from surface water samples collected in Bulgaria (2 samples), the Netherlands (814 samples) and Romania (1 sample) between 2017 and 2019;
- The NAIADES database (data retrieved on 3 April 2024) reports 53,001 analytical results from surface water samples collected in France from 2020 to 2022.

Among the 53,818 analytical results for difenoconazole, 663 were disregarded as found to report quantitative values below the analytical LOQ. Therefore, the number of water samples considered is 53,155.

Based on the screening process described in section 'Data and methodologies', for 99.8% of surface water samples analysed and reported in the above-mentioned databases (53,034 samples), the residue concentrations in these waters were below the screening Cw of 0.07 µg/L and, therefore, transfer of residues from surface water sources to plant commodities is unlikely.

For 0.2% of samples (121 out of 53,155 samples), the residue concentrations were or above the screening Cw of 0.07 µg/L and the potential transfer of residues to plant commodities if water containing residues at these levels is used for irrigation cannot be excluded.

In a study by Silva et al. (2023) carried out under the framework of the EU SPRINT project the authors assessed the presence of 209 pesticide residues in 58 surface water samples collected during the 2021 growing season across 10 study sites in Europe (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). Difenoconazole was quantified in three samples from Czechia at concentrations ranging between 0.003 and 0.03 µg/L. These water concentrations would not be expected to transfer residues of difenoconazole to plant commodities.

Overall, considering that for 99.8% of water samples analysed and reported for difenoconazole in EEA-WATERQUALITY, EMPODAT and NAIADES (53,155 samples), the residue concentrations were below the screening Cw of 0.07 µg/L, it can be concluded that the transfer of difenoconazole residues from water to plant commodities when this water is used to irrigate plants is unlikely.

3.20.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *difenoconazole*, *industry/industrial*, and *air/atmosphere*) did not identify any relevant European study.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water. Based on conservative estimations of the possible transfer of residues from water used for irrigation to plant commodities, the transfer of residues of difenoconazole from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 7, 2025, using the keywords *difenoconazole*, *industry/industrial*, and *water*) did not identify any relevant European study.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Although plant uptake of difenoconazole from soil containing difenoconazole cannot be excluded, there is no evidence showing that residues from industrial emissions are transferred to soil at levels that might be taken up by plants and their products.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 17, 2025, using the keywords *difenoconazole*, *industry/industrial*, and *soil/sediment*) did not identify any relevant European study.

3.20.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Medium and long-range aerial transport of residues

Silva et al. (2023) investigated the presence of difenoconazole in 20 outdoor air samples collected during the 2021 growing season across 10 study sites in Europe of organic and conventional agriculture (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark). The study was carried out under the framework of the EU SPRINT project. Organic fields had not been treated for five consecutive years. Difenoconazole was quantified in three out of 20 targeted samples (15%) from France, Spain and Portugal at a maximum concentration of 228.3 ng m⁻³ found in air samples from France. The sample with quantified residues from Portugal (40.7 ng m⁻³) had been collected from the surrounding area of an organic field.

In a study investigating the potential transport of pesticide residues from apple-growing fields in South Tyrol (Vinschgau Valley) to higher altitudes, an analysis of the soil showed an average concentration of 0.00123 mg/kg for difenoconazole in one out of 53 samples. In vegetation outside the treated areas, difenoconazole concentrations up to 0.104 mg/kg were found in five out of 53 samples (Brühl et al. 2024). The results of this study indicate the plausibility of aerial transport (through aerosols) as a potential source of residues of difenoconazole in plants outside the treated areas.

In another study published by Debler et al. (2024) under the EU SPRINT project, difenoconazole was quantified in air samples collected between April 2021 and June 2022 from one agricultural area of conventional farming in the Netherlands (potatoes, onions and sugar beet). The difenoconazole detection rate in the Netherlands was 44% with concentrations ranging from 15 to 864 pg/m³. All quantifiable levels were found in the particle phase. Note was taken that the field had undergone treatment with difenoconazole before the sample collection and measurement.

Overall, the results of these studies indicate that aerial transport of difenoconazole outside the treated areas cannot be excluded.

Uptake from organic fertilisers

In a study investigating pesticide residues in organic fertilisers, residues of difenoconazole and other pesticides were quantified (van der Blom et al., 2022, under 'Documentation as provided to EFSA'). The authors attributed the origin of the residues to the presence of plant protection products in the composted crop or in composted manure due to transfer from animal feed after digestion, or in straw used in stables. Analysis of solid organic fertilisers gave an average concentration of 0.177 mg/kg for difenoconazole in 14 out of 147 samples. Considering that (according to the authors) the use of completely free from residues organic fertilisers is currently unsustainable, transfer of difenoconazole residues from fertilisers used in organic production to organic products cannot be excluded. On the other hand, no residues of difenoconazole were found in any of the products of the crops discussed in the study (van der Blom et al., 2022, under 'Documentation as provided to EFSA').

3.20.4 Conclusions on difenoconazole

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use. Some of the residues quantified in the residue trials are higher than the current MRLs for the respective commodities. This is because these trials were evaluated in the more recent MRL review that has not been considered yet by the risk managers (see Section 3.20.3.2).
- Residue trials carried out to support the critical GAPs⁴ for difenoconazole, gave residue concentrations of up to 12 mg/kg in herbal infusions from flowers, leaves and herbs and up to 4.6 mg/kg in cereal straw. Concentrations in the ranges reported in Table 3.20.3.2-1 might be associated with active use of difenoconazole according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.
- Difenoconazole was quantified in the context of residue trials in several European countries in untreated (control) samples with the highest concentrations observed for one sample of witloof from Northern France (0.64 mg/kg).
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for difenoconazole in unprocessed commodities with authorised uses ranged from 0.014 mg/kg in stone fruits to 0.083 mg/kg in leaf vegetables, herbs and edible flowers.
- In organic unprocessed commodities that were analysed under the pesticide residues monitoring programme between 2020 and 2022 residues of difenoconazole were not quantified or were quantified in fewer than five samples per commodity.
- In organic processed commodities, residues of difenoconazole were quantified in two of the samples analysed. In samples from processed products not labelled as organic with five or more quantified findings, the median concentrations of residues of difenoconazole ranged from 0.017 mg/kg in berries and small fruits and oilseeds and oil fruits to 0.227 mg/kg in leaf vegetables, herbs and edible flowers. Considering that difenoconazole is stable under hydrolytic conditions, some food/feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that analytical methods with high sensitivity cannot quantify them.
- Overall, in commodities labelled as organic, difenoconazole was quantified in 0.17% of samples (17 out of 10,064 samples). This percentage is more than 27 times lower than the percentage reflecting the number of findings in samples not labelled as organic (4.69%) (see Appendix B, Tables B-20.1 and B-20.2). These results suggest that the occurrence of residues of difenoconazole in organic products is less likely when compared with the conventional commodities.
- Potential sources of the unintentional presence of residues of difenoconazole in commodities of plant origin are drift from conventional crops grown in the vicinity or from transfer of residues in the medium range through aerosol transport.

- Difenoconazole is persistent in soil. A study assessed by EFSA on crops growing in rotation showed that plant uptake of difenoconazole from soil containing residues cannot be excluded. The persistence in soil was confirmed from studies on soil under organic farming systems carried out under the EU SPRINT project that reported findings of difenoconazole in one of this soil. If difenoconazole is quantified in organic crops, analysis of the soil the plants were grown in is recommended.
- Plant uptake of residues of difenoconazole from organic fertilisers is considered a less likely explanation for residues found in crops where difenoconazole has not been actively used.
- Transfer of difenoconazole residues from EU water sources used for irrigation to plant commodities is unlikely.
- Conservative estimates of the possible transfer of residues of difenoconazole from water used for irrigation to plant commodities suggest that the transfer of residues of difenoconazole from industrial emissions to the water and from the water to plants and plant commodities is less likely. Although plant uptake of difenoconazole from soil containing difenoconazole cannot be excluded, there is no evidence showing that residues from industrial emissions are transferred to soil at levels that might be taken up by plants and their products.

The pathways of residues of difenoconazole to plants and plant commodities are summarised in Figure 20.



Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded

3.21 Deltamethrin

3.21.1 Method(s)

- What is/are the residues to be monitored for the active substance deltamethrin according to the residue definition for monitoring set in Regulation (EC) No 396/2005³?

For the active substance deltamethrin, the residue definition for enforcement in food and feed of plant origin has been proposed as 'deltamethrin (*cis*-deltamethrin) (F)^{91, 92} in the EFSA MRL review (EFSA, 2015I). This residue definition is applicable to primary crops, rotational crops and processed products. This residue definition for enforcement is implemented in Regulation (EC) No 396/2005³ and is also applicable to honey and other apiculture products.

Based on the above only residues of *cis*-deltamethrin are to be monitored in foods of plant origin, honey and other apiculture products.

- Is/are the method(s) of analysis based on multi-residue or are only single residue methodologies usually employed?

A multi-residue DFG S19 method using GC-MSD has been validated for the analysis of *cis*-deltamethrin⁹¹ residues in matrices with high water content, high acid content, high oil content, and dry commodities at an LOQ of 0.01 mg/kg (EFSA, 2018h, 2022k). Another multi-residue QuEChERS method using GC-MS has been validated at an LOQ of 0.01 mg/kg in high water content matrices. However, it remains unclear whether the method allows separation of the different deltamethrin isomers (EFSA, 2010d). Nevertheless, it is likely that the method allows the separation of diastereomers e.g. *cis*- from *trans*-deltamethrin.

A method using GC-MSD with EI ionisation has also been validated, along with its ILV, for the analysis of *cis*-deltamethrin⁹¹ residues in complex matrices, achieving an LOQ of 0.05 mg/kg (EFSA, 2022k).

According to EURL for Residues of Pesticides (EURL, 2024, under 'Documentation as provided to EFSA'), a multi-residue citrate-buffered QuEChERS method based on GC-MS/MS is validated to monitor *cis*-deltamethrin⁹¹ residues in honey samples at an LOQ of 0.002 mg/kg. Lower sensitivities are achieved by utilising a multi-residue GC-Orbitrap method (LOQ: 0.005 mg/kg).

Overall, multi-residue methods are available for the enforcement of *cis*-deltamethrin residues in high water, high acid, high oil content, dry and complex plant commodities, as well as in honey and other apiculture products with LOQs ranging from 0.002 to 0.05 mg/kg.

3.21.2 Authorisation status and use

- Is deltamethrin currently authorised for conventional agriculture or can it be legally used (authorised or not) for purposes other than plant protection in the EU? If not, has deltamethrin ever been authorised for conventional agriculture or for other than PPP use in the EU? If so until when?

⁹¹ Deltamethrin contains three chiral carbon atoms (8 stereoisomers). The active substance is the [1R, *cis*, alpha-S]-isomer (also reported as *cis*-deltamethrin).

⁹² (F) indicates that the residue definition is fat soluble.

a) Authorisations for plant protection use

Deltamethrin has been approved for plant protection purposes in conventional agriculture in the EU with Regulation (EU) 1107/2009³¹. The expiry date of approval of the active substance is on 15 August 2026, as indicated by the EU Pesticide Database⁵ (accessed 1 August 2024). The application for the renewal of the approval of deltamethrin is under assessment. According to Regulation (EU) 2021/1165⁶², deltamethrin is authorised in organic products for plant protection purposes providing that it will be used only in traps with specific attractants against *Bactrocera oleae* and *Ceratitis capitata*.

According to the EU Pesticides Database⁵, at national level the substance has been authorised for use in Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Estonia, Greece, Spain, Finland, France, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, and Slovakia.

b) Authorisations for purposes other than plant protection

Biocidal use

Deltamethrin has been approved for biocidal use in the EU Member States, Iceland, Liechtenstein and Norway, in accordance with Regulation (EU) No 528/2012⁷ since 1 October 2013. The expiry date of approval of the active substance is on 31 March 2026 as indicated in the ECHA website⁶ (accessed 12 February 2024). The application for the renewal of the approval of deltamethrin is under assessment.

According to the ECHA website⁶, at national level, deltamethrin has received authorisation for use in biocidal product formulations in Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden.

Other authorisations

A search carried out on the ECHA website⁹ on 6 June 2024 indicated that deltamethrin is not currently registered under REACH.

According to the EU Veterinary Medicines Database^{24, 24}, deltamethrin has been authorised as a veterinary medicine in dogs, cattle, goat, sheep, trout and Atlantic salmon.

- What is/was the actual use of deltamethrin? On what crops? For what purposes? Are there uses other than PPPs in the EU? For what purposes?

a) Use for plant protection purposes in conventional agriculture

Mode of action of deltamethrin

Deltamethrin is a non-systemic insecticide from the pyrethroid chemical class. It disrupts the nervous system of target organisms by inhibiting the transmission of nerve impulses. This insecticide is widely utilised to control various insect species, in particular *Lepidoptera*, *Coleoptera* and *Homoptera* in a wide range of crops. Additionally, deltamethrin is used topically to manage ectoparasites in cattle and sheep (EFSA, 2015I).

Conditions of use and applicable crops

The uses reported in the EFSA MRL review for deltamethrin included applications from northern and southern Europe in food and feed commodities belonging to the following crop groups: citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, cultivated fungi, pulses (dried), oilseeds and oil fruits, cereals, herbal infusions from flowers, leaves and roots, seed spices (dried), fruit spices (dried), root and rhizome spices (dried), bud spices (dried), flower pistil spices (dried), sugar plants, alfalfa, clover, fodder beet and grass (EFSA, 2015I). Note was taken that the uses for seed spices (dried) were not supported by data (see Section 3.21.3.2 'Active use (all legitimate uses of the substance)').

After the EFSA MRL review, applications were submitted to EFSA to modify the existing MRLs or support new uses for brassica vegetables (excluding brassica roots and brassica baby leaf crops), stem vegetables, cereals and carobs (EFSA, 2017e, 2018h, 2020h, 2022I).

Deltamethrin treatment included outdoor and indoor foliar applications, and post-harvest treatments by spraying and powdering:

- Foliar applications were reported for commodities belonging to the following crop groups: citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, cultivated fungi, pulses (dried), oilseeds and oil fruits, cereals, herbal infusions from flowers, leaves and roots (dried), seed spices (dried), fruit spices (dried), root and rhizome spices (dried), bud spices (dried), flower pistil spices (dried), sugar plants, alfalfa, clover, fodder beet and grass (EFSA, 2015I, 2017e, 2018h, 2022k). Application rates range from 5.00 g a.s./ha to 17.50 g a.s./ha for outdoor cultivation and 7.50 g a.s./ha to 22.50 g a.s./ha for indoor cultivation (EFSA, 2015I, 2017e, 2018h, 2022k).
- Post-harvest treatments (indoor) of deltamethrin were reported for pulses (dried), cereals and carobs by spraying at 0.5–1.0 g a.s./ton and for potatoes by powdering at 0.75 g a.s./ton (EFSA, 2015I, 2020h, 2022k,I).

Use of deltamethrin in traps containing specific attractants against *Bactrocera oleae* and *Ceratitidis capitata* is not expected to result in residues in plant commodities (EC, 2022).

b) Uses for purposes other than plant protection

Biocidal use

Biocidal products containing deltamethrin are reported to be used as insecticides for pest control (indoors and/or outdoors) (Sweden, 2011b).

They can be applied by professionals and non-professionals users. Product application rates range for crawling and flying insects from 0.00625 g a.s./m² to 0.0125 g a.s./m² (Sweden, 2011b) (see also 'authorisations for purposes other than plant protection/biocidal use').

Other use

According to the ECHA website⁹, deltamethrin is not registered under REACH (see 'authorisations for purposes other than plant protection/other uses').

Deltamethrin is a veterinary medicine^{23, 24} used in dogs, cattle, goat, sheep, trout and Atlantic salmon (see previous section).

3.21.3 Sources of residues in plants

3.21.3.1 Natural occurrence

- Is there evidence that deltamethrin occurs naturally? What is known about the natural origin of this substance?

Deltamethrin is a synthetic chemical, produced industrially through chemical processes (Lewis et al., 2016). No information on the potential natural presence of deltamethrin was found in the literature²².

3.21.3.2 Active use (all legitimate uses of the substance)

- When used as intended in conventional farming, what levels of deltamethrin per food/feed product would be consistent with active use of the substance?

Results from analysis of residues of deltamethrin in the context of residue trials carried out for the critical GAP⁴ per crop and under the 2020–2022 monitoring control programme at national level are reported in Tables 3.21.3.2-1 to 3.21.3.2-4. Findings relating to residues in control (untreated) samples are also discussed in this section.

In all matrices and for both residue trials and results from monitoring, deltamethrin residue concentrations refer to the residue definition for enforcement (i.e. *cis*-deltamethrin) if not otherwise specified.

Occurrence of deltamethrin from residue trials carried out for the critical GAP per crop

Following product applications based on the critical GAPs⁴ reported to EFSA, residue levels of deltamethrin were below the LOQ in tree nuts and sugar plants (EFSA, 2015I).

Residues of deltamethrin were quantified in citrus fruits, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, cultivated fungi, pulses (dried), oilseeds and oil fruits, cereals, herbal infusions from flowers, leaves and roots, carobs, fruit spices (dried), root and rhizome spices (dried), bud spices (dried), flower pistil spices (dried), alfalfa, clover, fodder beet and grass (EFSA, 2015I, 2017e, 2018h, 2020h, 2022k,l).

Although EU GAPs were reported for all uses indicated under 3.21.2 'Conditions of use and applicable crops', uses in seed spices (dried) were not supported by data not making it possible to create MRL proposals for this crop (EFSA, 2015I).

The results from residue trials carried out for the critical GAP per crop for deltamethrin in commodities for which uses were submitted to EFSA are summarised in Table 3.21.3.2-1 'Occurrence of deltamethrin from residue trials carried out for the critical GAP per crop'.

Table 3.21.3.2-1: Occurrence of deltamethrin from residue trials carried out for the critical GAP per crop.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Deltamethrin (RD) ^{b)} occurrence from residue trials based on the most critical GAP ^{c)} per crop	
			Range (mg/kg)	Median (mg/kg)
Food				
0110000	Citrus fruits	0.02	<LOQ (0.01)–0.02	0.01
0120000	Tree nuts	0.01*	<LOQ (0.01) – <LOQ (0.02)	<LOQ (0.02)
0130000	Pome fruits	0.09–0.2	<LOQ (0.01)–0.08	0.03
0140000	Stone fruits	0.01*–0.15	<LOQ (0.01)–0.08	0.03
0150000	Berries and small fruits	0.08–0.6	<LOQ (0.01)–0.3	0.02
0160000	Miscellaneous fruits	0.01*–1	0.01–0.31	0.17
0210000	Root and tuber vegetables	0.01*–0.02	<LOQ (0.005)–0.11 ^{d)}	0.01
0220000	Bulb vegetables	0.01*–0.3	<LOQ (0.01)–0.13	0.02
0230000	Fruiting vegetables	0.01*–0.4	<LOQ (0.01)–0.2	0.02
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*–0.2	<LOQ (0.005)–0.39 ^{e)}	0.01
0250000	Leaf vegetables, herbs and edible flowers	0.01*–2	<LOQ (0.01)–1.38	0.05
0260000	Legume vegetables	0.2	<LOQ (0.005)–0.14	0.01
0270000	Stem vegetables	0.01*–0.3	<LOQ (0.02)–0.16	0.04
0280010	Cultivated fungi	0.05	<LOQ (0.02)–0.0012	0.02
0300000	Pulses (dried)	0.01*–1	0.13–0.26	0.20
0400000	Oilseeds and oil fruits	0.01*–0.6	<LOQ (0.01)–0.31	0.05
0500000	Cereals	0.01*–2	<LOQ (0.01)–1.4	0.05
0631000	Herbal infusions from flowers	9	0.14–7 ^{f)}	0.60
0632000	Herbal infusions from leaves and herbs	9	0.14–7 ^{f)}	0.60
0633000	Herbal infusions from roots	0.3	<LOQ (0.07)–0.14	0.07
0650000	Carobs/Saint John's breads	0.7	0.33–0.41	0.36
0810000	Seed spices (dried) ^{g)}	0.05*	NR	-
0820000	Fruit spices (dried)	0.05*	0.56–7 ^{f) h)}	1.05
0840000	Root and rhizome spices (dried)	0.5	<LOQ (0.07)–0.14	0.07
0850000	Bud spices (dried)	0.05*	0.56–7 ^{f) h)}	1.05
0860000	Flower pistil spices (dried)	0.05*	0.56–7 ^{f) h)}	1.05
0900000	Sugar plants	0.01*–0.04	<LOQ (0.01) – <LOQ (0.02)	<LOQ (0.02)
Feed				
1200000	Cereal straw	NA	<LOQ (0.02)–0.47	0.14
	Grass	NA	<LOQ (0.01)–0.06	0.04
	Alfalfa	NA	<LOQ (0.02)–0.18	0.07
	Clover	NA	<LOQ (0.02)–0.18	0.07
	Fodder beet	NA	<LOQ (0.01)–0.04	0.02

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; NR – no residue trials data are available; '-': not estimated due to lack of data.

a) Maximum Residue Level in Reg. (EU) No 2024/1342 amending Annex II of Reg. (EC) No 396/2005; b) Not all laboratories have analysed the samples for different deltamethrin isomers. Consequently, some results may include additional deltamethrin isomers other than the regulated *cis*-isomer and, therefore, be overestimated; c) GAP tables per crop are available in EFSA, 2015l, 2017e, 2018h, 2020h, 2022k,l; d) The evaluation of confirmatory data (EFSA, 2022l) identified an acute risk for consumers at the previous MRL of 0.3 mg/kg for potatoes, leading to its reduction to the appropriate LOQ. Therefore, some residue trial results exceed what is now the applicable MRL; e) The results above the MRL relate to the trial results on kale that have been replaced by new trials (EFSA, 2018h); g) For uses not supported by data, the MRLs were lowered to the LOQ; f) Residue trial results from EFSA MRL review (2015l) were carried out on spinach and a dehydration factor was applied. h) EFSA notes that an extrapolation from spinach trials to spices is not appropriate. Therefore, in the absence of data the MRL should be lowered to the appropriate LOQ (EFSA, 2022l).

Occurrence of deltamethrin under monitoring results for the period 2020–2022 in plant commodities, honey and other apiculture products not labelled as organic

The MRLs applicable to deltamethrin for the years 2020–2022 are given in Regulation (EU) 2018/832⁵³.

Regarding commodities not labelled as organic, 115,852 samples were collected and analysed for deltamethrin in plant commodities, honey and other apiculture products under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 107,072 (92.42%) were unprocessed and 8,780 (7.58%) processed commodities. No residues were quantified in 113,507 samples out of the 115,852 samples (97.98%). In 2,273 samples out of

Findings of not authorised substances in organic products

the 115,852 samples (1.96%) deltamethrin was found at or above the analytical LOQ but below or at the MRL. These findings are summarised in Appendix B, Table B-21.1. MRLs were exceeded in 72 samples out of the 115,852 samples (0.06%). The highest concentration for samples exceeding the MRLs was 1.5 mg/kg in cereals (rice).

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues of deltamethrin are summarised in Table 3.21.3.2-2a for unprocessed and in Table 3.21.3.2-2b for processed plant commodities, honey and other apiculture products not labelled as organic. No monitoring data on deltamethrin in feed not labelled as organic were submitted to EFSA.

Table 3.21.3.2-2a: Occurrence of deltamethrin monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in unprocessed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Deltamethrin (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in unprocessed commodities for which EU GAPs were submitted to EFSA						
Food						
0110000	Citrus fruits	0.02	0.002	0.007–0.155	34	0.019
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.09–0.2	0.001	0.003–0.12	126	0.017
0140000	Stone fruits	0.01*–0.15	0.001	0.002–0.35	889	0.019
0150000	Berries and small fruits	0.08–0.6	0.001	0.005–0.170	156	0.024
0160000	Miscellaneous fruits	0.01*–1	0.002	0.002–0.2	70	0.016
0210000	Root and tuber vegetables	0.01*–0.02	0.002	0.003–0.15	7	0.02
0220000	Bulb vegetables	0.01*–0.3	0.002	0.008–0.024	2	0.016
0230000	Fruiting vegetables	0.01*–0.4	0.001	0.002- 0.25	92	0.013
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*–0.2	0.002	0.002–0.15	55	0.016
0250000	Leaf vegetables, herbs and edible flowers	0.01*–2	0.001	0.002–1.4	354	0.041
0260000	Legume vegetables	0.2	0.002	0.001–0.083	7	0.024
0270000	Stem vegetables	0.01*–0.3	0.002	0.003–0.042	51	0.02
0280010	Cultivated fungi ^{d)}	0.05	0.002	0.008–0.092	12	0.023
0300000	Pulses (dried)	0.01*–1	0.003	0.013–0.48	13	0.075
0400000	Oilseeds and oil fruits	0.01*–0.6	0.001	0.012–0.048	7	0.026
0500000	Cereals	0.01*–2	0.001	0.004–1.5	236	0.056
0631000	Herbal infusions from flowers ^{d)}	9	0.01	<LOQ	0	<LOQ
0632000	Herbal infusions from leaves and herbs ^{d)}	9	0.01	<LOQ	0	<LOQ
0633000	Herbal infusions from roots ^{d)}	0.3	ND	ND	ND	ND
0650000	Carobs/Saint John's breads ^{d)}	0.7	0.01	<LOQ	0	<LOQ
0810000	Seed spices (dried) ^{d)}	0.05*	0.01	<LOQ	0	<LOQ
0820000	Fruit spices (dried) ^{d)}	0.05*	0.01	<LOQ	0	<LOQ
0840000	Root and rhizome spices (dried) ^{d)}	0.5	0.01	<LOQ	0	<LOQ
0850000	Bud spices (dried) ^{d)}	0.05*	ND	ND	ND	ND
0860000	Flower pistil spices (dried) ^{d)}	0.05*	ND	ND	ND	ND
0900000	Sugar plants	0.01*–0.04	0.005	<LOQ	0	<LOQ
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
	Grass	NA	ND	ND	ND	ND
	Alfalfa	NA	ND	ND	ND	ND
	Clover	NA	ND	ND	ND	ND
	Fodder beet	NA	ND	ND	ND	ND
Findings in unprocessed commodities for which EU GAPs were not submitted to EFSA (use of deltamethrin is not expected)						
0280000	Fungi, mosses and lichens	0.01*–0.05	0.002	0.008–0.092	12	0.023
0290000	Algae and prokaryotes organisms	0.01*	0.01	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*–9	0.005	0.016–0.16	6	0.06

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Deltamethrin (RD) occurrence results from the monitoring of unprocessed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0700000	Hops (dried)	0.05*	0.02	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*-0.5	0.01	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.001	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2024/1342 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Cultivated fungi, herbal infusions from flowers, leaves, herbs and roots, carobs/Saint John's breads, seed spices, fruit spices, root and rhizome spices, bud spices and flower pistil spices appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0280010, 0631000, 0632000, 0633000, 0650000, 0810000, 0820000, 0840000, 0850000 and 0860000 and non-use of the substance for all other commodities '028N000' or '06N0000' or '08N0000' that are reported under the 'broader' category 0280000 or 0600000 or 0800000 on the table. This creates an inconsistency in the results indicating non-uses which are overestimated.

Table 3.21.3.2-2b: Occurrence of deltamethrin from monitoring data submitted from EU Member States¹¹, Iceland and Norway, from 2020 to 2022 in processed plant commodities, honey and other apiculture products not labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Deltamethrin (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
Findings in processed commodities for which EU GAPs were submitted to EFSA for unprocessed commodities						
Food						
0110000	Citrus fruits	0.02	0.002	<LOQ	0	<LOQ
0120000	Tree nuts	0.01*	0.01	0.012	1	0.012
0130000	Pome fruits	0.09–0.2	0.002	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*–0.15	0.001	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.08–0.6	0.001	0.011–0.11	18	0.029
0160000	Miscellaneous fruits	0.01*–1	0.001	0.01–0.046	7	0.037
0210000	Root and tuber vegetables	0.01*–0.02	0.002	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*–0.3	0.01	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*–0.4	0.002	0.021–0.18	2	0.101
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*–0.2	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*–2	0.005	0.019–0.67	6	0.028
0260000	Legume vegetables	0.2	0.001	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*–0.3	0.01	<LOQ	0	<LOQ
0280010	Cultivated fungi ^{d)}	0.05	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.01*–1	0.01	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–0.6	0.005	0.01–0.21	110	0.019
0500000	Cereals	0.01*–2	0.0004	0.006–0.51	83	0.023
0631000	Herbal infusions from flowers ^{d)}	9	0.01	<LOQ	0	<LOQ
0632000	Herbal infusions from leaves and herbs ^{d)}	9	0.01	<LOQ	0	<LOQ
0633000	Herbal infusions from roots ^{d)}	0.3	ND	ND	ND	ND
0650000	Carobs/Saint John's breads ^{d)}	0.7	ND	ND	ND	ND
0810000	Seed spices ^{d)}	0.05*	0.01	<LOQ	0	<LOQ
0820000	Fruit spices ^{d)}	0.05*	0.01	<LOQ	0	<LOQ
0840000	Root and rhizome spices ^{d)}	0.5	ND	ND	ND	ND
0850000	Bud spices ^{d)}	0.05*	0.01	<LOQ	0	<LOQ
0860000	Flower pistil spices ^{d)}	0.05*	ND	ND	ND	ND
0900000	Sugar plants	0.01*–0.04	0.01	<LOQ	0	<LOQ
Feed						
1200000	Cereal straw	NA	ND	ND	ND	ND
	Grass	NA	ND	ND	ND	ND

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Deltamethrin (RD) occurrence results from the monitoring of processed commodities not labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
	Alfalfa	NA	ND	ND	ND	ND
	Clover	NA	ND	ND	ND	ND
	Fodder beet	NA	ND	ND	ND	ND

Findings in processed commodities for which EU GAPs were not submitted to EFSA for unprocessed commodities (use of deltamethrin is not expected)

0280000	Fungi, mosses and lichens	0.01*-0.05	0.01	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*-9	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	0.05	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*-0.5	0.01	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.001	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; NA – not applicable; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2024/1342 amending Annex II of Reg. (EC) No 396/2005; b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017); d) Cultivated fungi, herbal infusions from flowers, leaves, herbs and roots, carobs/Saint John's breads, seed spices, fruit spices, root and rhizome spices, bud spices and flower pistil spices appear in both higher and lower parts of the table to indicate the use of the substance for commodities 0280010, 0631000, 0632000, 0633000, 0650000, 0810000, 0820000, 0840000, 0850000 and 0860000 and non-use of the substance for all other commodities '028N000' or '06N0000' or '08N0000' that are reported under the 'broader' category 0280000 or 0600000 or 0800000 on the table. This creates an inconsistency in the results indicating non-uses which are overestimated.

Occurrence of deltamethrin in monitoring results 2020–2022 in plant commodities, honey and other apiculture products labelled as organic

Regarding organic production, 9,918 samples were collected and analysed for deltamethrin from plant commodities, honey and other apiculture products labelled as organic under the monitoring programme for pesticide residues for the period 2020–2022. Among these samples, 8,244 (83.12%) were unprocessed and 1,674 (16.88%) processed commodities. No residues were quantified in 9,911 samples out of the 9,918 samples (99.93%). In six samples out of the 9,918 samples (0.06%) deltamethrin was found at or above the analytical LOQ but below or at the MRL. MRLs exceeded in one sample from organic production with the quantified level of 0.036 mg/kg in miscellaneous fruits (miscellaneous fruits with edible peel – figs). These findings are summarised in Appendix B, Table B-21.2.

The minimum analytical LOQ per food category, range of concentrations and median estimates for samples with quantified residues are summarised in Table 3.21.3.2-3a for unprocessed and in Table 3.21.3.2-3b for processed plant commodities, honey and other apiculture products labelled as organic. No monitoring data on deltamethrin in feed labelled as organic were submitted to EFSA.

Table 3.21.3.2-3a: Occurrence of deltamethrin from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in unprocessed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Deltamethrin (RD) occurrence results from the monitoring of unprocessed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.02	0.002	<LOQ	0	<LOQ
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.09–0.2	0.002	0.09	1	0.09
0140000	Stone fruits	0.01*–0.15	0.002	0.045	1	0.045
0150000	Berries and small fruits	0.08–0.6	0.002	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*–1	0.002	0.036	1	0.036
0210000	Root and tuber vegetables	0.01*–0.02	0.002	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*–0.3	0.002	<LOQ	0	<LOQ
0230000	Fruiting vegetables	0.01*–0.4	0.002	<LOQ	0	<LOQ
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*–0.2	0.002	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*–2	0.002	0.027–0.073	2	0.05
0260000	Legume vegetables	0.2	0.002	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*–0.3	0.002	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*–0.05	0.002	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	0.01	<LOQ	0	<LOQ
0300000	Pulses (dried)	0.01*–1	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*–0.6	0.001	<LOQ	0	<LOQ
0500000	Cereals	0.01*–2	0.001	<LOQ	0	<LOQ
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*–9	0.01	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	0.02	<LOQ	0	<LOQ
0800000	Spices (dried)	0.05*–0.5	0.01	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*–0.04	0.02	<LOQ	0	<LOQ
1040000	Honey and other apiculture products	0.05*	0.005	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities.

a) Maximum Residue Level in Reg. (EU) No 2024/1342 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Table 3.21.3.2-3b: Occurrence of deltamethrin from monitoring data submitted from EU Member States¹¹, Iceland and Norway from 2020 and 2022 in processed plant commodities, honey and other apiculture products labelled as organic.

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Deltamethrin (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0110000	Citrus fruits	0.02	0.002	<LOQ	0	<LOQ
0120000	Tree nuts	0.01*	0.01	<LOQ	0	<LOQ
0130000	Pome fruits	0.09–0.2	0.002	<LOQ	0	<LOQ
0140000	Stone fruits	0.01*–0.15	0.01	<LOQ	0	<LOQ
0150000	Berries and small fruits	0.08–0.6	0.001	<LOQ	0	<LOQ
0160000	Miscellaneous fruits	0.01*–1	0.002	0.003	1	0.003
0210000	Root and tuber vegetables	0.01*–0.02	0.01	<LOQ	0	<LOQ
0220000	Bulb vegetables	0.01*–0.3	ND	ND	ND	ND
0230000	Fruiting vegetables	0.01*–0.4	0.002	<LOQ	0	<LOQ

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Deltamethrin (RD) occurrence results from the monitoring of processed commodities labelled as organic			
			Min. analytical LOQ (mg/kg)	Concentration ranges from samples with quantified residues ^{b)} only (mg/kg)	Total no. of quantified results ^{c)}	Median of results from samples with quantified residues only (mg/kg)
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.01*-0.2	0.01	<LOQ	0	<LOQ
0250000	Leaf vegetables, herbs and edible flowers	0.01*-2	0.01	<LOQ	0	<LOQ
0260000	Legume vegetables	0.2	0.01	<LOQ	0	<LOQ
0270000	Stem vegetables	0.01*-0.3	0.01	<LOQ	0	<LOQ
0280000	Fungi, mosses and lichens	0.01*-0.05	0.01	<LOQ	0	<LOQ
0290000	Algae and prokaryotes organisms	0.01*	ND	ND	ND	ND
0300000	Pulses (dried)	0.01*-1	0.005	<LOQ	0	<LOQ
0400000	Oilseeds and oil fruits	0.01*-0.6	0.005	<LOQ	0	<LOQ
0500000	Cereals	0.01*-2	0.0001	0.018	1	0.018
0600000	Teas, coffee, herbal infusions, cocoa and carobs	0.05*-9	0.001	<LOQ	0	<LOQ
0700000	Hops (dried)	0.05*	ND	ND	ND	ND
0800000	Spices (dried)	0.05*-0.5	0.025	<LOQ	0	<LOQ
0900000	Sugar plants	0.01*-0.04	0.02	<LOQ	0	<LOQ
1040000	Processed apiculture products	0.05*	0.001	<LOQ	0	<LOQ

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level in Reg. (EU) No 2024/1342 amending Annex II of Reg. (EC) No 396/2005 (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)'); c) For fewer than five quantitative findings per commodity results are not statistically robust and no conclusions can be drawn (David and Nagaraja, 2003; Meeker et al., 2017).

Occurrence of deltamethrin in the EU Organic Farming Information System

The EU OFIS reported 9 findings for deltamethrin in 2021 and 2022. Six of the products sampled and analysed had EU origin and three were of non-EU origin. Residues were found in three samples of citrus fruits (oranges), one sample of stone fruits (cherries), one sample of miscellaneous fruits with inedible peel, large (pomegranates), two samples of brassica vegetables (excluding brassica roots and brassica baby leaf crops) (flowering brassica – broccoli), one sample of oilseed and oil fruits (olives for oil production – olive oil) and one sample of honey and other apiculture products (beeswax). The concentrations of deltamethrin residues were above LOQ but below MRL in three samples; these values were between the LOQ and the MRLs for these crops, as set in Reg. (EC) No 396/2005³. MRLs exceeded in six samples. The highest concentration was reported in samples of oilseed and oil fruits (olives for oil production – olive oil) of EU origin, with the quantified level of 0.035 mg/kg. These findings are summarised in Table 3.21.3.2-4.

Table 3.21.3.2-4: Occurrence of deltamethrin from the EU OFIS in years 2021 and 2022

Code number	Commodity	Applicable MRL ^{a)} (mg/kg)	Quantified results ^{b)} per given unprocessed commodity (mg/kg)	Quantified results ^{b)} per given processed commodity (mg/kg)
Samples of EU origin				
0110020	Oranges	0.02	0.012; 0.025; 0.027 – Oranges	ND
0163050	Granate apples/pomegranates	0.01*	0.011 – Pomegranates	ND
0402010	Olives for oil production	0.6	ND	0.035 – Olive oil
1040000	Honey and other apiculture products	0.05*	ND	0.015 – Beeswax
Samples of non-EU origin				
0140020	Cherries (sweet)	0.1	0.018 – Cherries	ND
0241010	Broccoli	0.1	0.014; 0.018 – Broccoli	ND

* Limit of quantification in Reg. (EC) No 396/2005 for the unprocessed commodities; ND – no data available.

a) Maximum Residue Level for the unprocessed commodities in Reg. (EU) No 2024/1342 amending Annex II of Reg. (EC) No 396/2005 for the unprocessed commodity (conventional agriculture); b) Residue concentrations below the LOQ set in Reg. (EC) No 396/2005 for some commodities are the result of methods of analysis with higher sensitivity (see column 4 of the table 'Min. analytical LOQ (mg/kg)').

Occurrence of deltamethrin in untreated samples (control samples) from residue trials

Deltamethrin residues were quantified in control (untreated) cereal samples from residue trials across several European regions. *Cis*-deltamethrin was quantified in several apricot samples from southern France, garden pea samples from Spain and Greece, and in a raspberry sample from Italy (Austria, 2020; Belgium, 2020b). Additionally, residues of deltamethrin (isomers not specified) were present in apple and artichoke from Spain (Austria, 2020; Belgium, 2020b).

Cis-deltamethrin residues were also quantified in one maize/corn control sample from Germany (Austria, 2021b). The applicant stated that the sample was accidentally treated twice but no supporting information was found in the study.

No evidence-based explanations on the causes for these occurrences in control (untreated) samples were provided in the above-mentioned evaluation reports.

The summary of the quantified findings of *cis*-deltamethrin in control (untreated) samples from residue trials carried out for the critical GAP⁴ per crop is given below in Table 3.21.3.2-5.

Table 3.21.3.2-5: Summary of the quantified findings of *cis*-deltamethrin in control (untreated) samples from residue trials carried out for the critical GAP per crop.

Commodity	Country/Area	Cis-deltamethrin (mg/kg)
Apple (fruit)	Spain	0.01 ^{a)}
Apricot (fruit)	Southern France	0.020, 0.022, 0.024
Artichoke (flower head)	Spain	0.02
Garden pea	Spain	0.011 (pod)
	Greece	0.010 (pod), 0.022 (green seed)
Maize/corn (kernel)	Germany	0.5 ^{b)}
Raspberry (fruit)	Italy	0.023

a) Reported as 'deltamethrin' b) The applicant stated that the sample was accidentally treated twice but no supporting information was found in the study.

- Could the presence of deltamethrin and/or its residues be due to biocide use?

Deltamethrin is applied as a biocidal insecticide to control pests. Mitigation measures are proposed to prevent environmental exposure to deltamethrin (Sweden, 2011b). These include proposals to prevent emissions to the sewage treatment plant (STP) after cleaning surfaces.

The products are formulated at concentrations of 0.015–25%⁹³. PEC values have been calculated to predict the potential contamination of water and soil for different scenarios (e.g. indoor barrier treatment in domestic houses or large buildings) carried out by the Evaluation Member State. The highest estimated PEC_w was 0.0036 µg/L and the highest PEC_{soil} was 0.004 mg/kg. These PECs are covered by those estimated for agricultural uses of the substance (see Section 3.21.3.6).

Based on the above, it can be concluded that the release of residues of deltamethrin in the water and/or the soil after biocidal use cannot be excluded.

⁹³ <https://echa.europa.eu/documents/10162/2636afe0-209e-e92f-2255-7392b2c79145>

3.21.3.3 Behaviour in food and feed products

- What key physico-chemical properties of deltamethrin are expected to have an influence on its presence in plant produce? Indicate for the substance and its residues where one of these key properties will be a driver for assessing residues when the relevant physico-chemical properties of the substance are available.

The physico-chemical properties of deltamethrin are shown in Table 3.21.3.3.

Deltamethrin can show high persistence in soil (see Section 3.21.3.5). Regarding sorption to soil, the K_{Foc} in Table 3.21.3.3 indicates that the substance is immobile in soil.

The maximum calculated PEC_w for deltamethrin for the representative uses was 0.0664 µg/L (spray application on pome fruits 1 × 12.5 g a.s./ha) (United Kingdom³⁵, 2017b)⁹⁴.

Deltamethrin is hydrolytically stable under standard conditions of pasteurisation, baking, brewing or boiling. Under sterilisation conditions (20 minutes at 120°C, pH 6), significant degradation of deltamethrin and formation of two transformation products 3-phenoxybenzaldehyde and (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylic acid (Br2CA) occurs. Therefore, higher residue concentrations in dried commodities compared to raw (fresh) ones cannot be excluded. Considering that deltamethrin may degrade under some food/feed processing conditions, a potential formation of degradation products would not be captured by the analytical methods because these products are not included in the residue definition for monitoring and, therefore, are not analysed. This would be expected to result in a decrease in the measured residues in the processed commodity when compared with the raw commodity. On the other hand, some processes such as drying may result in higher concentrations of residues in the processed commodities. Therefore, both possibilities (decrease or increase of residues) are plausible in this case, depending on the process.

Deltamethrin has a very low vapour pressure ($<10^{-7}$ Pa) and an atmospheric half-life below 2 days (at 0.5 days) (United Kingdom³⁵, 2017b).

Table 3.21.3.3: Physico-chemical properties of deltamethrin (WHO, 2023; ATSDR, 2003)

Structural formula	
IUPAC name and isomeric composition	Deltamethrin is one of the eight possible stereoisomers having the structure above. Name: (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate
Appearance (state purity)	Colourless crystals (99.7%)
Melting point (state purity)	100–102°C (99.7 %)
Boiling point	Decomposes below boiling point (99.7%)
Temperature of decomposition	270°C (99.5 %)
Vapour pressure (state temperature, state purity)	20°C: 1.25×10^{-8} Pa 35°C: 4.13×10^{-8} Pa 45°C: 1.98×10^{-7} Pa OECD 104, gas sat. method (99.7%)

⁹⁴ Information on PEC_w included in the Rapporteur Assessment Report under public consultation has not undergone peer-review by EFSA.

Henry's law constant (state temperature)	12 Pa m ³ mol ⁻¹ (25°C)
Solubility in water (state temperature, state purity and pH)	2 × 10 ⁻⁷ g/l, 25°C; not pH dependent (99.6%)
Partition coefficient (state temperature, pH and purity)	log P _{OW} = 4.6 at 25°C (99.3%) not pH dependent
Partition coefficient (octanol/air)	NA
Atmospheric half-life	DT ₅₀ = 0.5 days derived by the Atkinson model (AOPWIN programme). OH (12h) radical concentration assumed = 1.5 × 10 ⁶ cm ⁻³ (Socorro et al. 2016).
Dissociation constant (state purity)	No dissociation within environmentally relevant pH range
Soil adsorption (geometric mean)⁹⁵	K _{Foc} > 1,000,000 mL/g
Hydrolytic degradation (>10%)	Hydrolytically stable (pH 5–7 at 25°C) Shows hydrolysis at pH 9 and 25°C (DT ₅₀ =2.5 days)

DT₅₀ – Disappearance time of 50% of the substance in field studies; NA – not applicable; pH – Potential of Hydrogen; Pow – Octanol/water Partition Coefficient

3.21.3.4 Drift

- What is the potential for spray/dust drift from conventional agriculture to organic agriculture? What is the typical/maximum drift distance in air? Depending on the drift distance, what levels of residues can be found? How does this differ by crop?

The drift values, assuming application via standard hydraulic nozzles, are those provided by Rautmann et al. (2001). This quantifies a 90th percentile drift value for single applications and an overall 90th percentile drift for multiple applications. The drift values provide the proportion of the application rate that will be deposited over a neighbouring downwind field surface considering the distance of the untreated downwind field. They are not dependent on the substance properties, but only on the method of application and the crop to which the substance is applied (essentially the height from soil surface at which it is applied).

The highest drift of deltamethrin to neighbouring fields may occur during its applications to fruit crops (up to 29.2%), vineyards and vegetables (up to 8.02%) and field crops (up to 2.77%). Drift values should be considered the rate received by neighbouring fields, expressed as a percentage of the intended single application rate in the treated field. Actual values with respect to seasonal intended use would vary depending on the distance of the neighbouring field, the number of applications and potential managerial measures in place (e.g. buffer zones or spray drift-reducing nozzles).

The use of deltamethrin in powder form has been identified (EFSA, 2015I), which necessitates consideration of potential dust drift. Although this powder is applied in an indoor post-harvest treatment, small dust particles that are small enough to be taken downwind by the wind may break off. Deposition percentiles values were considered for neighbouring fields, distinguish between seed treatments (up to 17%) and granule applications (9.6%) for different crops and techniques (EFSA, 2013b). According to Adriaanse et al. (2022), the use of techniques (deflectors), size of the dust particles and average wind speed were the most important factors determining the amount of dust drift.

If organic crops are present adjacent to the conventional crops treated, measurable residues of deltamethrin in the untreated crop cannot be excluded. However, since the nature of the

⁹⁵ <https://sitem.herts.ac.uk/aeru/vsdb/Reports/205.htm>

potential adjacent crops and their possible growing stage is not known, quantitative estimation of the likelihood and levels of residues that will result from this scenario is not possible.

3.21.3.5 Accumulated/historical residue levels in soil

- What is the persistence of deltamethrin and its residue(s) in soil and potential uptake by the plant(s)? What is the fate of the residue(s) when in plants?

According to available data (EFSA, 2015I), DT₉₀ of deltamethrin has a worst-case value of 390 days, indicating a potential for accumulation in soil and a continued presence after discontinued use of the substance.

Considering the persistence of deltamethrin in soil, one confined rotational crop study was carried out applying deltamethrin to soil where carrots, lettuce and barley were planted at different plant-back intervals and an overdose rate of 0.45 kg a.s./ha (86N). The results of the study suggested that no significant residues are expected in succeeding crops, if the substance is applied according to the respective GAPs⁴.

Based on the above, uptake of residues of deltamethrin from plants planted or sown in soil previously treated with deltamethrin is considered unlikely. This is also valid for organic crops, when planted in fields that previously used deltamethrin for conventional agriculture, considering that it requires at least 2 years after the last chemical treatment in order for organic crops to be planted in such area².

- What is the current level of accumulated/historical levels in the soil? Which geographical areas, are (most) affected by such accumulated/historical residues, and at what levels? In affected geographical areas what evidence is there of association with particular cropping systems or other relevant anthropogenic activity?

Evidence of deltamethrin in soil was provided by Silva et al. (2023) in a study carried out under the EU SPRINT project. The study assessed the presence of 209 pesticide residues in 100 soil samples from conventional agriculture and 63 soil samples from organic agriculture collected during the 2021 growing season across 10 study sites in Europe: Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, Czechia, the Netherlands, and Denmark. Deltamethrin was quantified in four conventional soil samples (4%) at concentrations from 0.0131 to 0.0355 mg/kg. The highest concentration was found in Croatia.

Considering the available evidence, plant uptake of deltamethrin from soil under organic farming systems is less likely.

3.21.3.6 Residues from water used for irrigation

- Is there evidence that residues of deltamethrin present in water might be transferred to plants following irrigation?

On the EC's IPCHEM¹² the following databases providing occurrence data for deltamethrin in water samples were considered:

- The EEA-WATERQUALITY³⁹ database (data retrieved on 10 April 2024) reports 12 analytical results from water samples collected in Estonia (1 sample), France (3 samples) and the Netherlands (8 samples) between 2018 and 2020.

- The EMPODAT database (data retrieved on 14 March 2024) reports 374 analytical results from the Netherlands (19,992 samples) between 2018 and 2020;
- The NAIADES database (data retrieved on 22 March 2024) reports 53,423 analytical results from surface water samples collected in France from 2020 to 2022.

Among the 53,809 analytical results for deltamethrin, 1019 were disregarded as found to report quantitative values below the analytical LOQ. Therefore, the number of water samples considered is 52,790.

Based on the screening process described in section 'Data and methodologies', for 99.1% of water samples analysed and reported in the above-mentioned databases (52,312 samples), the residue concentrations in these waters were or below the screening Cw of 0.05 µg/L and, therefore, transfer of residues from water sources to plant commodities is unlikely.

For 0.9% of samples (478 out of 52,790 samples), the residue concentrations were found to be at or above the screening Cw of 0.05 µg/L and the potential transfer of residues to plant commodities if water containing residues at these levels is used for irrigation cannot be excluded.

Overall, considering that for 99.1% of water samples analysed and reported for deltamethrin in EEA-WATERQUALITY, EMPODAT and NAIADES (52,790 samples), the residue concentrations were below the screening Cw of 0.05 µg/L, it can be concluded that the transfer of deltamethrin residues from water to plant commodities when this water is used to irrigate plants is unlikely.

3.21.3.7 Residues from industrial emissions

- Is there evidence that emissions of residues from industrial areas might be transferred to plants via the air, water or soil routes?

Emissions from industrial areas to plants via the air

This section examines the potential transfer of residues from industrial emissions to plants via air. A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on October 24, 2024, using the keywords *deltamethrin*, *industry/industrial*, and *air/atmosphere*) identified only one European study, which was considered irrelevant for this section.

Emissions from industrial areas to plants via water

This section examines the potential transfer of residues from industrial emissions to plants via water. Based on conservative estimations of the possible transfer of residues from water used for irrigation to plant commodities, the transfer of residues of deltamethrin from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 7, 2025, using the keywords *deltamethrin*, *industry/industrial*, and *water*) identified one potential relevant European study.

In a study by Bille et al. (2017), the presence of pyrethroids has been studied in water samples from the Sorgaglia drainage channel, which flows in the south of Padua Province in Italy. When a whitish liquid coming from the rainwater drain of an industrial area was seen to be spilling into the drainage channel in October 2014, a massive fish mortality was noticed, and water samples were analysed. Deltamethrin was quantified in the water samples at the maximum concentration

of 4,317 µg/L the day after the spilling event, with decreasing concentrations in the following days. The authors concluded that the presence of deltamethrin was reasonably due to the spilling event from the industrial area where many industrial facilities are located. However, the authors did not report specific information on which kinds of industries are present in the area.

Overall, with the exception of specific incidents like the one described above, the transfer of residues of deltamethrin from industrial emissions to water sources and from the water to plants and plant commodities is less likely.

Emissions from industrial areas to plants via soil

This section examines the potential transfer of residues from industrial emissions to plants via soil. Based on information on the possible plant uptake of deltamethrin from EU soil, the transfer of residues from industrial emissions to soil and from soil to plants and plant commodities is less likely.

A literature review was conducted to gather relevant information. A search in the Scopus database (conducted on February 17, 2025, using the keywords *deltamethrin*, *industry/industrial*, and *soil/sediment*) did not identify any relevant European study.

3.21.3.8 Other sources of residues in plants (not covered above)

- Is there evidence that residues from sources other than those mentioned above might be transferred to plants?

Medium and long-range aerial transport of residues

Silva et al. (2023) investigated the presence of deltamethrin in 20 outdoor air samples collected during the 2021 growing season across 10 study sites in Europe of organic and conventional agriculture (Spain, Portugal, France, Switzerland, Italy, Croatia, Slovenia, the Czechia, the Netherlands, and Denmark). The study was carried out under the framework of the EU SPRINT project. Organic fields had not been treated for 5 consecutive years. Deltamethrin was detected in three out of 20 targeted samples (15%) from conventional crops in the Czechia, Croatia and Spain at a maximum concentration of 33.2 ng m⁻³ found in air samples from the Czechia. These findings, being on conventional crops, do not give any confirmation of the possible aerial transfer of residues to untreated plants in medium-range distances from treated areas but do not exclude this possibility.

Use as veterinary medicine

The use of deltamethrin as veterinary medicine^{23, 24} might also result in the release of residues into the environment that could be taken up by plants. Information on the possible plant uptake of residues of deltamethrin from EU soil where residues could result from manure, suggests that the transfer of residues of deltamethrin to agricultural soil and, from there, to plants is less likely.

3.21.4 Conclusions on deltamethrin

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use. Some of the residues quantified in the residue trials are higher than the current MRLs for the respective commodities. The reasons

vary for different commodities (e.g. acute risk identified that led to a decrease in the MRL) and are detailed in Section 3.21.3.2.

- Residue trials carried out to support the critical GAPs⁴ for deltamethrin, gave residue concentrations of up to 7 mg/kg (highest value for herbal infusions from flowers, leaves and herbs as well as for fruit spices, bud spices and flower pistil spices). Since some methods of analysis cannot separate deltamethrin isomers, these results may be overestimated. Concentrations in the ranges reported in Table 3.21.3.2-1 might be associated with active use of deltamethrin according to the critical GAPs. For less critical GAPs, lower concentrations may also indicate active use.
- Deltamethrin was quantified in the context of residue trials in several European countries in untreated (control) samples. The highest concentration, with no proposed reasoning, was found in an apricot fruit sample from Southern France (0.024 mg/kg).
- Use of deltamethrin in traps containing specific attractants against *Bactrocera oleae* and *Ceratitis capitata* is not expected to result in residues in plant commodities.
- In products not labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 and had five or more quantified findings per commodity group, the median concentrations for deltamethrin in unprocessed commodities with authorised uses ranged from 0.013 mg/kg in fruiting vegetables to 0.075 mg/kg in pulses (dried).
- In unprocessed products labelled as organic that were analysed under the pesticide residues monitoring programme between 2020 and 2022 there were no commodity groups with five or more quantified findings.
- In organic processed commodities, residues of deltamethrin were not quantified in most commodities. In samples from processed products not labelled as organic with five or more quantified findings, the median concentrations of residues of deltamethrin ranged from 0.019 mg/kg in oilseeds and oil fruits to 0.037 mg/kg in miscellaneous fruits. Considering that deltamethrin may degrade under some food/feed processing conditions, a potential formation of degradation products would not be captured by the analytical methods because these products are not included in the residue definition for monitoring and, therefore, are not analysed. This would be expected to result in a decrease in the measured residues in the processed commodity when compared with the raw commodity. On the other hand, some processes such as drying may result in higher concentrations of residues in the processed commodities. Therefore, both possibilities (decrease or increase of residues) are plausible in this case, depending on the process.
- Overall, in commodities labelled as organic, deltamethrin was quantified in 0.07% of samples (7 out of 9,918 samples). This percentage is almost 30 times lower than the percentage reflecting the number of findings in samples not labelled as organic (2.02%) (see Appendix B, Tables B-21.1 and B-21.2). These results suggest that the occurrence of residues of deltamethrin in organic products is less likely when compared with the conventional commodities.
- A potential source of the unintentional presence of residues of deltamethrin in commodities of plant origin is drift from crops grown in the vicinity.

- Information was not available to preclude the potential aerial transport of residues of deltamethrin in the medium range from the treated areas.
- Deltamethrin is persistent in the soil. However, not all substances accumulating in the soil are taken up by plants. A study assessed by EFSA on crops growing in rotation showed that plant uptake of deltamethrin from soil containing residues is unlikely.
- Transfer of deltamethrin from EU water sources used for irrigation to plant commodities is unlikely.
- The use of deltamethrin in biocidal products and as veterinary medicine^{23, 24} might also result in the release of residues into the environment that could be taken up by plants.
- Conservative estimates of the possible transfer of residues of deltamethrin from water used for irrigation to plant commodities and information on the possible plant uptake of residues of deltamethrin from EU soil suggest that the transfer of residues of deltamethrin from biocidal, veterinary or other non-pesticide uses as well as the transfer from industrial emissions to the environment and from the environment to plants and plant commodities is less likely.

The pathways of residues of deltamethrin to plants and plant commodities are summarised in Figure 21.

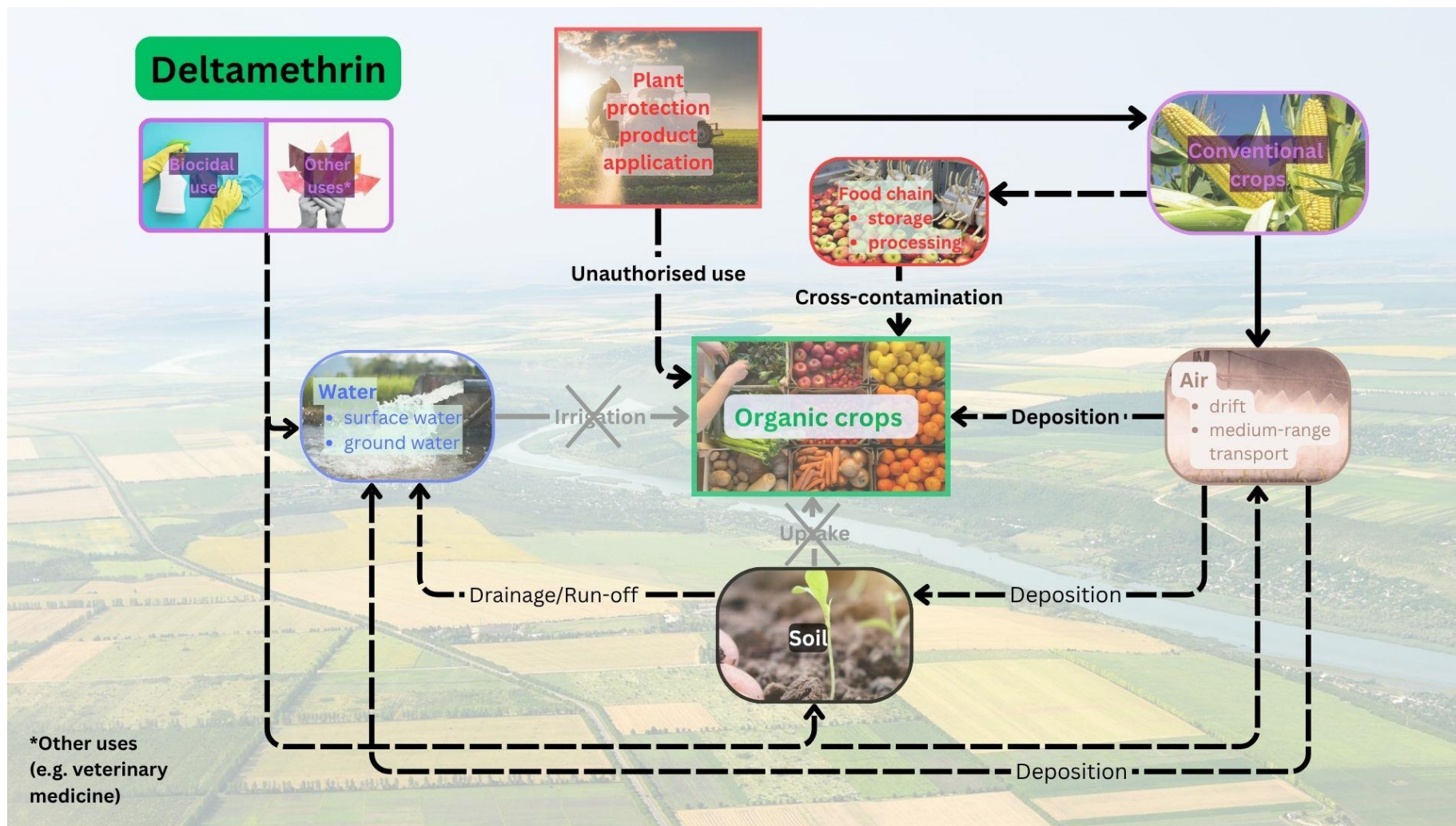


Figure 21: Pathways of residues of deltamethrin to plants and plant commodities

Solid lines indicate that transfer of residues is likely; dashed lines indicate that transfer of residues cannot be excluded

3.22 Other sources of unintentional presence

Cross-contamination in the laboratory that has carried out the analysis may result in the unintentional presence of residues. Simply “false positive” results cannot be ruled out either if the laboratory does not meet strict quality management procedures (e.g. GLP, ISO), especially if the results represent the findings in a single sample and the sample has not been reanalysed for confirmation.

Cross-contamination may also occur during the storage, transport, or processing of organic products, where equipment and installations may have been treated with insecticides for the control of storage pests. Furthermore, these facilities may be polluted by pesticides from storage, transport, or processing of conventional food (Schleiffer and Speiser, 2022). This, however, would not be expected to occur in products from organic agriculture where legal provisions in place to avoid such incidents have been adhered to.

Residues may also arise from water contamination pathways, including lateral movement of fluids in soil, leaching from soil and sediment particles (Pinasseau et al., 2020), drainage systems, and bank infiltration from rivers, as well as point sources such as spillage, tank washing, application machinery washing and waste disposal of contaminated items. Additionally, contamination from rainwater (causing wet deposition of spray aerosol air residues, the available monitored levels of which have been reported for each of the substances), particularly after long dry periods, may contribute to water and soil contamination (Schleiffer and Speiser, 2022). Another water source might be washing of the commodity post-harvest with water that contains residues.

An additional source of pesticide residues in food and feed commodities relates to other approved uses such as the uses on non-food items (e.g. ornamentals) and the uses on non-agricultural areas (e.g. forestry applications).

4 Conclusions

- None of the 21 active substances occurs naturally. Precursor salts and esters of fosetyl's transformation product phosphonic acid occur naturally. Phosphonates and organic phosphonates that may also generate phosphonic acid also occur naturally. Folpet's transformation product, phthalimide has been reported to occur naturally but in levels that cannot substantiate the transfer of residues to plants.

Methods of analysis

- Multi-residue methods of analysis are available for the analysis of 20 out of the 21 active substances considered in this report based on the applicable residue definition for enforcement of pesticide MRLs for the years 2020 to 2022. No multi-residue method was identified for the analysis of the residue definition of chloridazon. For folpet, multi-residue methods are available for all matrices except for apicultural products where only single residue methodologies were identified. For chlormequat, multi-residue methods are available for all matrices except for high oil matrices where only single residue methodologies were identified.

Considerations regarding active use

- Generally, quantified residues above the MRLs in commodities for which authorisations for conventional agriculture have been granted may indicate that the active substance has been used, but not according to the authorised use.
- Findings of residues within the ranges derived from residue trials submitted to EFSA to support active use of a substance might be associated with active use of the substance according to the critical GAPs⁴. For less critical GAPs, lower concentrations may also indicate active use.
- For the 21 active substances, monitoring results in food and feed of plant origin, honey and other apiculture products suggest that the occurrence of residues of these substances and their plant metabolites in organic products is less likely when compared with conventional commodities. For the 21 active substances considered in this report, the quantification rates of residues ranged from 0.04 to 3.95% in commodities labelled as organic (175,809 analytical results), and from 0.18 to 17.5% in commodities not labelled as organic (1,927,198 analytical results).

Effect of product processing

- Residues of fosetyl-Al, phosphonic acid, glyphosate, imidacloprid, boscalid, tebuconazole, azoxystrobin, fluopyram, acetamiprid, chlormequat, pendimethalin, cyprodinil, chloridazon, pyriproxyfen, fludioxonil and difenoconazole are stable under hydrolytic conditions. For these substances, some food and feed processes such as drying may result in an increase of residues in the processed commodity when compared with the raw commodity. This explains why residues may be concentrated and quantified as a result of some processes compared with the unprocessed product where residue levels can sometimes be so low that even analytical methods with high sensitivity cannot quantify them.
- Residues of cypermethrin, folpet, phthalimide, deltamethrin, pirimiphos-methyl, lambda-cyhalothrin and spirotetramat may degrade under some food/feed processing conditions. In such case, a potential formation of degradation products would not be captured by the analytical methods if these products are not included in the residue definition for monitoring and, therefore, are not analysed. This would be expected to result in a decrease in the measured residues in the processed commodity when compared with the raw commodity. On the other hand, some processes such as drying may result in higher concentrations of residues in the processed commodities. Therefore, both possibilities (decrease or increase of residues) are plausible, depending on the process and the hydrolytic stability of the substance.

Environmental sources of residues that may transfer residues to plants

- Fosetyl-Al, glyphosate, cypermethrin, tebuconazole, folpet, lambda-cyhalothrin, acetamiprid, chlormequat, spirotetramat, chloridazon, chloridazon-desphenyl and pyriproxyfen are not expected to accumulate in soil and plant uptake of residues from soil under organic farming systems is unlikely.
- Phosphonic acid, imidacloprid, boscalid, azoxystrobin, fluopyram, pendimethalin, cyprodinil, fludioxonil, difenoconazole and deltamethrin indicate a potential for

accumulation in soil and continued presence after discontinued use of the active substances.

- In LUCAS soil, the lack of information on the agricultural use history of the sites where soil was sampled precluded knowing whether the reported quantified findings were related to recent active use or historical levels in the soil. Information from studies carried out under the EU SPRINT project gave limited but relevant information on the presence of residues of glyphosate, tebuconazole, fluopyram, lambda-cyhalothrin, fludioxonil and difenoconazole in soil under organic farming systems.
- Not all substances accumulating in soil are taken up by plants. Based on studies assessed by EFSA on the nature and magnitude of residues of pesticides in rotational crops, plant uptake of azoxystrobin, pendimethalin, cyprodinil, fludioxonil and deltamethrin from soil containing these active substances is unlikely.
- Plant uptake of residues of phosphonic acid, boscalid, fluopyram, and difenoconazole from soil containing residues cannot be excluded.
- The transfer of residues from EU water sources used for irrigation to plant commodities is unlikely for the following substances: fosetyl, cypermethrin, imidacloprid, tebuconazole, folpet and phthalimide, pirimiphos-methyl, lambda-cyhalothrin, acetamiprid, chlormequat, chlormequat-chloride, pendimethalin, cyprodinil, chloridazon, chloridazon-desphenyl, pyriproxyfen, fludioxonil, difenoconazole and deltamethrin.
- The transfer of residues from EU water sources used for irrigation to plant commodities cannot be excluded for the following substances: glyphosate, boscalid, azoxystrobin, fluopyram, and spirotetramat.
- Limited data from the literature examined the potential transfer of residues from industrial activity to environmental sources in their vicinity (air, water and soil), but no study was retrieved that assessed the potential transfer from industrial emissions to plants.
- For substances for which the transfer of residues from EU water sources used for irrigation to plant commodities cannot be excluded, the potential impact of industrial activity in the surrounding areas was investigated. A mapping of the locations of these samples on IPCHEM with georeferenced data from the EEA's industrial emissions portal did not show associations between environmental occurrence and industrial activity in the surrounding areas.
- Drift from conventional crops treated with fosetyl-Al, cypermethrin, boscalid, tebuconazole, folpet, azoxystrobin, fluopyram, lambda-cyhalothrin, acetamiprid, chlormequat, spirotetramat, cyprodinil, pyriproxyfen, fludioxonil, difenoconazole and deltamethrin in the vicinity of organic crops may be a potential source of residues in organic crops.
- For imidacloprid, which is no longer approved for plant protection purposes in the EU, transfer of residues to organic crops due to drift from conventional crops is unlikely except for areas where emergency authorisations have been put in place, where dust drift from seed treatments might have been relevant.
- For glyphosate and pendimethalin where the worst-case drift was estimated to be lower than 3% of the applicable concentration in treated crops found at 1 m distance from organic agriculture, the transfer of residues to organic plants via drift was considered less likely.

- Drift and medium-range aerial transport of residues of pirimiphos-methyl, which is approved for indoor use only is unlikely.
- Chloridazon is no longer approved for plant protection purposes in the EU. Following the end of the grace period for the withdrawal of authorisations for chloridazon, transfer of chloridazon residues to plants from drift or from medium to long-range aerial transport is unlikely.
- Medium- to long-range aerial transport of residues of tebuconazole and pendimethalin cannot be excluded. There are indications for medium-range aerial transport of residues of fosetyl-Al, glyphosate, cypermethrin, boscalid, folpet, azoxystrobin, fluopyram, acetamiprid, spirotetramat, cyprodinil, fludioxonil and difenoconazole, so this cannot be excluded as an exposure route. Even for imidacloprid, which is no longer approved for plant protection purposes in the EU, the risk from the release of residues in the air due to its use in biocidal products cannot be excluded. For deltamethrin, the available evidence did not give indications for aerial transport of residues in the medium range from the treated areas, but neither can it be excluded.
- No information was retrieved regarding the medium range aerial transport of residues of chlormequat and pyriproxyfen.
- Medium-range aerial transport of residues of lambda-cyhalothrin is unlikely.
- Cypermethrin, imidacloprid, tebuconazole, folpet, azoxystrobin, lambda-cyhalothrin, acetamiprid, pyriproxyfen, fludioxonil and deltamethrin are used in biocidal products and may release residues in the environment. Such sources of residues are minor contributors to the overall uptake by plants.
- Cypermethrin, imidacloprid, cyhalothrin (transformation product of lambda-cyhalothrin), pyriproxyfen and deltamethrin are veterinary medicine^{23, 24} active substances, the consumption of which by the animals may release residues in the environment via manure. Such sources of residues are minor contributors to the overall uptake by plants.
- Imidacloprid, phthalimide, pirimiphos-methyl, lambda-cyhalothrin, pyriproxyfen and phosphonates (that may generate residues of phosphonic acid) were registered under REACH⁹ during the 2020–2022 period and their uses may also contribute to the overall occurrence of these substances in the environment. Such sources of residues are minor contributors to the overall uptake by plants.
- A potential source of the unintentional presence of residues of pirimiphos-methyl is the cross-contamination from treated storage facilities. This, however, would not be expected to occur in products from organic agriculture where the legal provisions in place to avoid such incidents are adhered to.
- When residues of phosphonic acid are measured in randomly collected samples of organic agriculture, these may relate to the unauthorised use of fosetyl-Al or phosphonates. They may also relate to the use of diammonium phosphate as oenological adjuvant, salts of phosphonic acid as fertilisers, plant strengtheners, manure or for soil amendments, or to the naturally occurring salts and esters of phosphonic acid or organic phosphonates.

Findings of not authorised substances in organic products

- The presence of phthalimide in commodities of plant origin for which there is no authorisation for use of folpet requires investigation considering that phthalimide is a transformation product of the active substances phosmet and ditalimfos.
- Glyphosate can be transferred to plants due to runoff from applications of the active substance for weed control at railway tracks, urban areas, road and infrastructure management and use by private gardeners.
- For all active substances, residues in the environment may arise from water contamination pathways, including lateral movement of fluids in soil, leaching from soil and sediment particles, drainage systems, and bank infiltration from rivers, as well as point sources such as spillage, tank washing, application machinery cleaning and waste disposal of contaminated items. Additionally, contamination from rainwater (causing wet deposition of spray aerosol air residues, the available monitored levels of which have been reported for each of the substances), particularly after long dry periods, may contribute to water and soil contamination. Another water source might be the washing of the commodity post-harvest with water that contained residues. Some transfer of residues to plants and their products from these sources cannot be excluded.
- Despite accredited laboratories taking measures to avoid potential cross-contamination of the samples analysed, cross-contamination in the laboratory cannot be completely ruled out.

A summary of the main outcomes per active substances is reported in Appendix D, Tables D.1 to D.3.

Figure 22 illustrates all possible pathways of residues to plants and plant commodities of organic agriculture.

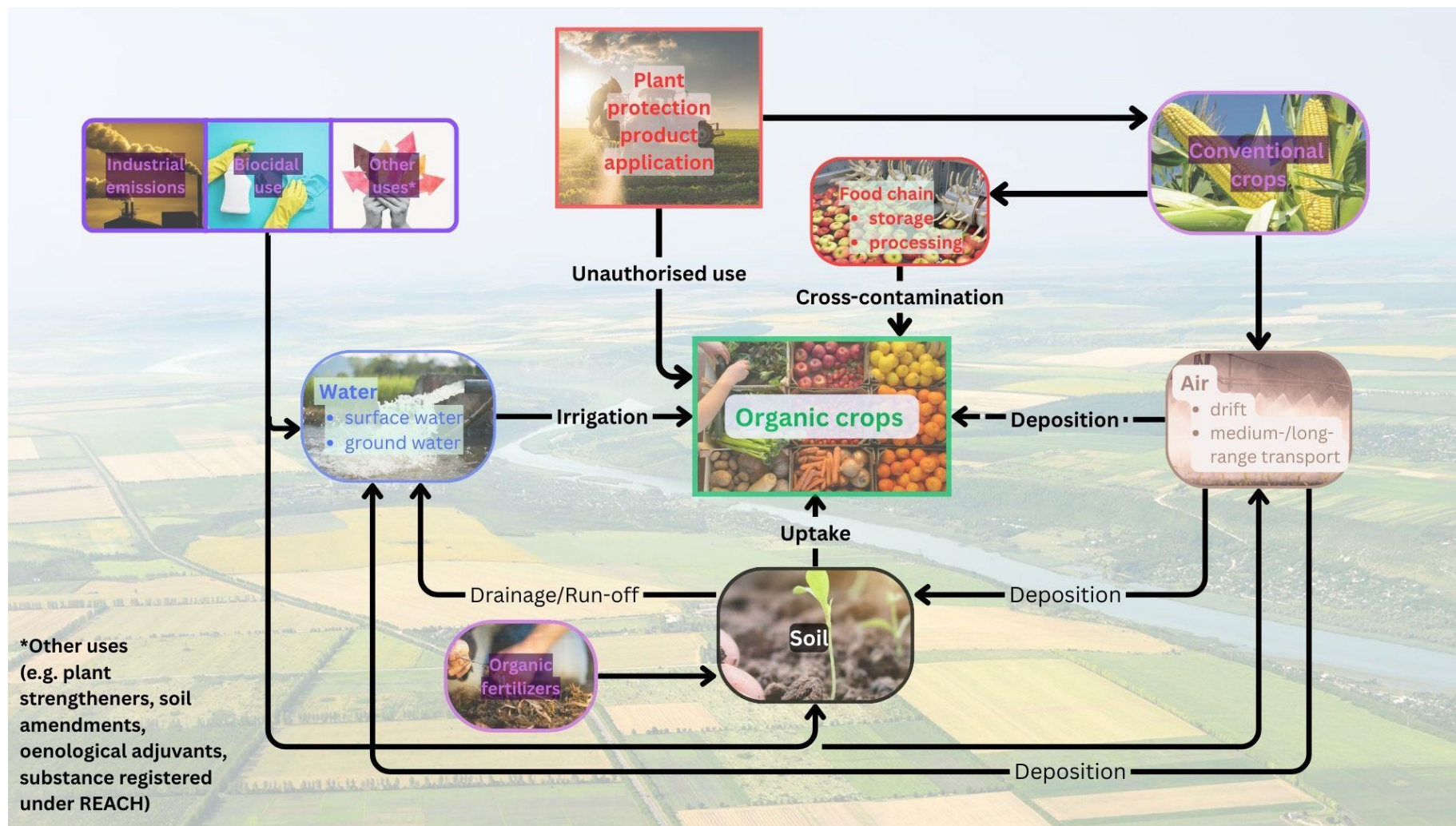


Figure 22: Pathways of residues to plants and plant commodities of organic agriculture

5 Recommendations

- When residues of the active substances considered in this report are quantified in organic commodities, the possibility of active use needs to be investigated.

In addition, EFSA recommends,

- when residues of phosphonic acid, boscalid, fluopyram and difenoconazole are quantified in organic commodities, to analyse the soil where the plants were grown;
- when residues of glyphosate, boscalid, azoxystrobin, fluopyram and spirotetramat, are quantified in organic commodities, to analyse the water source used to irrigate the plants;
- to investigate the use of pesticides around the organic production site in order to confirm or rule out the possible transfer of residues due to drift from conventional crops growing in the vicinity of organic crops;
- Member States to submit environmental monitoring data to IPCHEM⁹⁶ that follow the FAIR principles of findability, accessibility, interoperability and reusability. Regular updates of data on IPCHEM are recommended to ensure alignment with updates made in the data source.

Documentation as provided to EFSA

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⁹⁶ To be integrated into the common data platform for chemicals; see Proposal for a Regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals (https://environment.ec.europa.eu/publications/proposal-regulation-establishing-common-data-platform-chemicals_en)

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Abbreviations

a.s.	active substance
APCI	Atmospheric Pressure Chemical Ionisation
BPR	Biocidal Products Regulation
CA	Competent Authority
CEN	European Committee for Standardization
CS	Capsule Suspension
Cw	water residue concentration
DAR	Draft Assessment Report
DFG-S19	Deutsche Forschungsgemeinschaft Substance 19
DG AGRI	Directorate-General for Agriculture and Rural Development
DG SANTE	Directorate-General for Health and Food Safety
DT ₅₀ /DT ₉₀	Disappearance time of 50/90% of the substance in field studies
DTA	Differential Thermal Analysis
EBI	Ergosterol Biosynthesis Inhibitor
EC	European Commission
ECD	Electron Capture Detector
ECHA	European Chemicals Agency
EEA	European Environmental Agency
EFSA	European Food Safety Authority
EI	Electron Ionisation
EMPODAT	Database of georeferenced monitoring and bio-monitoring data on emerging substances
EMS	Evaluating Member State
EN	European Standard
ER	Evaluation Report
ESI	Electrospray Ionisation
EU	European Union
EURL	European Union Reference Laboratory
EURL-FV	European Union Reference Laboratory for Fruits and Vegetables
EURL-SRM	European Union Reference Laboratory for Single Residue Methods
FOCUS	Forum for the Co-ordination of pesticide fate models and their Use
GAP	Good Agricultural Practice
GC	Gas Chromatography

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GC-ECD	Gas Chromatography with Electron Capture Detector
GC-MS	Gas Chromatography-Mass Spectrometry
GC-MS/MS	Gas Chromatography-Tandem Mass Spectrometry
GC-MSD	Gas Chromatography-Mass Selective Detector
GC-NPD	Gas Chromatography with Nitrogen Phosphorus Detector
GC-QqQ/MS/MS	Gas Chromatography-Triple Quadrupole Tandem Mass Spectrometry
GLP	Good Laboratory Practice
HPLC-MS/MS	High-Performance Liquid Chromatography-Tandem Mass Spectrometry
ILV	Independent Laboratory Validation
IPCHEM	EC's Information Platform for Chemical Monitoring
ISO	International Organization for Standardization
JRC	European Commission's Joint Research Centre
LC	Liquid Chromatography
LC-ESI-MS/MS	Liquid Chromatography-Electrospray Ionisation-Tandem Mass Spectrometry
LC-MS/MS	Liquid Chromatography-Tandem Mass Spectrometry
LC-QqQ/MS/MS	Liquid Chromatography-Triple Quadrupole Mass Spectrometry
LOD	Limit of Detection
LOQ	Limit of Quantification
LUCAS	Land Use and Cover Area Frame Survey
MACP	Multiannual Control Programme
MANCP	Multiannual National Control Programme
MRL	Maximum Residue Level
NA	Not applicable
NAIADES	Database of surface water quality data
ND	No data available
No	Number
NR	No residue trials are available
OFIS	EU Organic Farming Information System
PBI	Plant-Back Interval
PEC	Predicted Environmental Concentration
pH	Potential of Hydrogen
pKa	Acid Dissociation Constant
P _{oa}	Octanol/air Partition Coefficient
P _{ow}	Octanol/water Partition Coefficient

Findings of not authorised substances in organic products

PPP	Plant Protection Product
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe
QuPPE	Quick Polar Pesticides
RAR	Renewal Assessment Report
RD	Residue Definition
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
Reg.	Regulation
RMS	Rapporteur Member State
RSD	Relative Standard Deviation
SC	Suspension Concentration
SPRINT	EU Sustainable Plant Protection Transition
STP	Sewage Treatment Plant
SW	Surface Water
TDMs	Triazole Derivative Metabolites
TGA	Thermo-Gravimetric Analysis
TRR	Total Radioactive Residue
UPLC-MS/MS	Ultra-Performance Liquid Chromatography-Tandem Mass Spectrometry
VMPR	Veterinary Medicinal Product Residues
WWTP	Wastewater Treatment Plant

Glossary

Active substance: According to Regulation (EC) No 1107/2009, 'active substance' (a.s.) is a substance, including micro-organisms, having general or specific action against harmful organisms or on plants, parts of plants or plant products.

Aerial transport: Aerial transport refers to the movement of a pesticide through the atmosphere after application, either due to direct losses during application or subsequent volatilisation from plant or soil surfaces. According to FOCUS (2008, SANCO/10553/2006 Rev. 2), the range of aerial transport can be classified as short-range (1–1000 m), medium-range (1–1000 km), and long-range (greater than 1000 km).

Biocidal products: According to Regulation (EC) No 528/2012, a 'biocidal product' is any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on harmful organisms by any means other than physical or mechanical action.

Critical GAP: According to Regulation (EC) No 396/2005, a 'critical GAP' is the GAP, where there is more than one GAP for an active substance/product combination, which gives rise to the highest acceptable level of pesticide residue in a treated crop and is the basis for establishing the MRL.

Draft assessment report (DAR) or Renewal assessment report (RAR) or Evaluation report (ER): The DAR/RAR/ER is the report provided by the evaluating Member State containing its scientific assessment, based on the dossier submitted by the applicant to support the approval or renewal of an active substance.

Evaluating Member State (EMS): In accordance with Regulation (EC) 396/2005, an Evaluating Member State is appointed to carry out an initial risk assessment for setting, modifying, or deleting the MRL, and to prepare an Evaluation Report which EFSA assesses.

Good agricultural practice (GAP): According to Regulation (EC) No 396/2005, 'good agricultural practice' means the nationally recommended, authorised or registered safe use of plant protection products under actual conditions at any stage of production, storage, transport, distribution and processing of food and feed. It also implies the application, in conformity with Regulation (EC) No 1107/2009, of the principles of integrated pest control in a given climate zone, as well as using the minimum quantity of pesticides and setting MRLs/temporary MRLs at the lowest level which allows the desired effect to be obtained.

Maximum residue level (MRL): According to Regulation (EC) No 396/2005 'maximum residue level' means the upper legal level of a concentration for a pesticide residue in or on food or feed set in accordance with this Regulation, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers.

Multi-residue analytical method: Analytical method developed and validated for the simultaneous determination of multiple pesticide residues within a single procedure.

Plant protection product (PPP): PPPs are formulations that contain at least one active substance, primarily used to maintain crop health and protect them from damage caused by

diseases and infestations. These products include herbicides, fungicides, insecticides, acaricides, plant growth regulators, and repellents.

Processing: Any action that substantially alters the initial agricultural product. According to the Compendium of Representative Processing Techniques Investigated in Regulatory Studies for Pesticides, relevant food processing operations include cooking in water, steaming, canning, jam and purée production, dehydration/drying, frying, baking, microwaving, juice and wine production, fermentation, oil extraction (including essential oils), tofu and soya drink production, beer brewing, milling, starch extraction, cocoa powder production, and sugar production.

Rapporteur member state (RMS): The RMS is the EU country designated to receive and evaluate the application and accompanying dossier for the approval of an active substance. The RMS is responsible for the initial scientific and technical evaluation of the active substance dossier, carrying out the first risk assessment.

REACH registration status: According to the ECHA Chemicals Database, the registration status indicates whether a substance is actively manufactured or imported into the European Economic Area i.e. EU Member States, Iceland, Liechtenstein and Norway. An *active* registration means the substance is being actively manufactured or imported to the European Economic Area. An *inactive* registration refers to a substance that is not currently being manufactured or imported; however, manufacture or import may resume at any time, which would return the registration status to active. An *annulled* registration refers to a legacy registration following a company merger or acquisition. A substance that is *no longer valid* is no longer considered registered under REACH and is not permitted to be manufactured or imported to the European Economic Area unless and until it is properly registered again.

Rotational crops: Crops planted following the harvest of a pesticide-treated crop as part of a planned sequence of different crops grown in succession.

Single residue analytical method: Analytical method developed and validated for the determination of a single pesticide residue in a given matrix.

Appendix A Total number of samples per active substance

Table A.1: Total number of samples analysed for residues of pesticides in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for the pesticide active substances covered by this report.

Active substance	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fosetyl-Al	17,088	14,222	2836	30
Glyphosate	24,504	24,113	289	102
Cypermethrin	105,548	104,606	888	54
Imidacloprid	104,136	103,357	728	51
Boscalid	106,975	95,219	11,745	11
Tebuconazole	105,957	100,825	5075	57
Folpet	52,280	52,066	203	11
Pirimiphos-methyl	106,819	106,378	417	24
Azoxystrobin	106,960	101,907	5042	11
Fluopyram	100,859	92,422	8420	17
Lambda-cyhalothrin	92,701	90,464	2161	76
Acetamiprid	104,034	96,361	7536	137
Chloromequat	23,135	22,238	876	21
Pendimethalin	104,341	103,168	1169	4
Spirotetramat	61,516	57964	3543	9
Cyprodinil	108,609	101,926	6666	17
Chloridazon	36,621	36,550	69	2
Pyriproxyfen	105,563	103,791	1767	5
Fludioxonil	99,935	90,227	9686	22
Difenoconazole	106,106	100,801	5301	4
Deltamethrin	107,072	104,955	2047	70
Total	1,780,759	1,703,560	76,464	735
Processed commodities				
Fosetyl-Al	1099	783	312	4
Glyphosate	2031	1992	32	7
Cypermethrin	8889	8707	179	3
Imidacloprid	9253	9188	62	3
Boscalid	9478	8979	498	1
Tebuconazole	8740	8570	168	2
Folpet	2910	2732	178	0
Pirimiphos-methyl	9222	8908	311	3
Azoxystrobin	9436	9259	173	4
Fluopyram	7583	7428	148	7
Lambda-cyhalothrin	7318	7218	99	1
Acetamiprid	9025	8877	144	4
Chloromequat	1512	1335	170	7
Pendimethalin	8997	8955	40	2
Spirotetramat	3622	3582	40	0
Cyprodinil	9804	9688	116	0
Chloridazon	1990	1990	0	0
Pyriproxyfen	9131	9095	35	1
Fludioxonil	8471	8364	106	1
Difenoconazole	9148	9045	103	0
Deltamethrin	8780	8552	226	2
Total	146,439	142,184	3,140	52
Ground total	1,927,198	1,846,807	79,604	787

Table A.2: Total number of samples analysed for residues of pesticides in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for the pesticide active substances covered by this report.

Findings of not authorised substances in organic products

Active substance	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fosetyl-Al	2042	1982	60	0
Glyphosate	2699	2696	3	0
Cypermethrin	8522	8515	7	0
Imidacloprid	8557	8551	6	0
Boscalid	8654	8610	44	0
Tebuconazole	8587	8573	14	0
Folpet	5031	5028	2	1
Pirimiphos-methyl	8567	8563	4	0
Azoxystrobin	8408	8387	21	0
Fluopyram	8218	8198	20	0
Lambda-cyhalothrin	7838	7837	1	0
Acetamiprid	8318	8290	26	2
Chloromequat	2424	2411	13	0
Pendimethalin	8504	8480	24	0
Spirotetramat	5694	5688	6	0
Cyprodinil	8460	8444	16	0
Chloridazon	3842	3839	3	0
Pyriproxyfen	8193	8186	7	0
Fludioxonil	7941	7922	18	1
Difenoconazole	8364	8349	15	0
Deltamethrin	8244	8239	4	1
Total	147,107	146,788	314	5
Processed commodities				
Fosetyl-Al	336	302	34	0
Glyphosate	550	550	0	0
Cypermethrin	1663	1661	2	0
Imidacloprid	1707	1707	0	0
Boscalid	1757	1755	2	0
Tebuconazole	1728	1727	1	0
Folpet	1089	1078	11	0
Pirimiphos-methyl	1701	1695	6	0
Azoxystrobin	1691	1690	1	0
Fluopyram	1618	1617	1	0
Lambda-cyhalothrin	1538	1535	3	0
Acetamiprid	1696	1696	0	0
Chloromequat	428	423	3	2
Pendimethalin	1713	1711	2	0
Spirotetramat	1144	1144	0	0
Cyprodinil	1820	1818	2	0
Chloridazon	774	774	0	0
Pyriproxyfen	1681	1681	0	0
Fludioxonil	1615	1614	1	0
Difenoconazole	1700	1698	2	0
Deltamethrin	1674	1672	2	0
Total	29,623	29,021	73	2
Ground total	176,730	176,336	387	7

Table A.3: Number of samples analysed for residues in plant commodities, honey and other apiculture products that were extracted from EU OFIS and are covered by this report.

Substance	Total no. of quantified results	Total no. of quantified results of EU origin	Total no. of quantified results from non-EU origin	Total no. of results below LOQ	No. of quantified results below applicable MRL	No. of quantified results above applicable MRL	No. of quantified results with no applicable MRL
Fosetyl	2	1	1	0	2	0	0
Phosphonic acid	1	1	0	0	1	0	0

Findings of not authorised substances in organic products

Substance	Total no. of quantified results	Total no. of quantified results of EU origin	Total no. of quantified results from non-EU origin	Total no. of results below LOQ	No. of quantified results below applicable MRL	No. of quantified results above applicable MRL	No. of quantified results with no applicable MRL
Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)	149	45	104	0	146	3	0
Glyphosate	115	38	77	0	102	13	0
Cypermethrin	51	12	39	0	47	4	0
Imidacloprid	30	4	26	0	16	12	2
Boscalid	29	19	10	0	28	0	1
Tebuconazole	27	19	8	0	23	3	1
Folpet	18	5	13	0	12	5	1
Pirimiphos-methyl	22	6	16	0	19	2	1
Azoxystrobin	19	9	10	0	19	0	0
Fluopyram	18	15	3	0	16	2	0
Lambda-cyhalothrin	17	7	10	0	16	1	0
Acetamiprid	15	4	11	1	10	4	0
Chlormequat (sum)	1	1	0	0	0	1	0
Chlormequat	9	3	6	0	4	3	2
Chlormequat - chloride	3	3	0	0	3	0	0
Pendimethalin	11	10	1	0	10	1	0
Spirotetramat	9	8	1	0	9	0	0
Spirotetramat - BYI08330-eno	2	2	0	0	2	0	0
Spirotetramat (BYI08330) (spirotetramat and its metabolites spirotetramat - enol, spirotetramat - ketohydroxy, spirotetramat - monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat)	1	1	0	0	1	0	0
Cyprodinil	9	4	5	2	7	0	0
Chloridazon	5	5	0	0	5	0	0
Chloridazon-desphenyl	2	2	0	0	2	0	0
Pyriproxyfen	9	8	1	0	9	0	0
Fludioxonil	8	5	3	0	8	0	0
Difenoconazole	7	4	3	0	7	0	0
Deltamethrin	9	6	3	0	3	6	0
Total	599	247	352	3	528	60	8

Appendix B Results per active substance and commodity group

B.1. Fosetyl-Al

Table B-1.1: Number of samples analysed for residues of fosetyl-Al in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	631	279	352	0
Tree nuts	44	34	10	0
Pome fruits	1204	659	545	0
Stone fruits	1129	976	148	5
Berries and small fruits	1895	1189	705	1
Miscellaneous fruits	565	493	72	0
Root and tuber vegetables	1247	1161	84	2
Bulb vegetables	304	251	52	1
Fruiting vegetables	3201	2905	296	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	1582	1504	75	3
Leaf vegetables, herbs and edible flowers	2243	1952	290	1
Legume vegetables	96	90	6	0
Stem vegetables	466	421	36	9
Fungi, mosses and lichens	633	557	76	0
Algae and prokaryotes organisms	1	1	0	0
Pulses (dried)	33	21	9	3
Oilseeds and oil fruits	97	91	5	1
Cereals	1612	1538	70	4
Teas, coffee, herbal infusions, cocoa and carobs	11	9	2	0
Hops (dried)	3	0	3	0
Spices (dried)	0	0	0	0
Sugar plants	5	5	0	0
Honey and other apiculture products	86	86	0	0
Total	17,088	14,222	2836	30
Processed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	79	21	58	0
Tree nuts	1	0	1	0
Pome fruits	17	13	4	0
Stone fruits	3	2	1	0
Berries and small fruits	364	139	225	0
Miscellaneous fruits	0	0	0	0
Root and tuber vegetables	6	6	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	23	16	7	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0	0	0	0
Leaf vegetables, herbs and edible flowers	36	35	1	0
Legume vegetables	0	0	0	0
Stem vegetables	2	2	0	0
Fungi, mosses and lichens	1	0	0	1
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	1	0	1	0
Oilseeds and oil fruits	201	201	0	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Cereals	360	348	9	3
Teas, coffee, herbal infusions, cocoa and carobs	0	0	0	0
Hops (dried)	5	0	5	0
Spices (dried)	0	0	0	0
Sugar plants	0	0	0	0
Processed apiculture products	0	0	0	0
Total	1099	783	312	4
Total no. of conventional samples	18,187	15,005	3148	34

Table B-1.2: Number of samples analysed for residues of fosetyl-Al in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	95	91	4	0
Tree nuts	1	1	0	0
Pome fruits	139	136	3	0
Stone fruits	50	47	3	0
Berries and small fruits	83	77	6	0
Miscellaneous fruits	53	48	5	0
Root and tuber vegetables	289	287	2	0
Bulb vegetables	45	44	1	0
Fruiting vegetables	408	400	8	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	105	104	1	0
Leaf vegetables, herbs and edible flowers	184	180	4	0
Legume vegetables	19	18	1	0
Stem vegetables	36	36	0	0
Fungi, mosses and lichens	41	34	7	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	22	21	1	0
Oilseeds and oil fruits	23	23	0	0
Cereals	446	432	14	0
Teas, coffee, herbal infusions, cocoa and carobs	0	0	0	0
Hops (dried)	0	0	0	0
Spices (dried)	2	2	0	0
Sugar plants	0	0	0	0
Honey and other apiculture products	1	1	0	0
Total	2042	1982	60	0
Processed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	4	3	1	0
Tree nuts	2	1	1	0
Pome fruits	11	10	1	0
Stone fruits	0	0	0	0
Berries and small fruits	82	52	30	0
Miscellaneous fruits	2	1	1	0
Root and tuber vegetables	1	1	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	1	1	0	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	1	1	0	0
Leaf vegetables, herbs and edible flowers	2	2	0	0
Legume vegetables	0	0	0	0
Stem vegetables	0	0	0	0
Fungi, mosses and lichens	1	1	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	2	2	0	0
Oilseeds and oil fruits	18	18	0	0
Cereals	208	208	0	0
Teas, coffee, herbal infusions, cocoa and carobs	0	0	0	0
Hops (dried)	0	0	0	0
Spices (dried)	1	1	0	0
Sugar plants	0	0	0	0
Processed apiculture products	0	0	0	0
Total	336	302	34	0
Total no. of organic samples	2378	2284	94	0

B.2. Glyphosate

Table B-2.1 Number of samples analysed for residues of glyphosate in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	1086	1077	8	1
Tree nuts	8	8	0	0
Pome fruits	1694	1683	8	3
Stone fruits	1258	1251	7	0
Berries and small fruits	2194	2183	10	1
Miscellaneous fruits	872	868	3	1
Root and tuber vegetables	2377	2372	5	0
Bulb vegetables	700	700	0	0
Fruiting vegetables	3750	3743	5	2
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	2388	2386	2	0
Leaf vegetables, herbs and edible flowers	2118	2117	1	0
Legume vegetables	235	231	2	2
Stem vegetables	496	495	1	0
Fungi, mosses and lichens	900	897	3	0
Algae and prokaryotes organisms	1	1	0	0
Pulses (dried)	232	198	33	1
Oilseeds and oil fruits	381	347	33	1
Cereals	3432	3198	151	83
Teas, coffee, herbal infusions, cocoa and carobs	25	17	8	0
Hops (dried)	3	3	0	0
Spices (dried)	0	0	0	0
Sugar plants	6	6	0	0
Honey and other apiculture products	348	332	9	7
Total	24,504	24,113	289	102
Processed commodities				

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Fruits and tree nuts	0	0	0	0
Citrus fruits	81	80	1	0
Tree nuts	1	1	0	0
Pome fruits	17	17	0	0
Stone fruits	3	3	0	0
Berries and small fruits	599	594	5	0
Miscellaneous fruits	0	0	0	0
Root and tuber vegetables	8	8	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	45	41	2	2
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0	0	0	0
Leaf vegetables, herbs and edible flowers	28	28	0	0
Legume vegetables	3	1	1	1
Stem vegetables	4	4	0	0
Fungi, mosses and lichens	2	2	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	3	3	0	0
Oilseeds and oil fruits	328	328	0	0
Cereals	894	868	22	4
Teas, coffee, herbal infusions, cocoa and carobs	1	1	0	0
Hops (dried)	5	5	0	0
Spices (dried)	0	0	0	0
Sugar plants	0	0	0	0
Processed apiculture products	9	8	1	0
Total	2031	1992	32	7
Total no. of conventional samples	26,535	26,105	321	109

Table B-2.2 Number of samples analysed for residues of glyphosate in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	120	120	0	0
Tree nuts	2	2	0	0
Pome fruits	171	171	0	0
Stone fruits	44	44	0	0
Berries and small fruits	98	98	0	0
Miscellaneous fruits	67	67	0	0
Root and tuber vegetables	343	342	1	0
Bulb vegetables	73	73	0	0
Fruiting vegetables	401	401	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	144	144	0	0
Leaf vegetables, herbs and edible flowers	192	192	0	0
Legume vegetables	21	21	0	0
Stem vegetables	33	33	0	0
Fungi, mosses and lichens	55	55	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	51	50	1	0
Oilseeds and oil fruits	42	42	0	0
Cereals	825	824	1	0
Teas, coffee, herbal infusions, cocoa and carobs	2	2	0	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Hops (dried)	0	0	0	0
Spices (dried)	2	2	0	0
Sugar plants	0	0	0	0
Honey and other apiculture products	13	13	0	0
Total	2699	2696	3	0
Processed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	4	4	0	0
Tree nuts	3	3	0	0
Pome fruits	13	13	0	0
Stone fruits	0	0	0	0
Berries and small fruits	107	107	0	0
Miscellaneous fruits	2	2	0	0
Root and tuber vegetables	3	3	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	4	4	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	1	1	0	0
Leaf vegetables, herbs and edible flowers	3	3	0	0
Legume vegetables	0	0	0	0
Stem vegetables	0	0	0	0
Fungi, mosses and lichens	1	1	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	4	4	0	0
Oilseeds and oil fruits	33	33	0	0
Cereals	369	369	0	0
Teas, coffee, herbal infusions, cocoa and carobs	1	1	0	0
Hops (dried)	0	0	0	0
Spices (dried)	1	1	0	0
Sugar plants	0	0	0	0
Processed apiculture products	1	1	0	0
Total	550	550	0	0
Total no. of organic samples	3249	3246	3	0

B.3. Cypermethrin

Table B-3.1 Number of samples analysed for residues of cypermethrin in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	6714	6643	71	0
Tree nuts	369	369	0	0
Pome fruits	8934	8894	40	0
Stone fruits	8583	8472	109	2
Berries and small fruits	9896	9806	78	12
Miscellaneous fruits	3350	3332	13	5
Root and tuber vegetables	11,786	11,760	21	5
Bulb vegetables	2998	2990	5	3
Fruiting vegetables	17,692	17,640	52	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	7622	7537	85	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Leaf vegetables, herbs and edible flowers	9621	9444	165	12
Legume vegetables	1882	1873	8	1
Stem vegetables	3654	3615	33	6
Fungi, mosses and lichens	2128	2114	13	1
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	924	922	2	0
Oilseeds and oil fruits	843	838	4	1
Cereals	6944	6772	170	2
Teas, coffee, herbal infusions, cocoa and carobs	404	384	18	2
Hops (dried)	4	4	0	0
Spices (dried)	103	100	1	2
Sugar plants	44	44	0	0
Honey and other apiculture products	1049	1049	0	0
Total	105,548	104,606	888	54
Processed commodities				
Fruits and tree nuts	14	14	0	0
Citrus fruits	320	320	0	0
Tree nuts	103	103	0	0
Pome fruits	134	134	0	0
Stone fruits	35	31	4	0
Berries and small fruits	2750	2716	34	0
Miscellaneous fruits	134	134	0	0
Root and tuber vegetables	61	61	0	0
Bulb vegetables	4	4	0	0
Fruiting vegetables	229	222	7	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	5	5	0	0
Leaf vegetables, herbs and edible flowers	239	223	16	0
Legume vegetables	27	27	0	0
Stem vegetables	9	9	0	0
Fungi, mosses and lichens	20	17	3	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	13	12	1	0
Oilseeds and oil fruits	1982	1965	14	3
Cereals	2563	2463	100	0
Teas, coffee, herbal infusions, cocoa and carobs	18	18	0	0
Hops (dried)	1	1	0	0
Spices (dried)	11	11	0	0
Sugar plants	20	20	0	0
Processed apiculture products	197	197	0	0
Total	8889	8707	179	3
Total no. of conventional samples	114,437	113,313	1067	57

Table B-3.2 Number of samples analysed for residues of cypermethrin in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	650	650	0	0
Tree nuts	30	30	0	0
Pome fruits	672	672	0	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Stone fruits	235	233	2	0
Berries and small fruits	396	396	0	0
Miscellaneous fruits	287	287	0	0
Root and tuber vegetables	1438	1438	0	0
Bulb vegetables	249	249	0	0
Fruiting vegetables	1447	1446	1	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	391	390	1	0
Leaf vegetables, herbs and edible flowers	603	603	0	0
Legume vegetables	101	101	0	0
Stem vegetables	167	167	0	0
Fungi, mosses and lichens	143	143	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	168	168	0	0
Oilseeds and oil fruits	98	98	0	0
Cereals	1306	1303	3	0
Teas, coffee, herbal infusions, cocoa and carobs	42	42	0	0
Hops (dried)	4	4	0	0
Spices (dried)	8	8	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	83	83	0	0
Total	8522	8515	7	0
Processed commodities				
Fruits and tree nuts				
Citrus fruits	10	10	0	0
Tree nuts	24	24	0	0
Pome fruits	12	12	0	0
Stone fruits	100	100	0	0
Berries and small fruits	3	3	0	0
Miscellaneous fruits	406	404	2	0
Root and tuber vegetables	17	17	0	0
Bulb vegetables	23	23	0	0
Fruiting vegetables	0	0	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	46	46	0	0
Leaf vegetables, herbs and edible flowers	4	4	0	0
Legume vegetables	13	13	0	0
Stem vegetables	15	15	0	0
Fungi, mosses and lichens	1	1	0	0
Algae and prokaryotes organisms	6	6	0	0
Pulses (dried)	0	0	0	0
Oilseeds and oil fruits	7	7	0	0
Cereals	211	211	0	0
Teas, coffee, herbal infusions, cocoa and carobs	725	725	0	0
Hops (dried)	5	5	0	0
Spices (dried)	0	0	0	0
Sugar plants	4	4	0	0
Processed apiculture products	1	1	0	0
Total	1663	1661	2	0
Total no. of organic samples	10,185	10,176	9	0

B.4. Imidacloprid

Table B-4.1 Number of samples analysed for residues of imidacloprid in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	6568	6494	74	0
Tree nuts	376	375	1	0
Pome fruits	8789	8754	32	3
Stone fruits	8289	8215	57	17
Berries and small fruits	9971	9934	37	0
Miscellaneous fruits	3286	3277	7	2
Root and tuber vegetables	11,694	11,657	33	4
Bulb vegetables	2967	2960	5	2
Fruiting vegetables	17,482	17,168	312	2
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	7571	7539	30	2
Leaf vegetables, herbs and edible flowers	9721	9650	63	8
Legume vegetables	1857	1853	4	0
Stem vegetables	3480	3476	4	0
Fungi, mosses and lichens	2143	2142	1	0
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	838	835	2	1
Oilseeds and oil fruits	856	847	5	4
Cereals	6424	6380	39	5
Teas, coffee, herbal infusions, cocoa and carobs	404	393	11	0
Hops (dried)	31	31	0	0
Spices (dried)	108	96	11	1
Sugar plants	43	43	0	0
Honey and other apiculture products	1234	1234	0	0
Total	104,136	103,357	728	51
Processed commodities				
Fruits and tree nuts	15	15	0	0
Citrus fruits	313	306	7	0
Tree nuts	105	104	0	1
Pome fruits	133	133	0	0
Stone fruits	36	36	0	0
Berries and small fruits	3096	3081	15	0
Miscellaneous fruits	132	132	0	0
Root and tuber vegetables	62	62	0	0
Bulb vegetables	4	4	0	0
Fruiting vegetables	219	189	30	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	6	6	0	0
Leaf vegetables, herbs and edible flowers	237	232	5	0
Legume vegetables	27	27	0	0
Stem vegetables	10	10	0	0
Fungi, mosses and lichens	20	19	0	1
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	12	12	0	0
Oilseeds and oil fruits	1949	1948	1	0
Cereals	2596	2593	3	0
Teas, coffee, herbal infusions, cocoa and carobs	18	18	0	0
Hops (dried)	6	5	1	0
Spices (dried)	11	10	0	1
Sugar plants	24	24	0	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Processed apiculture products	222	222	0	0
Total	9253	9188	62	3
Total no. of conventional samples	113,389	112,545	790	54

Table B-4.2 Number of samples analysed for residues of imidacloprid in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	653	651	2	0
Tree nuts	28	28	0	0
Pome fruits	676	676	0	0
Stone fruits	231	230	1	0
Berries and small fruits	411	411	0	0
Miscellaneous fruits	283	283	0	0
Root and tuber vegetables	1441	1441	0	0
Bulb vegetables	260	260	0	0
Fruiting vegetables	1442	1441	1	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	396	396	0	0
Leaf vegetables, herbs and edible flowers	618	616	2	0
Legume vegetables	99	99	0	0
Stem vegetables	163	163	0	0
Fungi, mosses and lichens	150	150	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	166	166	0	0
Oilseeds and oil fruits	99	99	0	0
Cereals	1296	1296	0	0
Teas, coffee, herbal infusions, cocoa and carobs	41	41	0	0
Hops (dried)	4	4	0	0
Spices (dried)	8	8	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	88	88	0	0
Total	8557	8551	6	0
Processed commodities				
Fruits and tree nuts	10	10	0	0
Citrus fruits	23	23	0	0
Tree nuts	14	14	0	0
Pome fruits	101	101	0	0
Stone fruits	5	5	0	0
Berries and small fruits	403	403	0	0
Miscellaneous fruits	17	17	0	0
Root and tuber vegetables	24	24	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	43	43	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	4	4	0	0
Leaf vegetables, herbs and edible flowers	14	14	0	0
Legume vegetables	15	15	0	0
Stem vegetables	1	1	0	0
Fungi, mosses and lichens	6	6	0	0
Algae and prokaryotes organisms	0	0	0	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Pulses (dried)	7	7	0	0
Oilseeds and oil fruits	213	213	0	0
Cereals	766	766	0	0
Teas, coffee, herbal infusions, cocoa and carobs	5	5	0	0
Hops (dried)	0	0	0	0
Spices (dried)	4	4	0	0
Sugar plants	2	2	0	0
Processed apiculture products	30	30	0	0
Total	1707	1707	0	0
Total no. of organic samples	10,264	10,258	6	0

B.5. Boscalid

Table B-5.1 Number of samples analysed for residues of boscalid in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	6764	6744	20	0
Tree nuts	379	377	2	0
Pome fruits	9046	7059	1986	1
Stone fruits	8669	6488	2180	1
Berries and small fruits	10,030	7691	2338	1
Miscellaneous fruits	3365	3309	54	2
Root and tuber vegetables	11,973	10,708	1265	0
Bulb vegetables	3041	2846	195	0
Fruiting vegetables	17,912	17,119	793	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	7734	7060	674	0
Leaf vegetables, herbs and edible flowers	9923	8182	1735	6
Legume vegetables	1937	1756	181	0
Stem vegetables	3602	3364	238	0
Fungi, mosses and lichens	2162	2161	1	0
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	919	897	22	0
Oilseeds and oil fruits	863	860	3	0
Cereals	6902	6888	14	0
Teas, coffee, herbal infusions, cocoa and carobs	401	395	6	0
Hops (dried)	31	11	20	0
Spices (dried)	110	108	2	0
Sugar plants	44	43	1	0
Honey and other apiculture products	1164	1149	15	0
Total	106,975	95,219	11,745	11
Processed commodities				
Fruits and tree nuts	15	14	1	0
Citrus fruits	334	334	0	0
Tree nuts	105	104	1	0
Pome fruits	138	134	4	0
Stone fruits	36	29	7	0
Berries and small fruits	3052	2647	405	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Miscellaneous fruits	133	133	0	0
Root and tuber vegetables	61	58	3	0
Bulb vegetables	4	4	0	0
Fruiting vegetables	223	201	22	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	5	5	0	0
Leaf vegetables, herbs and edible flowers	237	226	10	1
Legume vegetables	26	26	0	0
Stem vegetables	9	9	0	0
Fungi, mosses and lichens	20	20	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	12	12	0	0
Oilseeds and oil fruits	2088	2081	7	0
Cereals	2711	2707	4	0
Teas, coffee, herbal infusions, cocoa and carobs	14	14	0	0
Hops (dried)	6	1	5	0
Spices (dried)	12	11	1	0
Sugar plants	24	24	0	0
Processed apiculture products	213	185	28	0
Total	9478	8979	498	1
Total no. of conventional samples	116,453	104,198	12,243	12

Table B-5.2 Number of samples analysed for residues of boscalid in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	658	658	0	0
Tree nuts	28	28	0	0
Pome fruits	684	680	4	0
Stone fruits	233	229	4	0
Berries and small fruits	413	408	5	0
Miscellaneous fruits	288	287	1	0
Root and tuber vegetables	1444	1437	7	0
Bulb vegetables	260	254	6	0
Fruiting vegetables	1463	1461	2	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	398	398	0	0
Leaf vegetables, herbs and edible flowers	619	608	11	0
Legume vegetables	102	101	1	0
Stem vegetables	164	163	1	0
Fungi, mosses and lichens	150	150	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	166	166	0	0
Oilseeds and oil fruits	98	98	0	0
Cereals	1348	1348	0	0
Teas, coffee, herbal infusions, cocoa and carobs	41	41	0	0
Hops (dried)	4	3	1	0
Spices (dried)	9	9	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	80	79	1	0
Total	8654	8610	44	0
Processed commodities				

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Fruits and tree nuts	10	10	0	0
Citrus fruits	23	23	0	0
Tree nuts	14	14	0	0
Pome fruits	101	101	0	0
Stone fruits	5	5	0	0
Berries and small fruits	424	424	0	0
Miscellaneous fruits	17	17	0	0
Root and tuber vegetables	24	24	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	46	46	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	4	4	0	0
Leaf vegetables, herbs and edible flowers	14	14	0	0
Legume vegetables	15	15	0	0
Stem vegetables	1	1	0	0
Fungi, mosses and lichens	6	6	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	7	7	0	0
Oilseeds and oil fruits	223	223	0	0
Cereals	782	782	0	0
Teas, coffee, herbal infusions, cocoa and carobs	5	5	0	0
Hops (dried)	0	0	0	0
Spices (dried)	4	4	0	0
Sugar plants	2	2	0	0
Processed apiculture products	30	28	2	0
Total	1757	1755	2	0
Total no. of organic samples	10,411	10,365	46	0

B.6. Tebuconazole

Table B-6.1 Number of samples analysed for residues of tebuconazole in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	6370	6359	11	0
Tree nuts	380	380	0	0
Pome fruits	9052	8133	915	4
Stone fruits	8648	6109	2535	4
Berries and small fruits	10,039	9652	379	8
Miscellaneous fruits	3337	3324	10	3
Root and tuber vegetables	11,940	11,619	321	0
Bulb vegetables	3011	2961	49	1
Fruiting vegetables	17,800	17,593	205	2
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	7733	7577	133	23
Leaf vegetables, herbs and edible flowers	9890	9826	56	8
Legume vegetables	1921	1901	20	0
Stem vegetables	3568	3386	180	2
Fungi, mosses and lichens	2160	2159	1	0
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	895	886	9	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Oilseeds and oil fruits	874	865	9	0
Cereals	6767	6536	230	1
Teas, coffee, herbal infusions, cocoa and carobs	403	398	5	0
Hops (dried)	24	23	1	0
Spices (dried)	109	104	4	1
Sugar plants	44	44	0	0
Honey and other apiculture products	988	986	2	0
Total	105,957	100,825	5075	57
Processed commodities				
Fruits and tree nuts	15	14	1	0
Citrus fruits	285	285	0	0
Tree nuts	105	105	0	0
Pome fruits	136	135	1	0
Stone fruits	36	29	7	0
Berries and small fruits	2796	2729	67	0
Miscellaneous fruits	134	134	0	0
Root and tuber vegetables	62	62	0	0
Bulb vegetables	4	4	0	0
Fruiting vegetables	223	202	21	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	6	6	0	0
Leaf vegetables, herbs and edible flowers	236	225	9	2
Legume vegetables	27	27	0	0
Stem vegetables	10	10	0	0
Fungi, mosses and lichens	20	19	1	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	12	12	0	0
Oilseeds and oil fruits	1825	1795	30	0
Cereals	2655	2627	28	0
Teas, coffee, herbal infusions, cocoa and carobs	14	13	1	0
Hops (dried)	6	6	0	0
Spices (dried)	12	11	1	0
Sugar plants	24	24	0	0
Processed apiculture products	97	96	1	0
Total	8740	8570	168	2
Total no. of conventional samples	114,697	109,395	5243	59

Table B-6.2 Number of samples analysed for residues of tebuconazole in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	641	641	0	0
Tree nuts	28	28	0	0
Pome fruits	685	680	5	0
Stone fruits	233	230	3	0
Berries and small fruits	414	414	0	0
Miscellaneous fruits	286	286	0	0
Root and tuber vegetables	1441	1441	0	0
Bulb vegetables	258	253	5	0
Fruiting vegetables	1448	1448	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	398	398	0	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Leaf vegetables, herbs and edible flowers	617	617	0	0
Legume vegetables	101	101	0	0
Stem vegetables	164	164	0	0
Fungi, mosses and lichens	150	150	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	165	165	0	0
Oilseeds and oil fruits	101	101	0	0
Cereals	1340	1339	1	0
Teas, coffee, herbal infusions, cocoa and carobs	40	40	0	0
Hops (dried)	4	4	0	0
Spices (dried)	9	9	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	60	60	0	0
Total	8587	8573	14	0
Processed commodities				
Fruits and tree nuts	10	10	0	0
Citrus fruits	23	23	0	0
Tree nuts	14	14	0	0
Pome fruits	101	101	0	0
Stone fruits	5	5	0	0
Berries and small fruits	415	415	0	0
Miscellaneous fruits	17	17	0	0
Root and tuber vegetables	24	24	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	48	47	1	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	4	4	0	0
Leaf vegetables, herbs and edible flowers	14	14	0	0
Legume vegetables	15	15	0	0
Stem vegetables	1	1	0	0
Fungi, mosses and lichens	6	6	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	7	7	0	0
Oilseeds and oil fruits	219	219	0	0
Cereals	780	780	0	0
Teas, coffee, herbal infusions, cocoa and carobs	5	5	0	0
Hops (dried)	0	0	0	0
Spices (dried)	4	4	0	0
Sugar plants	2	2	0	0
Processed apiculture products	14	14	0	0
Total	1728	1727	1	0
Total no. of organic samples	10,315	10,300	15	0

B.7. Folpet

Table B-7.1 Number of samples analysed for residues of folpet in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	2342	2341	1	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Tree nuts	193	193	0	0
Pome fruits	4728	4678	49	1
Stone fruits	3959	3950	7	2
Berries and small fruits	5621	5520	98	3
Miscellaneous fruits	1480	1480	0	0
Root and tuber vegetables	6261	6254	6	1
Bulb vegetables	1382	1381	1	0
Fruiting vegetables	8674	8670	4	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	4312	4305	5	2
Leaf vegetables, herbs and edible flowers	5556	5548	6	2
Legume vegetables	979	979	0	0
Stem vegetables	1747	1747	0	0
Fungi, mosses and lichens	1142	1142	0	0
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	530	530	0	0
Oilseeds and oil fruits	339	339	0	0
Cereals	2540	2527	13	0
Teas, coffee, herbal infusions, cocoa and carobs	107	94	13	0
Hops (dried)	1	1	0	0
Spices (dried)	55	55	0	0
Sugar plants	17	17	0	0
Honey and other apiculture products	311	311	0	0
Total	52,280	52,066	203	11
Processed commodities				
Fruits and tree nuts	6	6	0	0
Citrus fruits	181	181	0	0
Tree nuts	17	17	0	0
Pome fruits	101	101	0	0
Stone fruits	16	16	0	0
Berries and small fruits	828	657	171	0
Miscellaneous fruits	70	70	0	0
Root and tuber vegetables	53	53	0	0
Bulb vegetables	4	4	0	0
Fruiting vegetables	141	139	2	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	3	3	0	0
Leaf vegetables, herbs and edible flowers	97	95	2	0
Legume vegetables	18	18	0	0
Stem vegetables	9	9	0	0
Fungi, mosses and lichens	3	3	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	12	12	0	0
Oilseeds and oil fruits	407	404	3	0
Cereals	925	925	0	0
Teas, coffee, herbal infusions, cocoa and carobs	1	1	0	0
Hops (dried)	2	2	0	0
Spices (dried)	4	4	0	0
Sugar plants	2	2	0	0
Processed apiculture products	10	10	0	0
Total	2910	2732	178	0
Total no. of conventional samples	55,190	54,798	381	11

Table B-7.2: Number of samples analysed for residues of folpet in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	318	318	0	0
Tree nuts	26	26	0	0
Pome fruits	401	401	0	0
Stone fruits	118	118	0	0
Berries and small fruits	217	217	0	0
Miscellaneous fruits	151	151	0	0
Root and tuber vegetables	906	906	0	0
Bulb vegetables	139	138	1	0
Fruiting vegetables	933	933	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	268	268	0	0
Leaf vegetables, herbs and edible flowers	377	376	0	1
Legume vegetables	48	48	0	0
Stem vegetables	112	112	0	0
Fungi, mosses and lichens	87	87	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	123	123	0	0
Oilseeds and oil fruits	76	76	0	0
Cereals	637	636	1	0
Teas, coffee, herbal infusions, cocoa and carobs	30	30	0	0
Hops (dried)	3	3	0	0
Spices (dried)	5	5	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	52	52	0	0
Total	5031	5028	2	1
Processed commodities				
Fruits and tree nuts	9	9	0	0
Citrus fruits	18	18	0	0
Tree nuts	11	11	0	0
Pome fruits	88	88	0	0
Stone fruits	4	4	0	0
Berries and small fruits	288	278	10	0
Miscellaneous fruits	14	14	0	0
Root and tuber vegetables	17	17	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	30	30	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	3	3	0	0
Leaf vegetables, herbs and edible flowers	9	9	0	0
Legume vegetables	14	14	0	0
Stem vegetables	1	1	0	0
Fungi, mosses and lichens	0	0	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	5	5	0	0
Oilseeds and oil fruits	97	97	0	0
Cereals	475	474	1	0
Teas, coffee, herbal infusions, cocoa and carobs	4	4	0	0
Hops (dried)	0	0	0	0
Spices (dried)	1	1	0	0
Sugar plants	1	1	0	0
Processed apiculture products	0	0	0	0
Total	1089	1078	11	0

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Total no. of organic samples	6120	6106	13	1

B.8. Pirimiphos-methyl

Table B-8.1 Number of samples analysed for residues of pirimiphos-methyl in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	6796	6793	0	3
Tree nuts	372	372	0	0
Pome fruits	9063	9062	0	1
Stone fruits	8659	8659	0	0
Berries and small fruits	9966	9965	0	1
Miscellaneous fruits	3344	3344	0	0
Root and tuber vegetables	11,971	11,971	0	0
Bulb vegetables	3032	3032	0	0
Fruiting vegetables	17,937	179,33	1	3
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	7740	7740	0	0
Leaf vegetables, herbs and edible flowers	9812	9810	1	1
Legume vegetables	1911	1909	0	2
Stem vegetables	3603	3603	0	0
Fungi, mosses and lichens	2147	2147	0	0
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	931	920	4	7
Oilseeds and oil fruits	862	847	14	1
Cereals	7195	6795	395	5
Teas, coffee, herbal infusions, cocoa and carobs	413	413	0	0
Hops (dried)	4	4	0	0
Spices (dried)	109	107	2	0
Sugar plants	44	44	0	0
Honey and other apiculture products	904	904	0	0
Total	106,819	106,378	417	24
Processed commodities				
Fruits and tree nuts	15	15	0	0
Citrus fruits	349	349	0	0
Tree nuts	104	104	0	0
Pome fruits	139	139	0	0
Stone fruits	36	36	0	0
Berries and small fruits	3140	3140	0	0
Miscellaneous fruits	133	133	0	0
Root and tuber vegetables	62	62	0	0
Bulb vegetables	4	4	0	0
Fruiting vegetables	224	223	1	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	6	6	0	0
Leaf vegetables, herbs and edible flowers	232	230	0	2
Legume vegetables	28	28	0	0
Stem vegetables	10	10	0	0
Fungi, mosses and lichens	20	20	0	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	13	13	0	0
Oilseeds and oil fruits	1639	1635	4	0
Cereals	2915	2608	306	1
Teas, coffee, herbal infusions, cocoa and carobs	18	18	0	0
Hops (dried)	1	1	0	0
Spices (dried)	11	11	0	0
Sugar plants	24	24	0	0
Processed apiculture products	99	99	0	0
Total	9222	8908	311	3
Total no. of conventional samples	116,041	115,286	728	27

Table B-8.2 Number of samples analysed for residues of pirimiphos-methyl in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	651	651	0	0
Tree nuts	30	30	0	0
Pome fruits	671	671	0	0
Stone fruits	235	235	0	0
Berries and small fruits	409	409	0	0
Miscellaneous fruits	284	284	0	0
Root and tuber vegetables	1444	1444	0	0
Bulb vegetables	252	252	0	0
Fruiting vegetables	1451	1451	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	393	393	0	0
Leaf vegetables, herbs and edible flowers	611	611	0	0
Legume vegetables	103	103	0	0
Stem vegetables	164	164	0	0
Fungi, mosses and lichens	148	148	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	168	168	0	0
Oilseeds and oil fruits	99	99	0	0
Cereals	1321	1317	4	0
Teas, coffee, herbal infusions, cocoa and carobs	44	44	0	0
Hops (dried)	4	4	0	0
Spices (dried)	8	8	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	73	73	0	0
Total	8567	8563	4	0
Processed commodities				
Fruits and tree nuts	10	10	0	0
Citrus fruits	24	24	0	0
Tree nuts	14	14	0	0
Pome fruits	101	101	0	0
Stone fruits	5	5	0	0
Berries and small fruits	417	417	0	0
Miscellaneous fruits	17	17	0	0
Root and tuber vegetables	24	24	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	44	44	0	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	4	4	0	0
Leaf vegetables, herbs and edible flowers	14	14	0	0
Legume vegetables	15	15	0	0
Stem vegetables	1	1	0	0
Fungi, mosses and lichens	6	6	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	7	7	0	0
Oilseeds and oil fruits	200	198	2	0
Cereals	775	771	4	0
Teas, coffee, herbal infusions, cocoa and carobs	5	5	0	0
Hops (dried)	0	0	0	0
Spices (dried)	4	4	0	0
Sugar plants	2	2	0	0
Processed apiculture products	12	12	0	0
Total	1701	1695	6	0
Total no. of organic samples	10,268	10,258	10	0

B.9. Azoxystrobin

Table B-9.1 Number of samples analysed for residues of azoxystrobin in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	6799	6733	66	0
Tree nuts	382	379	2	1
Pome fruits	9072	9060	12	0
Stone fruits	8668	8644	24	0
Berries and small fruits	10,062	9374	688	0
Miscellaneous fruits	3388	3246	135	7
Root and tuber vegetables	11,992	11,226	766	0
Bulb vegetables	3035	2952	83	0
Fruiting vegetables	17,939	16,987	952	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	7746	7118	627	1
Leaf vegetables, herbs and edible flowers	9898	9016	882	0
Legume vegetables	1929	1770	159	0
Stem vegetables	3585	3198	387	0
Fungi, mosses and lichens	2172	2168	4	0
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	917	889	27	1
Oilseeds and oil fruits	862	857	5	0
Cereals	6854	6667	187	0
Teas, coffee, herbal infusions, cocoa and carobs	409	398	11	0
Hops (dried)	30	18	12	0
Spices (dried)	109	105	3	1
Sugar plants	44	43	1	0
Honey and other apiculture products	1064	1055	9	0
Total	106,960	101,907	5042	11

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Processed commodities				
Fruits and tree nuts	15	15	0	0
Citrus fruits	330	330	0	0
Tree nuts	104	104	0	0
Pome fruits	135	135	0	0
Stone fruits	36	36	0	0
Berries and small fruits	3100	3042	58	0
Miscellaneous fruits	132	132	0	0
Root and tuber vegetables	62	62	0	0
Bulb vegetables	4	4	0	0
Fruiting vegetables	224	182	41	1
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	6	6	0	0
Leaf vegetables, herbs and edible flowers	241	203	37	1
Legume vegetables	28	28	0	0
Stem vegetables	10	10	0	0
Fungi, mosses and lichens	20	20	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	12	10	2	0
Oilseeds and oil fruits	1999	1984	14	1
Cereals	2824	2808	16	0
Teas, coffee, herbal infusions, cocoa and carobs	18	18	0	0
Hops (dried)	4	1	3	0
Spices (dried)	11	10	0	1
Sugar plants	24	24	0	0
Processed apiculture products	97	95	2	0
Total	9436	9259	173	4
Total no. of conventional samples	116,396	111,166	5215	15

Table B-9.2 Number of samples analysed for residues of azoxystrobin in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	609	609	0	0
Tree nuts	29	29	0	0
Pome fruits	679	679	0	0
Stone fruits	225	225	0	0
Berries and small fruits	389	389	0	0
Miscellaneous fruits	272	272	0	0
Root and tuber vegetables	1422	1420	2	0
Bulb vegetables	238	234	4	0
Fruiting vegetables	1403	1401	2	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	391	385	6	0
Leaf vegetables, herbs and edible flowers	617	615	2	0
Legume vegetables	88	88	0	0
Stem vegetables	164	163	1	0
Fungi, mosses and lichens	147	147	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	167	167	0	0
Oilseeds and oil fruits	99	99	0	0
Cereals	1348	1345	3	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Teas, coffee, herbal infusions, cocoa and carobs	40	40	0	0
Hops (dried)	4	3	1	0
Spices (dried)	9	9	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	64	64	0	0
Total	8408	8387	21	0
Processed commodities				
Fruits and tree nuts	10	10	0	0
Citrus fruits	23	23	0	0
Tree nuts	14	14	0	0
Pome fruits	101	101	0	0
Stone fruits	5	5	0	0
Berries and small fruits	403	403	0	0
Miscellaneous fruits	17	17	0	0
Root and tuber vegetables	24	24	0	0
Bulb vegetables				
Fruiting vegetables	48	48	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	4	4	0	0
Leaf vegetables, herbs and edible flowers	14	14	0	0
Legume vegetables	15	15	0	0
Stem vegetables	1	1	0	0
Fungi, mosses and lichens	6	6	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	7	7	0	0
Oilseeds and oil fruits	207	207	0	0
Cereals	767	767	0	0
Teas, coffee, herbal infusions, cocoa and carobs	5	5	0	0
Hops (dried)	0	0	0	0
Spices (dried)	4	4	0	0
Sugar plants	2	2	0	0
Processed apiculture products	14	13	1	0
Total	1691	1690	1	0
Total no. of organic samples	10,099	10,077	22	0

B.10. Fluopyram

Table B-10.1 Number of samples analysed for residues of fluopyram in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	6078	6077	1	0
Tree nuts	366	358	8	0
Pome fruits	8392	7545	847	0
Stone fruits	8052	6042	2010	0
Berries and small fruits	9787	7750	2037	0
Miscellaneous fruits	3175	3167	5	3
Root and tuber vegetables	11,440	11,148	292	0
Bulb vegetables	2904	2807	97	0
Fruiting vegetables	16,979	14,982	1996	1

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	7548	7352	194	2
Leaf vegetables, herbs and edible flowers	9647	9020	624	3
Legume vegetables	1849	1726	122	1
Stem vegetables	3483	3369	111	3
Fungi, mosses and lichens	2117	2115	1	1
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	884	879	5	0
Oilseeds and oil fruits	858	827	31	0
Cereals	6026	5988	35	3
Teas, coffee, herbal infusions, cocoa and carobs	399	398	1	0
Hops (dried)	28	28	0	0
Spices (dried)	96	96	0	0
Sugar plants	41	41	0	0
Honey and other apiculture products	706	703	3	0
Total	100,859	92,422	8420	17
Processed commodities				
Fruits and tree nuts	15	15	0	0
Citrus fruits	269	269	0	0
Tree nuts	104	103	1	0
Pome fruits	113	112	1	0
Stone fruits	35	30	5	0
Berries and small fruits	2510	2417	93	0
Miscellaneous fruits	128	128	0	0
Root and tuber vegetables	62	62	0	0
Bulb vegetables	4	4	0	0
Fruiting vegetables	140	124	16	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	6	6	0	0
Leaf vegetables, herbs and edible flowers	230	226	4	0
Legume vegetables	25	25	0	0
Stem vegetables	10	10	0	0
Fungi, mosses and lichens	19	19	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	12	12	0	0
Oilseeds and oil fruits	1422	1395	20	7
Cereals	2332	2330	2	0
Teas, coffee, herbal infusions, cocoa and carobs	14	14	0	0
Hops (dried)	3	0	3	0
Spices (dried)	11	11	0	0
Sugar plants	24	24	0	0
Processed apiculture products	95	92	3	0
Total	7583	7428	148	7
Total no. of conventional samples	108,442	99,850	8568	24

Table B-10.2 Number of samples analysed for residues of fluopyram in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	622	622	0	0
Tree nuts	28	28	0	0
Pome fruits	641	639	2	0
Stone fruits	217	216	1	0
Berries and small fruits	364	360	4	0
Miscellaneous fruits	251	251	0	0
Root and tuber vegetables	1423	1420	3	0
Bulb vegetables	255	255	0	0
Fruiting vegetables	1412	1405	7	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	380	380	0	0
Leaf vegetables, herbs and edible flowers	597	595	2	0
Legume vegetables	95	95	0	0
Stem vegetables	163	163	0	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Fungi, mosses and lichens	145	145	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	166	166	0	0
Oilseeds and oil fruits	95	94	1	0
Cereals	1246	1246	0	0
Teas, coffee, herbal infusions, cocoa and carobs	41	41	0	0
Hops (dried)	4	4	0	0
Spices (dried)	9	9	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	60	60	0	0
Total	8218	8198	20	0
Processed commodities				
Fruits and tree nuts	10	10	0	0
Citrus fruits	23	23	0	0
Tree nuts	14	14	0	0
Pome fruits	99	99	0	0
Stone fruits	5	5	0	0
Berries and small fruits	387	386	1	0
Miscellaneous fruits	17	17	0	0
Root and tuber vegetables	23	23	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	35	35	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	4	4	0	0
Leaf vegetables, herbs and edible flowers	14	14	0	0
Legume vegetables	15	15	0	0
Stem vegetables	1	1	0	0
Fungi, mosses and lichens	6	6	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	7	7	0	0
Oilseeds and oil fruits	180	180	0	0
Cereals	753	753	0	0
Teas, coffee, herbal infusions, cocoa and carobs	5	5	0	0
Hops (dried)	0	0	0	0
Spices (dried)	4	4	0	0
Sugar plants	2	2	0	0
Processed apiculture products	14	14	0	0
Total	1618	1617	1	0
Total no. of organic samples	9836	9815	21	0

B.11. Lambda-cyhalothrin

Table B-11.1 Number of samples analysed for residues of lambda-cyhalothrin in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	5632	5406	224	2
Tree nuts	278	278	0	0
Pome fruits	7715	7604	109	2
Stone fruits	7373	6778	594	1
Berries and small fruits	8756	8564	191	1
Miscellaneous fruits	3019	2872	137	10
Root and tuber vegetables	10,628	10,547	78	3
Bulb vegetables	2677	2667	10	0
Fruiting vegetables	15,323	15,240	83	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	7043	6878	126	39
Leaf vegetables, herbs and edible flowers	8884	8363	506	15
Legume vegetables	1742	1728	14	0
Stem vegetables	3423	3336	85	2

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Fungi, mosses and lichens	1962	1962	0	0
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	743	743	0	0
Oilseeds and oil fruits	503	503	0	0
Cereals	5500	5498	2	0
Teas, coffee, herbal infusions, cocoa and carobs	223	223	0	0
Hops (dried)	26	24	2	0
Spices (dried)	43	42	0	1
Sugar plants	32	32	0	0
Honey and other apiculture products	1172	1172	0	0
Total	92,701	90,464	2161	76
Processed commodities				
Fruits and tree nuts	9	8	1	0
Citrus fruits	305	304	1	0
Tree nuts	53	53	0	0
Pome fruits	84	84	0	0
Stone fruits	23	22	1	0
Berries and small fruits	2248	2224	24	0
Miscellaneous fruits	112	109	3	0
Root and tuber vegetables	58	58	0	0
Bulb vegetables	4	4	0	0
Fruiting vegetables	139	125	14	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	5	5	0	0
Leaf vegetables, herbs and edible flowers	186	174	12	0
Legume vegetables	14	14	0	0
Stem vegetables	9	9	0	0
Fungi, mosses and lichens	20	20	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	10	10	0	0
Oilseeds and oil fruits	1713	1669	43	1
Cereals	2143	2143	0	0
Teas, coffee, herbal infusions, cocoa and carobs	8	8	0	0
Hops (dried)	1	1	0	0
Spices (dried)	8	8	0	0
Sugar plants	2	2	0	0
Processed apiculture products	164	164	0	0
Total	7318	7218	99	1
Total no. of conventional samples	100,019	97,682	2260	77

Table B-11.2 Number of samples analysed for residues of lambda-cyhalothrin in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	546	546	0	0
Tree nuts	28	28	0	0
Pome fruits	623	623	0	0
Stone fruits	211	210	1	0
Berries and small fruits	337	337	0	0
Miscellaneous fruits	240	240	0	0
Root and tuber vegetables	1365	1365	0	0
Bulb vegetables	219	219	0	0
Fruiting vegetables	1332	1332	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	366	366	0	0
Leaf vegetables, herbs and edible flowers	580	580	0	0
Legume vegetables	83	83	0	0
Stem vegetables	165	165	0	0
Fungi, mosses and lichens	137	137	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	160	160	0	0
Oilseeds and oil fruits	94	94	0	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Cereals	1198	1198	0	0
Teas, coffee, herbal infusions, cocoa and carobs	37	37	0	0
Hops (dried)	4	4	0	0
Spices (dried)	7	7	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	102	102	0	0
Total	7838	7837	1	0
Processed commodities				
Fruits and tree nuts	6	6	0	0
Citrus fruits	23	23	0	0
Tree nuts	14	14	0	0
Pome fruits	93	93	0	0
Stone fruits	5	5	0	0
Berries and small fruits	376	376	0	0
Miscellaneous fruits	17	16	1	0
Root and tuber vegetables	17	17	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	39	39	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	2	2	0	0
Leaf vegetables, herbs and edible flowers	12	12	0	0
Legume vegetables	14	14	0	0
Stem vegetables	1	1	0	0
Fungi, mosses and lichens	6	5	1	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	5	5	0	0
Oilseeds and oil fruits	187	186	1	0
Cereals	686	686	0	0
Teas, coffee, herbal infusions, cocoa and carobs	4	4	0	0
Hops (dried)	0	0	0	0
Spices (dried)	4	4	0	0
Sugar plants	1	1	0	0
Processed apiculture products	26	26	0	0
Total	1538	1535	3	0
Total no. of organic samples	9376	9372	4	0

B.12. Acetamiprid

Table B-12.1 Number of samples analysed for residues of acetamiprid in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	6529	5871	658	0
Tree nuts	375	374	1	0
Pome fruits	8763	6711	2052	0
Stone fruits	8265	6451	1807	7
Berries and small fruits	9939	8998	934	7
Miscellaneous fruits	3267	3200	34	33
Root and tuber vegetables	11705	11699	6	0
Bulb vegetables	2974	2974	0	0
Fruiting vegetables	17494	16377	1101	16
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	7551	7424	106	21
Leaf vegetables, herbs and edible flowers	9741	9028	693	20
Legume vegetables	1851	1824	27	0
Stem vegetables	3472	3448	18	6
Fungi, mosses and lichens	2118	2116	1	1
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	849	849	0	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Oilseeds and oil fruits	854	854	0	0
Cereals	6402	6396	0	6
Teas, coffee, herbal infusions, cocoa and carobs	404	389	11	4
Hops (dried)	7	7	0	0
Spices (dried)	109	105	3	1
Sugar plants	43	43	0	0
Honey and other apiculture products	1318	1219	84	15
Total	104,034	96,361	7536	137
Processed commodities				
Fruits and tree nuts	15	14	1	0
Citrus fruits	313	295	18	0
Tree nuts	104	104	0	0
Pome fruits	133	120	13	0
Stone fruits	36	30	6	0
Berries and small fruits	3074	3038	36	0
Miscellaneous fruits	132	132	0	0
Root and tuber vegetables	62	62	0	0
Bulb vegetables	4	4	0	0
Fruiting vegetables	218	193	25	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	6	6	0	0
Leaf vegetables, herbs and edible flowers	237	211	26	0
Legume vegetables	27	27	0	0
Stem vegetables	10	10	0	0
Fungi, mosses and lichens	20	20	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	12	12	0	0
Oilseeds and oil fruits	1779	1773	5	1
Cereals	2565	2564	1	0
Teas, coffee, herbal infusions, cocoa and carobs	14	14	0	0
Hops (dried)	6	6	0	0
Spices (dried)	11	10	0	1
Sugar plants	24	24	0	0
Processed apiculture products	223	208	13	2
Total	9025	8877	144	4
Total no. of conventional samples	113,059	105,238	7680	141

Table B-12.2 Number of samples analysed for residues of acetamiprid in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	607	604	3	0
Tree nuts	28	28	0	0
Pome fruits	674	667	7	0
Stone fruits	225	224	1	0
Berries and small fruits	387	379	7	1
Miscellaneous fruits	269	268	1	0
Root and tuber vegetables	1419	1419	0	0
Bulb vegetables	237	237	0	0
Fruiting vegetables	1387	1386	1	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	389	389	0	0
Leaf vegetables, herbs and edible flowers	613	613	0	0
Legume vegetables	86	86	0	0
Stem vegetables	163	163	0	0
Fungi, mosses and lichens	145	145	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	166	165	1	0
Oilseeds and oil fruits	99	99	0	0
Cereals	1276	1275	0	1

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Teas, coffee, herbal infusions, cocoa and carobs	41	40	1	0
Hops (dried)	4	4	0	0
Spices (dried)	9	9	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	90	86	4	0
Total	8318	8290	26	2
Processed commodities				
Fruits and tree nuts	10	10	0	0
Citrus fruits	23	23	0	0
Tree nuts	14	14	0	0
Pome fruits	101	101	0	0
Stone fruits	5	5	0	0
Berries and small fruits	401	401	0	0
Miscellaneous fruits	17	17	0	0
Root and tuber vegetables	24	24	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	45	45	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	4	4	0	0
Leaf vegetables, herbs and edible flowers	14	14	0	0
Legume vegetables	15	15	0	0
Stem vegetables	1	1	0	0
Fungi, mosses and lichens	6	6	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	7	7	0	0
Oilseeds and oil fruits	216	216	0	0
Cereals	752	752	0	0
Teas, coffee, herbal infusions, cocoa and carobs	5	5	0	0
Hops (dried)	0	0	0	0
Spices (dried)	4	4	0	0
Sugar plants	2	2	0	0
Processed apiculture products	30	30	0	0
Total	1696	1696	0	0
Total no. of organic samples	10,014	9986	26	2

B.13. Chlormequat

Table B-13.1 Number of samples analysed for residues of chlormequat in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	978	978	0	0
Tree nuts	17	17	0	0
Pome fruits	1787	1719	61	7
Stone fruits	1391	1390	1	0
Berries and small fruits	2239	2238	0	1
Miscellaneous fruits	636	636	0	0
Root and tuber vegetables	2302	2300	0	2
Bulb vegetables	697	697	0	0
Fruiting vegetables	4240	4236	0	4
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	1724	1723	0	1
Leaf vegetables, herbs and edible flowers	2167	2167	0	0
Legume vegetables	162	162	0	0
Stem vegetables	605	605	0	0
Fungi, mosses and lichens	1106	951	154	1
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	91	90	0	1
Oilseeds and oil fruits	63	57	4	2
Cereals	2853	2195	656	2

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Teas, coffee, herbal infusions, cocoa and carobs	14	14	0	0
Hops (dried)	3	3	0	0
Spices (dried)	0	0	0	0
Sugar plants	5	5	0	0
Honey and other apiculture products	55	55	0	0
Total	23,135	22,238	876	21
Processed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	16	16	0	0
Tree nuts	8	8	0	0
Pome fruits	16	16	0	0
Stone fruits	0	0	0	0
Berries and small fruits	400	398	2	0
Miscellaneous fruits	1	1	0	0
Root and tuber vegetables	4	4	0	0
Bulb vegetables	1	1	0	0
Fruiting vegetables	45	34	4	7
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0	0	0	0
Leaf vegetables, herbs and edible flowers	18	18	0	0
Legume vegetables	3	3	0	0
Stem vegetables	1	1	0	0
Fungi, mosses and lichens	4	3	1	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	3	3	0	0
Oilseeds and oil fruits	244	244	0	0
Cereals	743	580	163	0
Teas, coffee, herbal infusions, cocoa and carobs	0	0	0	0
Hops (dried)	5	5	0	0
Spices (dried)	0	0	0	0
Sugar plants	0	0	0	0
Processed apiculture products	0	0	0	0
Total	1512	1335	170	7
Total no. of conventional samples	24,647	23,573	1046	28

Table B-13.2 Number of samples analysed for residues of chlormequat in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	114	114	0	0
Tree nuts	0	0	0	0
Pome fruits	149	149	0	0
Stone fruits	43	43	0	0
Berries and small fruits	92	92	0	0
Miscellaneous fruits	51	51	0	0
Root and tuber vegetables	356	356	0	0
Bulb vegetables	60	60	0	0
Fruiting vegetables	379	379	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	91	91	0	0
Leaf vegetables, herbs and edible flowers	162	162	0	0
Legume vegetables	14	14	0	0
Stem vegetables	41	41	0	0
Fungi, mosses and lichens	65	63	2	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	38	38	0	0
Oilseeds and oil fruits	30	30	0	0
Cereals	734	723	11	0
Teas, coffee, herbal infusions, cocoa and carobs	1	1	0	0
Hops (dried)	0	0	0	0
Spices (dried)	3	3	0	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Sugar plants	0	0	0	0
Honey and other apiculture products	1	1	0	0
Total	2424	2411	13	0
Processed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	4	4	0	0
Tree nuts	2	2	0	0
Pome fruits	8	8	0	0
Stone fruits	0	0	0	0
Berries and small fruits	61	60	0	1
Miscellaneous fruits	1	1	0	0
Root and tuber vegetables	2	2	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	8	8	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	1	1	0	0
Leaf vegetables, herbs and edible flowers	2	2	0	0
Legume vegetables	0	0	0	0
Stem vegetables	0	0	0	0
Fungi, mosses and lichens	4	4	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	4	4	0	0
Oilseeds and oil fruits	25	25	0	0
Cereals	305	301	3	1
Teas, coffee, herbal infusions, cocoa and carobs	0	0	0	0
Hops (dried)	0	0	0	0
Spices (dried)	1	1	0	0
Sugar plants	0	0	0	0
Processed apiculture products	0	0	0	0
Total	428	423	3	2
Total no. of organic samples	2852	2834	16	2

B.14. Pendimethalin

Table B-14.1 Number of samples analysed for residues of pendimethalin in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	6432	6423	9	0
Tree nuts	373	373	0	0
Pome fruits	8955	8899	56	0
Stone fruits	8388	8363	25	0
Berries and small fruits	9860	9812	47	1
Miscellaneous fruits	3296	3294	2	0
Root and tuber vegetables	11,685	11,385	300	0
Bulb vegetables	3021	3011	10	0
Fruiting vegetables	17,508	17,479	29	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	7671	7568	102	1
Leaf vegetables, herbs and edible flowers	9762	9279	482	1
Legume vegetables	1886	1884	2	0
Stem vegetables	3544	3446	97	1
Fungi, mosses and lichens	2131	2130	1	0
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	896	893	3	0
Oilseeds and oil fruits	858	858	0	0
Cereals	6932	6932	0	0
Teas, coffee, herbal infusions, cocoa and carobs	410	406	4	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Hops (dried)	4	4	0	0
Spices (dried)	107	107	0	0
Sugar plants	42	42	0	0
Honey and other apiculture products	576	576	0	0
Total	104,341	103,168	1169	4
Processed commodities				
Fruits and tree nuts	15	15	0	0
Citrus fruits	333	333	0	0
Tree nuts	105	105	0	0
Pome fruits	135	135	0	0
Stone fruits	36	36	0	0
Berries and small fruits	3068	3068	0	0
Miscellaneous fruits	130	130	0	0
Root and tuber vegetables	62	62	0	0
Bulb vegetables	3	3	0	0
Fruiting vegetables	220	212	8	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	5	4	1	0
Leaf vegetables, herbs and edible flowers	238	207	29	2
Legume vegetables	26	26	0	0
Stem vegetables	9	9	0	0
Fungi, mosses and lichens	20	20	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	12	12	0	0
Oilseeds and oil fruits	1698	1697	1	0
Cereals	2733	2733	0	0
Teas, coffee, herbal infusions, cocoa and carobs	17	16	1	0
Hops (dried)	1	1	0	0
Spices (dried)	12	12	0	0
Sugar plants	24	24	0	0
Processed apiculture products	95	95	95	95
Total	8997	8955	40	2
Total no. of conventional samples	113,338	112,123	1209	6

Table B-14.2 Number of samples analysed for residues of pendimethalin in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	638	638	0	0
Tree nuts	27	27	0	0
Pome fruits	675	675	0	0
Stone fruits	228	226	2	0
Berries and small fruits	401	399	2	0
Miscellaneous fruits	277	277	0	0
Root and tuber vegetables	1422	1420	2	0
Bulb vegetables	259	258	1	0
Fruiting vegetables	1439	1437	2	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	397	389	8	0
Leaf vegetables, herbs and edible flowers	617	610	7	0
Legume vegetables	101	101	0	0
Stem vegetables	161	161	0	0
Fungi, mosses and lichens	148	148	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	165	165	0	0
Oilseeds and oil fruits	96	96	0	0
Cereals	1344	1344	0	0
Teas, coffee, herbal infusions, cocoa and carobs	41	41	0	0
Hops (dried)	4	4	0	0
Spices (dried)	9	9	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	51	51	0	0
Total	8504	8480	24	0

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Processed commodities				
Fruits and tree nuts	10	10	0	0
Citrus fruits	23	23	0	0
Tree nuts	14	14	0	0
Pome fruits	101	101	0	0
Stone fruits	5	5	0	0
Berries and small fruits	422	422	0	0
Miscellaneous fruits	17	17	0	0
Root and tuber vegetables	24	24	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	46	45	1	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	4	4	0	0
Leaf vegetables, herbs and edible flowers	14	13	1	0
Legume vegetables	15	15	0	0
Stem vegetables	1	1	0	0
Fungi, mosses and lichens	6	6	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	7	7	0	0
Oilseeds and oil fruits	194	194	0	0
Cereals	785	785	0	0
Teas, coffee, herbal infusions, cocoa and carobs	5	5	0	0
Hops (dried)	0	0	0	0
Spices (dried)	4	4	0	0
Sugar plants	2	2	0	0
Processed apiculture products	14	14	0	0
Total	1713	1711	2	0
Total no. of organic samples	10,217	10,191	26	0

B.15. Spirotetramat

Table B-15.1 Number of samples analysed for residues of spirotetramat (spirotetramat and its 4 metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-monohydroxy, and BYI08330 enol-glucoside, expressed as spirotetramat and spirotetramat and its metabolite BYI08330-enol expressed as spirotetramat) in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	3556	3122	434	0
Tree nuts	231	225	6	0
Pome fruits	4952	4857	95	0
Stone fruits	4710	4516	194	0
Berries and small fruits	6152	5641	507	4
Miscellaneous fruits	1792	1746	46	0
Root and tuber vegetables	7866	7846	20	0
Bulb vegetables	1695	1559	136	0
Fruiting vegetables	9944	9662	282	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	5077	3913	1159	5
Leaf vegetables, herbs and edible flowers	5999	5427	572	0
Legume vegetables	1132	1128	4	0
Stem vegetables	2428	2357	71	0
Fungi, mosses and lichens	1408	1408	0	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	554	553	1	0
Oilseeds and oil fruits	444	444	0	0
Cereals	2916	2915	1	0
Teas, coffee, herbal infusions, cocoa and carobs	149	148	1	0
Hops (dried)	29	18	11	0
Spices (dried)	28	28	0	0
Sugar plants	28	28	0	0
Honey and other apiculture products	422	419	3	0
Total	61,516	57,964	3543	9
Processed commodities				
Fruits and tree nuts	9	9	0	0
Citrus fruits	185	157	28	0
Tree nuts	37	37	0	0
Pome fruits	57	57	0	0
Stone fruits	20	20	0	0
Berries and small fruits	1126	1119	7	0
Miscellaneous fruits	101	101	0	0
Root and tuber vegetables	22	22	0	0
Bulb vegetables	3	3	0	0
Fruiting vegetables	97	94	3	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	4	3	1	0
Leaf vegetables, herbs and edible flowers	105	104	1	0
Legume vegetables	11	11	0	0
Stem vegetables	9	9	0	0
Fungi, mosses and lichens	6	6	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	7	7	0	0
Oilseeds and oil fruits	725	725	0	0
Cereals	1063	1063	0	0
Teas, coffee, herbal infusions, cocoa and carobs	8	8	0	0
Hops (dried)	3	3	0	0
Spices (dried)	6	6	0	0
Sugar plants	6	6	0	0
Processed apiculture products	12	12	0	0
Total	3622	3582	40	0
Total no. of conventional samples	65,138	61,546	3583	9

Table B-15.2 Number of samples analysed for residues of spirotetramat (spirotetramat and its 4 metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-monohydroxy, and BYI08330 enol-glucoside, expressed as spirotetramat and spirotetramat and its metabolite BYI08330-enol expressed as spirotetramat) in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Citrus fruits	403	402	1	0
Tree nuts	25	25	0	0
Pome fruits	460	459	1	0
Stone fruits	123	123	0	0
Berries and small fruits	248	247	1	0
Miscellaneous fruits	154	154	0	0
Root and tuber vegetables	1046	1046	0	0
Bulb vegetables	171	171	0	0
Fruiting vegetables	972	972	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	268	265	3	0
Leaf vegetables, herbs and edible flowers	467	467	0	0
Legume vegetables	62	62	0	0
Stem vegetables	124	124	0	0
Fungi, mosses and lichens	101	101	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	143	143	0	0
Oilseeds and oil fruits	75	75	0	0
Cereals	762	762	0	0
Teas, coffee, herbal infusions, cocoa and carobs	32	32	0	0
Hops (dried)	4	4	0	0
Spices (dried)	7	7	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	43	43	0	0
Total	5694	5688	6	0
Processed commodities				
Fruits and tree nuts	5	5	0	0
Citrus fruits	12	12	0	0
Tree nuts	9	9	0	0
Pome fruits	79	79	0	0
Stone fruits	5	5	0	0
Berries and small fruits	298	298	0	0
Miscellaneous fruits	16	16	0	0
Root and tuber vegetables	14	14	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	20	20	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	3	3	0	0
Leaf vegetables, herbs and edible flowers	5	5	0	0
Legume vegetables	9	9	0	0
Stem vegetables	1	1	0	0
Fungi, mosses and lichens	6	6	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	2	2	0	0
Oilseeds and oil fruits	123	123	0	0
Cereals	527	527	0	0
Teas, coffee, herbal infusions, cocoa and carobs	3	3	0	0
Hops (dried)	0	0	0	0
Spices (dried)	3	3	0	0
Sugar plants	2	2	0	0
Processed apiculture products	2	2	0	0
Total	1144	1144	0	0
Total no. of organic samples	6838	6832	6	0

B.16. Cyprodinil

Table B-16.1 Number of samples analysed for residues of cyprodinil in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	6805	6804	1	0
Tree nuts	310	310	0	0
Pome fruits	8919	8079	840	0
Stone fruits	8922	8191	731	0
Berries and small fruits	10,318	7336	2980	2
Miscellaneous fruits	3384	3376	8	0
Root and tuber vegetables	11,339	11,185	152	2
Bulb vegetables	2638	2594	42	2
Fruiting vegetables	19,024	18,089	934	1
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	7751	7743	5	3
Leaf vegetables, herbs and edible flowers	10,344	9726	611	7
Legume vegetables	1833	1663	170	0
Stem vegetables	3730	3547	183	0
Fungi, mosses and lichens	2865	2865	0	0
Algae and prokaryotes organisms	2	2	0	0
Pulses (dried)	695	693	2	0
Oilseeds and oil fruits	879	879	0	0
Cereals	7372	7365	7	0
Teas, coffee, herbal infusions, cocoa and carobs	445	445	0	0
Hops (dried)	3	3	0	0
Spices (dried)	119	119	0	0
Sugar plants	28	28	0	0
Honey and other apiculture products	884	884	0	0
Total	108,609	101,926	6666	17
Processed commodities				
Fruits and tree nuts	22	22	0	0
Citrus fruits	365	365	0	0
Tree nuts	87	87	0	0
Pome fruits	128	125	3	0
Stone fruits	21	21	0	0
Berries and small fruits	3073	2969	104	0
Miscellaneous fruits	164	164	0	0
Root and tuber vegetables	95	95	0	0
Bulb vegetables	4	4	0	0
Fruiting vegetables	253	248	5	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	6	6	0	0
Leaf vegetables, herbs and edible flowers	325	321	4	0
Legume vegetables	18	18	0	0
Stem vegetables	8	8	0	0
Fungi, mosses and lichens	27	27	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	15	15	0	0
Oilseeds and oil fruits	2049	2049	0	0
Cereals	2998	2998	0	0
Teas, coffee, herbal infusions, cocoa and carobs	17	17	0	0
Hops (dried)	2	2	0	0
Spices (dried)	13	13	0	0
Sugar plants	32	32	0	0
Processed apiculture products	82	82	0	0
Total	9804	9688	116	0
Total no. of conventional samples	118,413	111,614	6782	17

Findings of not authorised substances in organic products

Table B-16.2 Number of samples analysed for residues of cyprodinil in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	603	603	0	0
Tree nuts	36	36	0	0
Pome fruits	675	673	2	0
Stone fruits	237	231	6	0
Berries and small fruits	400	394	6	0
Miscellaneous fruits	260	260	0	0
Root and tuber vegetables	1442	1442	0	0
Bulb vegetables	169	169	0	0
Fruiting vegetables	1459	1459	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	379	379	0	0
Leaf vegetables, herbs and edible flowers	619	617	2	0
Legume vegetables	100	100	0	0
Stem vegetables	180	180	0	0
Fungi, mosses and lichens	182	182	0	0
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	161	161	0	0
Oilseeds and oil fruits	99	99	0	0
Cereals	1343	1343	0	0
Teas, coffee, herbal infusions, cocoa and carobs	49	49	0	0
Hops (dried)	7	7	0	0
Spices (dried)	7	7	0	0
Sugar plants	0	0	0	0
Honey and other apiculture products	49	49	0	0
Total	8460	8444	16	0
Processed commodities				
Fruits and tree nuts	10	10	0	0
Citrus fruits	32	32	0	0
Tree nuts	11	11	0	0
Pome fruits	88	88	0	0
Stone fruits	4	4	0	0
Berries and small fruits	413	411	2	0
Miscellaneous fruits	20	20	0	0
Root and tuber vegetables	28	28	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	43	43	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	4	4	0	0
Leaf vegetables, herbs and edible flowers	17	17	0	0
Legume vegetables	14	14	0	0
Stem vegetables	0	0	0	0
Fungi, mosses and lichens	6	6	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	7	7	0	0
Oilseeds and oil fruits	240	240	0	0
Cereals	852	852	0	0
Teas, coffee, herbal infusions, cocoa and carobs	5	5	0	0
Hops (dried)	0	0	0	0
Spices (dried)	6	6	0	0
Sugar plants	2	2	0	0
Processed apiculture products	18	18	0	0
Total	1820	1818	2	0
Total no. of organic samples	10,280	10,262	18	0

B.17. Chloridazon

Table B-17.1 Number of samples analysed for residues of chloridazon in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	2312	2312	0	0
Tree nuts	203	203	0	0
Pome fruits	2802	2801	1	0
Stone fruits	2877	2876	1	0
Berries and small fruits	3400	3398	2	0
Miscellaneous fruits	1267	1267	0	0
Root and tuber vegetables	4602	4596	6	0
Bulb vegetables	921	921	0	0
Fruiting vegetables	6061	6061	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	2716	2701	13	2
Leaf vegetables, herbs and edible flowers	4138	4099	39	0
Legume vegetables	753	749	4	0
Stem vegetables	1511	1509	2	0
Fungi, mosses and lichens	780	780	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	387	387	0	0
Oilseeds and oil fruits	365	365	0	0
Cereals	1347	1346	1	0
Teas, coffee, herbal infusions, cocoa and carobs	78	78	0	0
Hops (dried)	4	4	0	0
Spices (dried)	24	24	0	0
Sugar plants	19	19	0	0
Honey and other apiculture products	51	51	0	0
Total	36,621	36,550	69	2
Processed commodities				
Fruits and tree nuts	1	1	0	0
Citrus fruits	23	23	0	0
Tree nuts	35	35	0	0
Pome fruits	23	23	0	0
Stone fruits	6	6	0	0
Berries and small fruits	410	410	0	0
Miscellaneous fruits	90	90	0	0
Root and tuber vegetables	20	20	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	40	40	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	1	1	0	0
Leaf vegetables, herbs and edible flowers	65	65	0	0
Legume vegetables	7	7	0	0
Stem vegetables	6	6	0	0
Fungi, mosses and lichens	7	7	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	3	3	0	0
Oilseeds and oil fruits	698	698	0	0
Cereals	533	533	0	0
Teas, coffee, herbal infusions, cocoa and carobs	4	4	0	0
Hops (dried)	5	5	0	0
Spices (dried)	3	3	0	0
Sugar plants	5	5	0	0
Processed apiculture products	5	5	0	0
Total	1990	1990	0	0
Total no. of conventional samples	38,611	38,540	69	2

Findings of not authorised substances in organic products

Table B-17.2 Number of samples analysed for residues of chloridazon in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	250	250	0	0
Tree nuts	18	18	0	0
Pome fruits	353	353	0	0
Stone fruits	100	100	0	0
Berries and small fruits	158	158	0	0
Miscellaneous fruits	109	109	0	0
Root and tuber vegetables	663	663	0	0
Bulb vegetables	90	90	0	0
Fruiting vegetables	727	727	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	145	145	0	0
Leaf vegetables, herbs and edible flowers	301	299	2	0
Legume vegetables	41	40	1	0
Stem vegetables	72	72	0	0
Fungi, mosses and lichens	54	54	0	0
Algae and prokaryotes organisms	1	1	0	0
Pulses (dried)	141	141	0	0
Oilseeds and oil fruits	57	57	0	0
Cereals	508	508	0	0
Teas, coffee, herbal infusions, cocoa and carobs	16	16	0	0
Hops (dried)	3	3	0	0
Spices (dried)	4	4	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	30	30	0	0
Total	3842	3839	3	0
Processed commodities				
Fruits and tree nuts	2	2	0	0
Citrus fruits	8	8	0	0
Tree nuts	8	8	0	0
Pome fruits	58	58	0	0
Stone fruits	3	3	0	0
Berries and small fruits	216	216	0	0
Miscellaneous fruits	15	15	0	0
Root and tuber vegetables	10	10	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	13	13	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	2	2	0	0
Leaf vegetables, herbs and edible flowers	6	6	0	0
Legume vegetables	2	2	0	0
Stem vegetables	0	0	0	0
Fungi, mosses and lichens	3	3	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	3	3	0	0
Oilseeds and oil fruits	111	111	0	0
Cereals	309	309	0	0
Teas, coffee, herbal infusions, cocoa and carobs	2	2	0	0
Hops (dried)	0	0	0	0
Spices (dried)	1	1	0	0
Sugar plants	2	2	0	0
Processed apiculture products	0	0	0	0
Total	774	774	0	0
Total no. of organic samples	4616	4613	3	0

B.18. Pyriproxyfen

Table B-18.1 Number of samples analysed for residues of pyriproxyfen in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	6752	5353	1398	1
Tree nuts	372	372	0	0
Pome fruits	8980	8948	31	1
Stone fruits	8579	8548	31	0
Berries and small fruits	10,041	10,034	7	0
Miscellaneous fruits	3389	3360	29	0
Root and tuber vegetables	11832	11831	0	1
Bulb vegetables	3014	3014	0	0
Fruiting vegetables	17,745	17,486	259	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	7716	7716	0	0
Leaf vegetables, herbs and edible flowers	9777	9769	7	1
Legume vegetables	1891	1890	1	0
Stem vegetables	3568	3568	0	0
Fungi, mosses and lichens	2166	2166	0	0
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	913	913	0	0
Oilseeds and oil fruits	874	873	0	1
Cereals	6698	6698	0	0
Teas, coffee, herbal infusions, cocoa and carobs	412	408	4	0
Hops (dried)	4	4	0	0
Spices (dried)	101	101	0	0
Sugar plants	43	43	0	0
Honey and other apiculture products	692	692	0	0
Total	105,563	103,791	1767	5
Processed commodities				
Fruits and tree nuts	15	15	0	0
Citrus fruits	329	298	31	0
Tree nuts	103	103	0	0
Pome fruits	135	135	0	0
Stone fruits	36	36	0	0
Berries and small fruits	3179	3179	0	0
Miscellaneous fruits	134	134	0	0
Root and tuber vegetables	62	62	0	0
Bulb vegetables	4	4	0	0
Fruiting vegetables	221	219	2	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	6	6	0	0
Leaf vegetables, herbs and edible flowers	241	241	0	0
Legume vegetables	28	28	0	0
Stem vegetables	10	10	0	0
Fungi, mosses and lichens	20	20	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	12	12	0	0
Oilseeds and oil fruits	1650	1647	2	1
Cereals	2796	2796	0	0
Teas, coffee, herbal infusions, cocoa and carobs	18	18	0	0
Hops (dried)	1	1	0	0
Spices (dried)	12	12	0	0
Sugar plants	24	24	0	0
Processed apiculture products	95	95	0	0
Total	9131	9095	35	1
Total no. of conventional samples	114,694	112,886	1802	6

Table B-18.2 Number of samples analysed for residues of pyriproxyfen in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Findings of not authorised substances in organic products

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	600	594	6	0
Tree nuts	29	29	0	0
Pome fruits	663	663	0	0
Stone fruits	214	214	0	0
Berries and small fruits	360	360	0	0
Miscellaneous fruits	253	253	0	0
Root and tuber vegetables	1416	1416	0	0
Bulb vegetables	233	233	0	0
Fruiting vegetables	1369	1368	1	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	372	372	0	0
Leaf vegetables, herbs and edible flowers	598	598	0	0
Legume vegetables	84	84	0	0
Stem vegetables	164	164	0	0
Fungi, mosses and lichens	141	141	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	168	168	0	0
Oilseeds and oil fruits	101	101	0	0
Cereals	1319	1319	0	0
Teas, coffee, herbal infusions, cocoa and carobs	41	41	0	0
Hops (dried)	4	4	0	0
Spices (dried)	9	9	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	51	51	0	0
Total	8193	8186	7	0
Processed commodities				
Fruits and tree nuts	10	10	0	0
Citrus fruits	23	23	0	0
Tree nuts	14	14	0	0
Pome fruits	101	101	0	0
Stone fruits	5	5	0	0
Berries and small fruits	409	409	0	0
Miscellaneous fruits	17	17	0	0
Root and tuber vegetables	24	24	0	0
Bulb vegetables				
Fruiting vegetables	48	48	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	4	4	0	0
Leaf vegetables, herbs and edible flowers	14	14	0	0
Legume vegetables	15	15	0	0
Stem vegetables	1	1	0	0
Fungi, mosses and lichens	6	6	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	7	7	0	0
Oilseeds and oil fruits	198	198	0	0
Cereals	760	760	0	0
Teas, coffee, herbal infusions, cocoa and carobs	5	5	0	0
Hops (dried)	0	0	0	0
Spices (dried)	4	4	0	0
Sugar plants	2	2	0	0
Processed apiculture products	14	14	0	0
Total	1681	1681	0	0
Total no. of organic samples	9874	9867	7	0

B.19. Fludioxonil

Table B-19.1 Number of samples analysed for residues of fludioxonil in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	6111	5702	409	0
Tree nuts	355	355	0	0
Pome fruits	8384	5905	2478	1
Stone fruits	7968	6422	1543	3
Berries and small fruits	9626	6671	2954	1
Miscellaneous fruits	3123	2782	339	2
Root and tuber vegetables	11257	10959	298	0
Bulb vegetables	2906	2892	14	0
Fruiting vegetables	16,748	15,937	808	3
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	7339	7320	12	7
Leaf vegetables, herbs and edible flowers	9220	8543	676	1
Legume vegetables	1756	1674	81	1
Stem vegetables	3550	3484	66	0
Fungi, mosses and lichens	2098	2097	1	0
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	821	820	1	0
Oilseeds and oil fruits	855	854	1	0
Cereals	6464	6460	1	3
Teas, coffee, herbal infusions, cocoa and carobs	384	380	4	0
Hops (dried)	4	4	0	0
Spices (dried)	100	100	0	0
Sugar plants	43	43	0	0
Honey and other apiculture products	819	819	0	0
Total	99,935	90,227	9686	22
Processed commodities				
Fruits and tree nuts	15	14	1	0
Citrus fruits	330	318	12	0
Tree nuts	80	80	0	0
Pome fruits	135	135	0	0
Stone fruits	34	34	0	0
Berries and small fruits	2920	2838	82	0
Miscellaneous fruits	122	122	0	0
Root and tuber vegetables	0	0	0	0
Bulb vegetables	4	4	0	0
Fruiting vegetables	194	187	7	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	6	6	0	0
Leaf vegetables, herbs and edible flowers	231	228	3	0
Legume vegetables	28	28	0	0
Stem vegetables	10	10	0	0
Fungi, mosses and lichens	19	19	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	12	12	0	0
Oilseeds and oil fruits	1525	1525	0	0
Cereals	2678	2678	0	0
Teas, coffee, herbal infusions, cocoa and carobs	7	7	0	0
Hops (dried)	1	1	0	0
Spices (dried)	11	11	0	0
Sugar plants	24	24	0	0
Processed apiculture products	85	83	1	1
Total	8471	8364	106	1
Total no. of conventional samples	108,406	98,591	9792	23

Findings of not authorised substances in organic products

Table B-19.2 Number of samples analysed for residues of fludioxonil in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	570	570	0	0
Tree nuts	29	29	0	0
Pome fruits	628	625	3	0
Stone fruits	202	201	1	0
Berries and small fruits	346	344	2	0
Miscellaneous fruits	231	227	4	0
Root and tuber vegetables	1389	1386	3	0
Bulb vegetables	230	230	0	0
Fruiting vegetables	1341	1340	1	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	372	372	0	0
Leaf vegetables, herbs and edible flowers	585	581	4	0
Legume vegetables	83	83	0	0
Stem vegetables	165	165	0	0
Fungi, mosses and lichens	142	142	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	159	159	0	0
Oilseeds and oil fruits	98	98	0	0
Cereals	1263	1262	0	1
Teas, coffee, herbal infusions, cocoa and carobs	36	36	0	0
Hops (dried)	4	4	0	0
Spices (dried)	9	9	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	55	55	0	0
Total	7941	7922	18	1
Processed commodities				
Fruits and tree nuts	10	10	0	0
Citrus fruits	23	23	0	0
Tree nuts	14	14	0	0
Pome fruits	101	101	0	0
Stone fruits	2	2	0	0
Berries and small fruits	398	397	1	0
Miscellaneous fruits	17	17	0	0
Root and tuber vegetables	24	24	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	43	43	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	4	4	0	0
Leaf vegetables, herbs and edible flowers	14	14	0	0
Legume vegetables	15	15	0	0
Stem vegetables	1	1	0	0
Fungi, mosses and lichens	6	6	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	7	7	0	0
Oilseeds and oil fruits	180	180	0	0
Cereals	732	732	0	0
Teas, coffee, herbal infusions, cocoa and carobs	5	5	0	0
Hops (dried)	0	0	0	0
Spices (dried)	4	4	0	0
Sugar plants	2	2	0	0
Processed apiculture products	13	13	0	0
Total	1615	1614	1	0
Total no. of organic samples	9556	9536	19	1

B.20. Difenoconazole

Table B-20.1 Number of samples analysed for residues of difenoconazole in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	6742	6733	9	0
Tree nuts	381	381	0	0
Pome fruits	9034	8463	571	0
Stone fruits	8592	8145	446	1
Berries and small fruits	10,044	9423	621	0
Miscellaneous fruits	3395	3380	15	0
Root and tuber vegetables	11795	10900	895	0
Bulb vegetables	3039	3023	16	0
Fruiting vegetables	17,698	16,999	699	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	7752	7086	665	1
Leaf vegetables, herbs and edible flowers	9753	9132	620	1
Legume vegetables	1906	1877	29	0
Stem vegetables	3589	2919	670	0
Fungi, mosses and lichens	2166	2166	0	0
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	913	913	0	0
Oilseeds and oil fruits	866	864	2	0
Cereals	6912	6877	34	1
Teas, coffee, herbal infusions, cocoa and carobs	410	405	5	0
Hops (dried)	24	23	1	0
Spices (dried)	107	106	1	0
Sugar plants	43	41	2	0
Honey and other apiculture products	941	941	0	0
Total	106,106	100,801	5301	4
Processed commodities				
Fruits and tree nuts	15	15	0	0
Citrus fruits	330	330	0	0
Tree nuts	104	104	0	0
Pome fruits	135	135	0	0
Stone fruits	36	35	1	0
Berries and small fruits	3122	3089	33	0
Miscellaneous fruits	134	134	0	0
Root and tuber vegetables	62	62	0	0
Bulb vegetables	4	4	0	0
Fruiting vegetables	224	192	32	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	6	6	0	0
Leaf vegetables, herbs and edible flowers	241	217	24	0
Legume vegetables	27	27	0	0
Stem vegetables	10	10	0	0
Fungi, mosses and lichens	20	20	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	12	12	0	0
Oilseeds and oil fruits	1734	1723	11	0
Cereals	2776	2776	0	0
Teas, coffee, herbal infusions, cocoa and carobs	18	17	1	0
Hops (dried)	6	6	0	0
Spices (dried)	12	11	1	0
Sugar plants	24	24	0	0
Processed apiculture products	96	96	0	0
Total	9148	9045	103	0
Total no. of conventional samples	115,254	109,846	5404	4

Findings of not authorised substances in organic products

Table B-20.2 Number of samples analysed for residues of difenoconazole in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	606	606	0	0
Tree nuts	28	28	0	0
Pome fruits	680	678	2	0
Stone fruits	226	224	2	0
Berries and small fruits	388	388	0	0
Miscellaneous fruits	269	269	0	0
Root and tuber vegetables	1423	1421	2	0
Bulb vegetables	238	238	0	0
Fruiting vegetables	1398	1397	1	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	389	385	4	0
Leaf vegetables, herbs and edible flowers	617	616	1	0
Legume vegetables	88	88	0	0
Stem vegetables	164	162	2	0
Fungi, mosses and lichens	145	145	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	166	166	0	0
Oilseeds and oil fruits	98	98	0	0
Cereals	1332	1331	1	0
Teas, coffee, herbal infusions, cocoa and carobs	40	40	0	0
Hops (dried)	4	4	0	0
Spices (dried)	9	9	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	52	52	0	0
Total	8364	8349	15	0
Processed commodities				
Fruits and tree nuts	10	10	0	0
Citrus fruits	23	23	0	0
Tree nuts	14	14	0	0
Pome fruits	101	101	0	0
Stone fruits	5	5	0	0
Berries and small fruits	404	404	0	0
Miscellaneous fruits	17	17	0	0
Root and tuber vegetables	24	24	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	48	46	2	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	4	4	0	0
Leaf vegetables, herbs and edible flowers	14	14	0	0
Legume vegetables	15	15	0	0
Stem vegetables	1	1	0	0
Fungi, mosses and lichens	6	6	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	7	7	0	0
Oilseeds and oil fruits	216	216	0	0
Cereals	766	766	0	0
Teas, coffee, herbal infusions, cocoa and carobs	5	5	0	0
Hops (dried)	0	0	0	0
Spices (dried)	4	4	0	0
Sugar plants	2	2	0	0
Processed apiculture products	14	14	0	0
Total	1700	1698	2	0
Total no. of organic samples	10,064	10,047	17	0

B.21. Deltamethrin

Table B-21.1 Number of samples analysed for residues of deltamethrin in plant commodities, honey and other apiculture products not labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	6650	6616	29	5
Tree nuts	366	366	0	0
Pome fruits	8991	8865	125	1
Stone fruits	8629	7740	877	12
Berries and small fruits	10075	9919	156	0
Miscellaneous fruits	3370	3300	59	11
Root and tuber vegetables	11903	11896	6	1
Bulb vegetables	3022	3020	2	0
Fruiting vegetables	17877	17785	89	3
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	7742	7687	52	3
Leaf vegetables, herbs and edible flowers	9818	9464	324	30
Legume vegetables	1894	1887	7	0
Stem vegetables	3647	3596	51	0
Fungi, mosses and lichens	2169	2157	9	3
Algae and prokaryotes organisms	4	4	0	0
Pulses (dried)	934	921	13	0
Oilseeds and oil fruits	856	849	7	0
Cereals	7150	6914	235	1
Teas, coffee, herbal infusions, cocoa and carobs	414	408	6	0
Hops (dried)	4	4	0	0
Spices (dried)	109	109	0	0
Sugar plants	44	44	0	0
Honey and other apiculture products	1404	1404	0	0
Total	107,072	104,955	2047	70
Processed commodities				
Fruits and tree nuts	15	14	1	0
Citrus fruits	264	264	0	0
Tree nuts	102	101	1	0
Pome fruits	138	138	0	0
Stone fruits	36	36	0	0
Berries and small fruits	2646	2628	18	0
Miscellaneous fruits	135	128	7	0
Root and tuber vegetables	62	62	0	0
Bulb vegetables	4	4	0	0
Fruiting vegetables	224	222	2	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	5	5	0	0
Leaf vegetables, herbs and edible flowers	237	231	6	0
Legume vegetables	27	27	0	0
Stem vegetables	9	9	0	0
Fungi, mosses and lichens	20	20	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	13	13	0	0
Oilseeds and oil fruits	1878	1768	108	2
Cereals	2713	2630	83	0
Teas, coffee, herbal infusions, cocoa and carobs	17	17	0	0
Hops (dried)	1	1	0	0
Spices (dried)	12	12	0	0
Sugar plants	24	24	0	0
Processed apiculture products	198	198	0	0
Total	8780	8552	226	2
Total no. of conventional samples	115,852	113,507	2273	72

Findings of not authorised substances in organic products

Table B-21.2 Number of samples analysed for residues of deltamethrin in plant commodities, honey and other apiculture products labelled as organic in the 2020–2022 monitoring programme for pesticide residues.

Commodity	Total no. of samples	No. of results below analytical LOQ	No. of results between analytical LOQ and applicable MRL	No. of results above applicable MRL
Unprocessed commodities				
Fruits and tree nuts	0	0	0	0
Citrus fruits	596	596	0	0
Tree nuts	29	29	0	0
Pome fruits	663	662	1	0
Stone fruits	218	217	1	0
Berries and small fruits	357	357	0	0
Miscellaneous fruits	252	251	0	1
Root and tuber vegetables	1422	1422	0	0
Bulb vegetables	226	226	0	0
Fruiting vegetables	1378	1378	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	373	373	0	0
Leaf vegetables, herbs and edible flowers	597	595	2	0
Legume vegetables	83	83	0	0
Stem vegetables	167	167	0	0
Fungi, mosses and lichens	141	141	0	0
Algae and prokaryotes organisms	3	3	0	0
Pulses (dried)	168	168	0	0
Oilseeds and oil fruits	96	96	0	0
Cereals	1317	1317	0	0
Teas, coffee, herbal infusions, cocoa and carobs	44	44	0	0
Hops (dried)	4	4	0	0
Spices (dried)	8	8	0	0
Sugar plants	1	1	0	0
Honey and other apiculture products	101	101	0	0
Total	8244	8239	4	1
Processed commodities				
Fruits and tree nuts	10	10	0	0
Citrus fruits	23	23	0	0
Tree nuts	12	12	0	0
Pome fruits	101	101	0	0
Stone fruits	5	5	0	0
Berries and small fruits	402	402	0	0
Miscellaneous fruits	17	16	1	0
Root and tuber vegetables	23	23	0	0
Bulb vegetables	0	0	0	0
Fruiting vegetables	44	44	0	0
Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	4	4	0	0
Leaf vegetables, herbs and edible flowers	13	13	0	0
Legume vegetables	15	15	0	0
Stem vegetables	1	1	0	0
Fungi, mosses and lichens	6	6	0	0
Algae and prokaryotes organisms	0	0	0	0
Pulses (dried)	7	7	0	0
Oilseeds and oil fruits	189	189	0	0
Cereals	762	761	1	0
Teas, coffee, herbal infusions, cocoa and carobs	4	4	0	0
Hops (dried)	0	0	0	0
Spices (dried)	4	4	0	0
Sugar plants	2	2	0	0
Processed apiculture products	30	30	0	0
Total	1674	1672	2	0
Total no. of organic samples	9918	9911	6	1

Appendix C Medium-range aerial/aerosol transport of pendimethalin residues

Excerpts of the RAR are reproduced below (Netherlands, 2015).

Schlechtriemen, 2014

The passive air samplers were installed at two monitoring sites, one at a field where pendimethalin had been applied and a second one in a fennel field appr. 11 km away. The amount of pendimethalin found was in the range of 54 to 196 ng/m³ near the treated field and 4 to 16 ng/m³ in the untreated fennel field. Air quality bark monitoring results were in good agreement with the passive samplers ranging from 54 to 214 ng/m³ near the treated field and 3 to 12 ng/m³ in the fennel field. Results from curly kale and fennel field were not available in the report.

In addition to the results given above the RMS was informed by the notifier who was personally informed by German BVL about the concentrations of pendimethalin in organic fennel and kale measured on October 26 and 27, 2014, but which are not given in the report. Results were in the range of < 0.02–0.06 mg/kg (LOQ 0.02 mg/kg) and linked to the direct application of pendimethalin onto nearby fields.

These results were after published as a technical report: Hofmann, Frieder & Schlechtriemen, Ulrich. (2015).

Air monitoring data in France

-Measurements of pendimethalin in air monitoring from France, 2001–2007 (2009/1100369), provided in CA 7.5/1 (Table B.8.4-8)

Table C.8.4-8: Measurements of pendimethalin in local and regional areas: Air monitoring data from France, based on nearby agricultural use of pendimethalin, 2001–2007, in alphabetical order of the location, BASF DocID 2009/1100369, provided in study CA 7.5/1

Location (commune)	Area type	Distance from field	Year	Sampling design	Analysed samples (number)	LOQ ng/m ³	Number of hits	Frequency of detection	Max concentration value	Date	Additional information
Arbois	vineyard area	≥ 1 km	2004	April–Dec	7	0.12	7	100%	< 1 ng/m ³ *		all less than the LOQ
Aurillac	urban area	≥ 3 km	2006	April–Sept	22	NR	2	9%	< 1 ng/m ³		
Ay	vineyard area	< 1 km	2005	out of application time: January	5	0.01	2	40%	< 1 ng/m ³		max 0.35 ng/m ³ ; 2 results less than LOQ
Ay	vineyard area	< 1 km	2005	application period: Jun/Jul	17	0.01	0	0%	< 1 ng/m ³		17 results less than LOQ
Ay	vine field	< 1 km	2002	dec	4	0.01	4	100%	< 1 ng/m ³		
Ay	vine field	< 1 km	2003	winter = January	4	0.01	0	0%	< 1 ng/m ³		
Ay	vine field	< 1 km	2004	F&I application period = end of June	4	0.01	3	75%	< 1 ng/m ³		
Ay	vine field	< 1 km	2005	winter = January	4	0.01	3	75%	< 1 ng/m ³		
Ay	village downtown	1–2 km	2005	application period: Jun/Jul	18	0.01	0	0%	< 1 ng/m ³		18 results less than LOQ
Bergères-les-vertus	village (far from vines)	≥ 10 km	2004	F&I application period = early July	4	0.01	4	100%	2.0 ng/m ³	July	

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Location (commune)	Area type	Distance from field	Year	Sampling design	Analysed samples (number)	LOQ ng/m ³	Number of hits	Frequency of detection	Max concentration value	Date	Additional information
Besançon	urban area	≥ 10 km	2004	April–Dec	3	0.12	1	33%	< 1 ng/m ³		max 0.15 ng/m ³ (week 23)
Blois	urban area	≥ 5 km	2004	weekly – May to August	15	0.1	3	20%	< 1 ng/m ³		
Bois Herpin	rural area	< 1 km	2006	March–June	14	0.1	14	100%	39.2 ng/m ³	March	on 21st, other results between 0.1 and 17.8 ng/m ³
Briacé	vineyard area	< 1 km	2004	April–Aug	19	0.1	3	16%	< 1 ng/m ³		
Briacé (DA 80)	vineyard area	< 1 km	2002	May–July	20	0.16	10	50%	< 1 ng/m ³		
Briacé (Partisol)	vineyard area	< 1 km	2002	May–July	9	0.1	4	44%	< 1 ng/m ³		
Buxy	vineyard area	< 2 km	2006	July–Aug	6	NR	0	0%	< LOQ		3 outside and 3 inside samplings
Carentan	natural area	≥ 10 km	2003	weekly; July	3	0.05	0	0%	< 1 ng/m ³		
Carentan	natural area	≥ 10 km	2004	weekly; March–April then May–June	6	0.05	6	100%	< 1 ng/m ³		
Caudry	rural area	< 1 km	03–05	all year long	94	0.05	36	38%	18.35 ng/m ³	Apr 03	other max 1.24 ng/m ³ on April 2004
Celles-sur-Ource	village (far from vines)	≥ 10 km	2004	1 application period = end of June	4	0.01	1	25%	< 1 ng/m ³		
Châlons-en-Ch	urban area	NA	2003	application period = May	3	0.01	3	100%	< 1 ng/m ³		
Châlons-en-Ch	urban area	NA	2004	application period = mid-June	4	0.01	4	100%	< 1 ng/m ³		
Chambord	urban area	NA	2001	weekly – April to May	3	0.1	1	33%	< 1 ng/m ³		
Chambord	urban area	NA	2002	weekly – April to May	8	0.1	7	88%	< 1 ng/m ³		
Charleville-Mézières	urban area	NA	2003	application period = May	3	0.01		0%	< 1 ng/m ³		
Charleville-Mézières	urban area	NA	2003	application period = May	3	0.01	3	100%	< 1 ng/m ³		
Charleville-Mézières	urban area	NA	2004	application period = mid-June	4	0.01	4	100%	< 1 ng/m ³		
Chartres Lucé	periurban area	NR	2005	weekly – March to Sept	25	NR	12	48%	4.38 ng/m ³	week 12	12 results between 0.7 and 4.38 ng/m ³ (week 12)
Chaumont	urban area	NA	2004	application period = mid-June	4	0.01	4	100%	< 1 ng/m ³		
Chaumont	urban area	NA	2003	application period = June	3	0.01	3	100%	1.2 ng/m ³	June	
Chelles	periurban area	≥ 3 km	2006	March–June	13	0.1	13	100%	4.6 ng/m ³	March	on 21 st, other results between 0.2 and 0.8 ng/m ³
Chenôve	periurban area	< 2 km	2005	all the year round	52	NR	23	44%	6.04 ng/m ³	Oct.	max on week 42; year average concentration at 0.55
Chenôve	periurban area	< 2 km	2006	June–July	6	NR	0	0%	< LOQ		3 outside and 3 inside samplings
Clermont-Ferrand	urban area	≥ 5 km	2007	April–June	8	NR	0	0%	< 1 ng/m ³		no detection
Clermont-Ferrand	urban area	≥ 5 km	2005	March–Oct	30	NR	5	17%	< 1 ng/m ³		
Cognac	vineyard area	< 1 km	2002	April to June	10	0.02	9	90%	< 1 ng/m ³		
Coulommiers	urban area	≥ 5 km	2006	March–June	14	0.1	13	93%	15.7 ng/m ³	March	on 21 st, other results between

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Location (commune)	Area type	Distance from field	Year	Sampling design	Analysed samples (number)	LOQ ng/m ³	Number of hits	Frequency of detection	Max concentration value	Date	Additional information
											0.4 and 3.3 ng/m ³
Courcelle-les-Lens	periurban area	< 1 km	03-05	all year long	104	0.05	35	34%	6.29 ng/m ³	Apr 03	other max 1.62 ng/m ³ on April 2004
Coutances	rural – veg area	1–10 km	2003	weekly; July	3	0.05	0	0%	< 1 ng/m ³		
Coutances	rural – veg area	1–10 km	2004	weekly; March–April then May–June	6	0.05	6	100%	1,2 ng/m ³	May	
Cramant	vine field	< 1 km	2004	F&I application period = early July	4	0.01	4	100%	< 1 ng/m ³		
Damery	vine field	< 1 km	2004	F&I application period = end of June	4	0.01	3	75%	< 1 ng/m ³		
Dijon	urban area	≥ 5 km	2006	June	6	NR	0	0%	< LOQ		3 outside and 3 inside samplings
Entraigues	rural area	< 1 km	2005	March–Oct	30	NR	9	30%	< 1 ng/m ³		
Entraigues	rural area	< 1 km	2007	April–June	11	NR	4	36%	< 1 ng/m ³		max 0,69
Falgoux	rural mountain area	≥ 10 km	2006	April–Sept	22	NR	0	0%	< 1 ng/m ³		
Gennevilliers	urban area	≥ 10 km	2006	March–June	12	0.1	12	100%	1.9 ng/m ³	March	on 21 st, other results between 0.1 and 0.6 ng/m ³
Gray	rural area	≥ 1 km	2004	April–Dec	4	0.12	1	25%	< 1 ng/m ³		max 0.5 ng/m ³ (week 15)
Jonville en Woëvre	rural area	< 1 km	2002	May	4	0.12	0	0%	< LOQ		
Joué-les-Tours	periurban	< 1 km	2001	weekly – May to June	9	0.1	7	78%	< 1 ng/m ³		
Joué-les-Tours	periurban	< 1 km	2002	weekly – May to June	8	0.1	7	88%	< 1 ng/m ³		
Juillac le Coq	vineyard area	< 1 km	2006	March–Dec	6	0.03	4	67%	1.41 ng/m ³	April	4 results < 0.2 of which 1 less than LOQ; 2 results between 0.2 and 1.41
La Rochelle	urban area	1–10 km	2002	April to June	10	0.02	7	70%	< 1 ng/m ³		
Le Rheu	periurban area	≥ 2 km	2004	April–July: weekly sampling	13	NR	5	38%	< 1 ng/m ³		max 0.43 ng/m ³ (week 22)
Les Riceys	vine field	< 1 km	2004	F&I application period = end of June	4	0.01	4	100%	3.2 ng/m ³	June	
Lille	urban area	5–10 km	03-05	all year long	92	0.05	29	32%	1.69 ng/m ³	Apr 03	other max 0.77 ng/m ³ on April 2004
Lille	urban area	≥ 5 km	2006	April–November	30	0.05	17	57%	9.48 ng/m ³		no other detailed information
Lille	urban area	≥ 5 km	2007	April–November	32	0.05	17	53%	1.05 ng/m ³		no other detailed information
Mareau-aux-prés	pomefruit, vine, corn	< 1 km	2004	weekly – July to November		0.1					
Mordelles	periurban area	≥ 2 km	2005	April–July: weekly sampling	12	NR	5	42%	1.03 ng/m ³	May	max on week 20
Mordelles	periurban area	≥ 2 km	2006	April–July: weekly sampling	12	NR	8	67%	< 1 ng/m ³		max about 0.58 ng/m ³ (week 19)
Nancy	urban area	≥ 10 km	2002	June–July	2	0.06	0	0%	< LOQ		
Nantes	urban area	≥ 5 km	2004	April– Aug	19	0.1	7	37%	< 1 ng/m ³		

Findings of not authorised substances in organic products

Location (commune)	Area type	Distance from field	Year	Sampling design	Analysed samples (number)	LOQ ng/m ³	Number of hits	Frequency of detection	Max concentration value	Date	Additional information
Nantes (Partisol)	urban area	≥ 5 km	2002	May–July	9	0.1	4	44%	< 1 ng/m ³		
Nantes (Partisol)	urban area	≥ 5 km	2002	Aug–Sept	4	0.1	0	0%	< 1 ng/m ³		
Niort	urban area	1–10 km	2002	Autumn–winter (Sept02 to Jan03)	3	0.02		0%	< 1 ng/m ³		
Orléans	urban area	≥ 5 km	2003	weekly – March to Feb	48	0.1	12	25%	< 1 ng/m ³		
Orléans Fbg Bann.	urban area	NR	2006	weekly – March–Sept	23	NR	11	48%	1.3 ng/m ³	week 12	
Orléans Fbg Bann.	urban area	NR	2007	weekly – April to July	13	NR	10	77%	< 1 ng/m ³		max 0.83 ng/m ³ (week 16)
Oysonville	arable field	< 1 km	2001	weekly – April to June	8	0.1	6	75%	12,1 ng/m ³	April	
Oysonville	arable field	< 1 km	2002	weekly – April to June	10	0.1	9	90%	5,7 ng/m ³	April	
Oysonville	arable field	< 1 km	2002	weekly – July to August	4	0.1	4	100%	< 1 ng/m ³		max 0,18 ng/m ³ (week 33)
Oysonville	rural area	NR	2007	weekly – April to July	13	NR	13	100%	1.75 ng/m ³	May	max on week 22
Oysonville	rural area	NR	2006	weekly – March–Sept	26	NR	22	85%	117.3 ng/m ³	March	max on week 12
Paris Halles Les	urban area	≥ 10 km	2006	March–June	12	0.1	10	83%	2.2 ng/m ³	March	on 21st, other results between 0.1 and 0.8 ng/m ³
Pesmes	rural area	> 1 km	2004	April–Dec	2	0.12	2	100%	< 1 ng/m ³		max 0.21 ng/m ³ (week 43)
Poitiers	urban area	1–10 km	2003	July–Dec	19	0.02		0%	< 1 ng/m ³		
Poitiers	urban area	1–10 km	2004	Jan–Dec	19	0.02		0%	< 1 ng/m ³		
Poitiers	urban area	1–2 km	2005	Jan–Dec	21	0.03	15	71%	< 1 ng/m ³		max at 0,48 ng/m ³ on week 19, 6 results < LOQ
Poitiers	urban area	1–2 km	2006	Jan–Dec	13	0.03	8	62%	< 1 ng/m ³		max at 0,21 ng/m ³ on week 16, 18 and 45, 5 results < LOQ,
Pontivy	periurban area	≥ 2 km	2005	April–July: weekly sampling	12	NR	10	83%	1.91 ng/m ³	May	max on week 22
Pusignan	village area		2007	September	8	0.01/0.03	8	100%	< 1 ng/m ³		max: 0,17
Quétingny	rural area	< 3 km	2006	May–June	6	NR	0	0%	< LOQ		3 outside and 3 inside samplings
Reims Murigny –	urban area	NA	2003	application period = May	3	0.01	3	100%	< 1 ng/m ³		
Reims Murigny –	urban area	NA	2003	application period = June	3	0.01	2	67%	< 1 ng/m ³		
Reims Murigny –	urban area	NA	2003	application period = July	3	0.01	3	100%	< 1 ng/m ³		
Reims Murigny –	urban area	NA	2004	application period = mid-June	4	0.01	4	100%	< 1 ng/m ³		
Reims Murigny –	urban area	NA	2004	application period = end of June	4	0.01	4	100%	< 1 ng/m ³		
Reims Murigny –	urban area	NA	2004	F&I application period = early July	7	0.01	4	57%	< 1 ng/m ³		
Reims Murigny –	urban area	NA	2005	winter = January	4	0.01	2	50%	< 1 ng/m ³		
Reims Murigny –	urban area	NA	2002	winter = dec	8	0.01	8	100%	< 1 ng/m ³		
Reims Murigny –	urban area	NA	2003	winter = January	8	0.01	4	50%	< 1 ng/m ³		

Findings of not authorised substances in organic products

Location (commune)	Area type	Distance from field	Year	Sampling design	Analysed samples (number)	LOQ ng/m ³	Number of hits	Frequency of detection	Max concentration value	Date	Additional information
Reims E. Zola	urban area	3 to 5 km	2007	application period: Jun/Jul	8	0.1	8	100%	3,2 ng/m ³	Jun	3 results between 1.0 and 1.4 ng/m ³ ; 4 results between 0.3 and 0.9 ng/m ³
Reims Murigny	urban area	< 1 km	2005	out of application time: Jan	5	0.01	3	60%	< 1 ng/m ³		max 0.21 ng/m ³ ; 3 results less than LOQ
Reims Murigny	urban area	3 to 5 km	2005	application period	18	0.01	14	78%	<1 ng/m ³		14 results less than LOQ; 4 results 0.1–0.2
Reims Murigny	urban area	3 to 5 km	2007	application period: Jun/Jul	8	0.1	7	88%	< 1 ng/m ³		7 results between 0.1 and 0.4 ng/m ³
Reims Notre Dame	urban area	3 to 5 km	2007	application period: Jun/Jul	8	0.1	5	63%	< 1 ng/m ³		5 results between 0.1 and 0.6 ng/m ³ ; 3 less than LOQ
Reims Sacré Cœur	urban area	3 to 5 km	2007	application period: Jun/Jul	8	0.1	8	100%	< 1 ng/m ³		8 results between 0.1 and 0.2 ng/m ³
Reims Yser	urban area	3 to 5 km	2007	application period: June/July	8	0.1	7	88%	< 1 ng/m ³		7 results between 0.1 and 0.3 ng/m ³ ; 1 undefined result
Rennes ENSP	periurban area	≥ 5 km	2003	April–July: weekly sampling	10	NR	4	40%	< 1 ng/m ³		max 0.24 ng/m ³ (week 22)
Saint Omer	urban area	about 4 km	2006	April–November	34	0.05	14	41%	9.90 ng/m ³		no other detailed information
Saint Omer	urban area	about 4 km	2007	April–November	32	0.05	14	44%	< 1 ng/m ³		no other detailed information
Saint Preuil	vineyard area	< 1 km	2006	March–Dec	23	0.03	17	77%	1,61 ng/m ³	April	14 results < 0.2 of which 1 less than LOQ; 9 results between 0,2 and 1,61
Seichamps	periurban area	≥ 5 km	2002	Aug–Sept	2	0.12	0	0%	< LOQ		
Somme-Vesles	arable field	< 1 km	2002	dec	4	0.01	4	100%	< 1 ng/m ³		
Somme-Vesles	arable field	< 1 km	2003	winter = January	4	0.01	4	100%	< 1 ng/m ³		
St Aignan	rural area	NR	2006	weekly – May–Sept	18	NR	4	22%	2.5 ng/m ³	July	max on week 31
St Aignan	rural area	NR	2007	weekly – April to July	13	NR	11	85%	< 1 ng/m ³		max 0.99 (week 18)
St Julien Concelles	periurban area	~ 2 km	2002	Aug–Sept	4	0.1	3	75%	< 1 ng/m ³		
St Julien Concelles	periurban area	~ 2 km	2002	Aug–Sept	8	0.16	2	25%	< 1 ng/m ³		
St Martin d'Auxigny	pomefruit	< 1 km	2003	weekly – April to December	33	0.1	1	3%	< 1 ng/m ³		
St Martin d'Auxigny	rural area	NR	2006	weekly – March–Sept	25	NR	11	44%	< 1 ng/m ³		max 0.8 ng/m ³ (week 13)
St Martin d'Auxigny	rural area	NR	2007	weekly – April to July	22	NR	19	86%	1.39 ng/m ³	April	max on week 15
St. Martin Le Beau	rural area	NR	2005	weekly – March to Sept	26	NR	11	42%	< 1 ng/m ³		11 results between 0.35 and 0.85 ng/m ³ (week 15)
Surgères	rural area	?	2001	June, then Oct to Nov	11	0.02	1	9%	< 1 ng/m ³		
Tavaux	urban area	≥ 5 km	2004	April–Dec	3	0.12	2	67%	< 1 ng/m ³		max 0.35 ng/m ³ (week 41)
Tavaux	periurban area	≥ 3 km	2004	April–Dec	3	0.12	3	100%	5.17 ng/m ³	April	max on week 15
Tours	urban area	≥ 5 km	2004	weekly – April to March	51	0.1	32	63%	4,47 ng/m ³		
Tours La Bruyère	urban area	NR	2006	weekly – March–Sept	22	NR	11	50%	1.1 ng/m ³	March	max on week 11

Findings of not authorised substances in organic products

Location (commune)	Area type	Distance from field	Year	Sampling design	Analysed samples (number)	LOQ ng/m ³	Number of hits	Frequency of detection	Max concentration value	Date	Additional information
Tours La Bruyère	urban area	NR	2007	weekly – April to July	13	NR	10	77%	1.67 ng/m ³	April	max on week 18
Troyes	urban area	NA	2004	application period = mid-June	4	0.01	4	100%	< 1 ng/m ³		
Troyes	urban area	NA	2003	application period = early July	3	0.01	2	67%	< 1 ng/m ³		
Vallet	vineyard area	< 1 km	2004	April- Aug	19	0.1	3	16%	< 1 ng/m ³		
Verzenay	village (far from vines)	≥ 10 km	2004	F&I application period = early July	4	0.01	3	75%	< 1 ng/m ³		
Verzenay	village downtown	1–2 km	2005	application period: Jun/Jul	18	0.01	0	0%	< 1 ng/m ³		18 results less than LOQ
Verzenay	vineyard area	< 1 km	2005	application period: June/July	18	0.01	1	6%	< 1 ng/m ³		17 results less than LOQ; 1 result max 0.5 ng/m ³
Vezin Coquet	periurban area	≥ 2 km	2004	April–July: weekly sampling	13	NR	3	23%	< 1 ng/m ³		max 0.62 ng/m ³ (week 18)
Vezin Coquet	periurban area	≥ 2 km	2004	May: daily sampling	7	NR	3	43%	< 1 ng/m ³		max 0.22 ng/m ³ (week 20)
Villedomange	village (far from vines)	≥ 10 km	2004	F&I application period = early July	4	0.01	0	0%	< 1 ng/m ³		
TOTAL					1765		825	47%			

NA – not available; NR – not reported.

* < 1 ng/m³ corresponds to very low concentrations, sometimes reported for non-application periods, e.g. late fall and winter.



Appendix D Summary of the main outcomes per active substance

Table D.1: Approval status, authorised uses and other general information^{a)}

	Substance	EU Approval Status ^{b)} for plant protection purposes in April 2025	Authorised uses for plant protection purposes	EU Approval Status for biocidal use	Other authorised uses (e.g. veterinary medicine use, REACH registration, etc.)	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Method of analysis and sensitivity (LOQ, mg/kg)	Hydrolytic stability
1	Fosetyl-Al	Approved - Expiry of approval: 31/10/2026 (renewal under assessment)	Citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber veg., bulb veg., fruiting veg., brassica veg. (excluding brassica roots and brassica baby leaf crops), leaf veg., herbs and edible flowers, stem veg., pulses (dried), herbal infusions from flowers, hops (dried), seed spices (dried), fruits spices (dried), sugar plants	NA	Fosetyl-Al: NA	Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)	Fosetyl	Multi-residue, 0.01–2 mg/kg	Yes
					Phosphonic acid and its salts: - REACH registrations: (several active during 2020–2022) - Use as fertilisers, plant strengtheners, manure, and for soil amendments		Phosphonic acid and their salts	Multi-residue, 0.1–20 mg/kg	Yes
							Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)	NA	NA
2	Glyphosate	Approved - Expiry of approval: 15/12/2033	Citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, cultivated and wild fungi, pulses (dried), oilseeds and oil fruits, cereals, teas, coffee beans, herbal infusions, carobs, hops (dried), spices (dried), sugar plants, alfalfa, clover, grass and fodder beets	NA	NA	Glyphosate	Glyphosate	Multi-residue, 0.02–0.1 mg/kg	Yes
3	Cypermethrin	Approved - Expiry of approval: 31/01/2029	Pome fruits, stone fruits, berries and small fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and	Approved as wood preservative - Expiry of approval: 31/05/2025	Veterinary medicine for cats, dogs, horses, cattle, goat,	Cypermethrin (cypermethrin including other mixtures of constituent	Cypermethrin (sum of isomers)	Multi-residue, 0.01–0.1 mg/kg	- Yes, under pasteurisation, boiling, brewing and baking



Findings of not authorised substances in organic products

	Substance	EU Approval Status ^{b)} for plant protection purposes in April 2025	Authorised uses for plant protection purposes	EU Approval Status for biocidal use	Other authorised uses (e.g. veterinary medicine use, REACH registration, etc.)	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Method of analysis and sensitivity (LOQ, mg/kg)	Hydrolytic stability
			brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds and oil fruits, cereals, herbal infusions from leaves and herbs, hops (dried), sugar plants, beans and peas for forage, fodder beets, alfalfa forage, trefoil and vetch forage and cereal forage	Approved as broad-spectrum insecticide - Expiry of approval: 31/05/2030	sheep and Atlantic salmon	isomers (sum of isomers)) (F)			-No, under sterilisation
4	Imidacloprid	Not approved - Expiry of approval: 01/12/2020	NA	Approved as insecticide in livestock installations and in residential and commercial buildings - Expiry of approval: 31/12/2025 (renewal under assessment)	- REACH registrations: 1 inactive (since 2012), 2 active (since 2021 and 2023) - Veterinary medicine in cats, dogs, rabbits and ferrets	Imidacloprid	Imidacloprid	Multi-residue, 0.002–0.2 mg/kg	Yes
5	Boscalid	Approved - Expiry of approval: 15/04/2026 (renewal under assessment)	Pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds, cereals, hops (dried)	NA	NA	Boscalid (R) (F)	Boscalid	Multi-residue, 0.01–0.05 mg/kg	Yes



Findings of not authorised substances in organic products

	Substance	EU Approval Status ^{b)} for plant protection purposes in April 2025	Authorised uses for plant protection purposes	EU Approval Status for biocidal use	Other authorised uses (e.g. veterinary medicine use, REACH registration, etc.)	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Method of analysis and sensitivity (LOQ, mg/kg)	Hydrolytic stability
6	Tebuconazole	Approved - Expiry of approval: 15/08/2026 (renewal under assessment)	Citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds and oil fruits, cereals, hops (dried), seed spices (dried), sugar plants and grass	Approved as film preservative and construction material preservative -Expiry of approval: 30/06/2025 Approved as wood preservative (renewal under assessment) -Expiry of approval: 30/06/2026	NA	Tebuconazole (R)	Tebuconazole	Multi-residue, 0.001–0.02 mg/kg	Yes
7	Folpet (sum)	Approved - Expiry of approval: 31/10/2039	Berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, oil fruits, cereals and hops (dried)	Folpet: Approved as preservative for products during storage -Expiry of approval: 31/12/2025 Folpet: Approved as film preservative and fibre, leather, rubber and polymerised materials preservative 30/09/2026 as Phthalimide: NA	Folpet: NA Phthalimide: - REACH registrations (1 inactive since 2021 and 2 active since 2010, 1 industrial use as intermediate in chemical synthesis and 1 professional use	Folpet (sum of folpet and phthalimide, expressed as folpet) (R)	Folpet Phthalimide	Multi-residue for all matrices except honey, LOQ 0.005–0.05 mg/kg. Single residues for honey, LOQ 0.002 mg/kg Multi-residue for all matrices except honey, LOQ 0.05–0.075 mg/kg. Single residues for honey, LOQ 0.005 mg/kg	No -Yes at 25°C, pH 4–7 -No under baking, boiling, brewing and sterilisation



Findings of not authorised substances in organic products

	Substance	EU Approval Status ^{b)} for plant protection purposes in April 2025	Authorised uses for plant protection purposes	EU Approval Status for biocidal use	Other authorised uses (e.g. veterinary medicine use, REACH registration, etc.)	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Method of analysis and sensitivity (LOQ, mg/kg)	Hydrolytic stability
8	Pirimiphos-methyl	Approved - Expiry of approval: 15/06/2025 (renewal under assessment)	Direct indoor seed treatment of cereals, pulses, oilseeds and palm nuts at 4 g active substance per tonne by fogging, and structural treatment of empty storehouses for storage of cereals, tree nuts, sunflower seeds and soya beans at application rates up to 500 g active substance per 1000 m ²	NA	as laboratory agent) REACH registrations: 1 active (since 2022)	Pirimiphos-methyl (F)	Pirimiphos-methyl	Multi-residue, 0.002–0.05 mg/kg	- Yes, in neutral and alkaline aqueous solutions, under baking - No information is available on hydrolytic stability under pasteurisation or sterilisation conditions.
9	Azoxystrobin	Approved - Expiry of approval: 31/05/2027	Berries and small fruits, miscellaneous fruits (banana), root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds, cereals, herbal infusions from flowers and leaves, hops (dried), seed spices (dried), fruit and berry spices (dried) and sugar plants	Approved as fungicide in paints, silicon coatings, mineral sealants and grouts, in paper for the production of wall lining and in masonry building indoor -Expiry of approval: 31/10/2025	NA	Azoxystrobin	Azoxystrobin	Multi-residue, 0.001 to 0.01 mg/kg	Yes
10	Fluopyram	Approved - Expiry of approval: 30/06/2026 (renewal under assessment)	Tree nuts, pome fruits, stone fruits, berries and small fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem	NA	NA	Fluopyram (R)	Fluopyram	Multi-residue, 0.001 to 0.01 mg/kg	Yes



Findings of not authorised substances in organic products

	Substance	EU Approval Status ^{b)} for plant protection purposes in April 2025	Authorised uses for plant protection purposes	EU Approval Status for biocidal use	Other authorised uses (e.g. veterinary medicine use, REACH registration, etc.)	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Method of analysis and sensitivity (LOQ, mg/kg)	Hydrolytic stability
			vegetables, pulses (dried), oilseeds, cereals, hops (dried), and sugar plants						
11	Lambda-cyhalothrin	Approved - Expiry of approval: 31/08/2026 (renewal under assessment)	Citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, wild fungi, pulses (dried), oilseeds and oil fruits, cereals, hops (dried), sugar plants and alfalfa forage; in organic products use only in traps with specific attractants against <i>Bactrocera oleae</i> and <i>Ceratitis capitata</i>	Approved as insecticide in livestock installations, buildings and structures -Expiry of approval: 31/03/2026 (renewal under assessment)	Veterinary medicine (cyhalothrin)	Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers) (F)	Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)	Multi-residue, 0.002 to 0.1 mg/kg	- Yes, under pasteurisation, boiling, brewing and baking -No, under sterilisation
12	Acetamiprid	Approved - Expiry of approval: 28/02/2033	Citrus fruits, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds and oil fruits, honey and other apiculture products, cereals and alfalfa	Approved as physico-chemical barrier against termites (<i>Reticulitermes</i> sp.) in France - Expiry of approval: 31/01/2027	NA	Acetamiprid (R)	Acetamiprid	Multi-residue, 0.01 to 0.05 mg/kg	Yes
13	Chlormequat	Approved - Expiry of approval: 28/02/2027	Cereals, cereal straw, and grass	NA	NA	Chlormequat (sum of chlormequat and its salts, expressed as chlormequat chloride)	Chlormequat (sum of chlormequat and its salts, expressed as chlormequat chloride)	Multi-residue (except for high-oil-content matrices), 0.01 to 0.08 mg/kg	Yes
14	Pendimethalin	Approved	Citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, root and tuber vegetables, bulb	NA	NA	Pendimethalin (F)	Pendimethalin	Multi-residue, 0.002 to 0.02 mg/kg	Yes



Findings of not authorised substances in organic products

	Substance	EU Approval Status ^{b)} for plant protection purposes in April 2025	Authorised uses for plant protection purposes	EU Approval Status for biocidal use	Other authorised uses (e.g. veterinary medicine use, REACH registration, etc.)	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Method of analysis and sensitivity (LOQ, mg/kg)	Hydrolytic stability
		- Expiry of approval: 15/01/2027	vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds, cereals, herbal infusions from roots, seed spices (dried), fruit spices (dried, caraway), sugar plants.						
15	Spirotetramat	Not approved - Expiry of approval: 30/04/2024	NA Previously used in <i>Citrus fruits, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oil fruits, herbal infusions from leaves and herbs, hops (dried), and sugar plants</i>	NA	NA	Spirotetramat and spirotetramat-enol (sum of), expressed as spirotetramat (R) ^{c)}	Spirotetramat Spirotetramat-enol Spirotetramat-ketohydroxy (included in RD before 2021) Spirotetramat-monohydroxy (included in RD before 2021) Spirotetramat-enol-glucoside (included in RD before 2021)	Multi-residue, 0.01 mg/kg Multi-residue, 0.01 mg/kg Multi-residue, 0.002 mg/kg (only in honey) Multi-residue, 0.002 mg/kg (only in honey) Multi-residue, 0.002 mg/kg (only in honey)	-Yes, under pasteurisation -No, under baking and sterilisation Yes -Yes, under pasteurisation -No, under sterilisation, cooking, boiling, and baking Yes -Yes, under pasteurisation -No under cooking, boiling, baking and sterilisation



Findings of not authorised substances in organic products

	Substance	EU Approval Status ^{b)} for plant protection purposes in April 2025	Authorised uses for plant protection purposes	EU Approval Status for biocidal use	Other authorised uses (e.g. veterinary medicine use, REACH registration, etc.)	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Method of analysis and sensitivity (LOQ, mg/kg)	Hydrolytic stability
16	Cyprodinil	Approved - Expiry of approval: 31/10/2026 (renewal under assessment)	Pome fruits, stone fruits, berries and small fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, leaf vegetables, herbs, and edible flowers, legume vegetables, stem vegetables, pulses (dried), cereals, herbal infusions from roots, and root and rhizome spices (dried)	NA	NA	Cyprodinil (R) (F)	Cyprodinil	Multi-residue, 0.001 to 0.02 mg/kg	Yes
17	Chloridazon	Not approved - Expiry of approval: 31/12/2018	NA Previously used in <i>root and tuber vegetables, bulb vegetables, leaf vegetables, herbs and edible flowers, sugar plants and fodder beet</i>	NA	NA	Chloridazon (sum of chloridazon and chloridazon-desphenyl, expressed as chloridazon) (R)	Chloridazon	Multi-residue, 0.01 to 0.05 mg/kg	Yes
							Chloridazon-desphenyl	Single residue, 0.01 to 0.05 mg/kg	Yes
18	Pyriproxyfen	Approved - Expiry of approval: 31/07/2035	Citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, fruiting vegetables, and oilseeds and oil fruits	Approved as insecticide in livestock installations and in residential and commercial buildings - Expiry of approval: 31/07/2027	- Veterinary medicine - REACH registration: 1 inactive (since 2022)	Pyriproxyfen (F)	Pyriproxyfen	Multi-residue, 0.001 to 0.01 mg/kg	Yes
19	Fludioxonil	Approved - Expiry of approval: 15/06/2025 (renewal under assessment)	Citrus fruits, pome fruits, stone fruits, berries and small fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds, cereals, herbal infusions from roots, root and rhizome spices (dried)	Approved as fungicide in paints, silicon coatings, mineral sealants and grouts, in paper for the production of wall lining and in masonry building - Expiry of approval: 31/03/2028	NA	Fludioxonil (R) (F)	Fludioxonil	Multi-residue, 0.0005 to 0.05 mg/kg	Yes



Findings of not authorised substances in organic products

	Substance	EU Approval Status ^{b)} for plant protection purposes in April 2025	Authorised uses for plant protection purposes	EU Approval Status for biocidal use	Other authorised uses (e.g. veterinary medicine use, REACH registration, etc.)	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Method of analysis and sensitivity (LOQ, mg/kg)	Hydrolytic stability
20	Difenoconazole	Approved - Expiry of approval: 15/03/2026 (renewal under assessment)	Pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, pulses (dried), oilseeds and oil fruits, cereals, herbal infusions from flowers, leaves, herbs and roots, spices (dried), and sugar plants	NA	NA	Difenoconazole	Difenoconazole	Multi-residue, 0.001 to 0.05 mg/kg	Yes
21	Deltamethrin	Approved - Expiry of approval: 15/08/2026 (renewal under assessment)	Citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, miscellaneous fruits, root and tuber vegetables, bulb vegetables, fruiting vegetables, brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers, legume vegetables, stem vegetables, cultivated fungi, pulses (dried), oilseeds and oil fruits, cereals, carobs, herbal infusions from flowers, leaves and roots, fruit spices (dried), root and rhizome spices (dried), bud spices (dried), flower pistil spices (dried), sugar plants, alfalfa, clover, fodder beet and grass; in organic products use only in traps with specific attractants against <i>Bactrocera oleae</i> and <i>Ceratitis capitata</i>	Approved as insecticide for pest control - Expiry of approval: 31/03/2026 (renewal under assessment)	Veterinary medicine	Deltamethrin (<i>cis</i> -deltamethrin) (F)	<i>cis</i> -deltamethrin	Multi-residue, 0.002 to 0.05 mg/kg	-Yes, under conditions of pasteurisation, baking, brewing and boiling -No under conditions of sterilisation

NA – not applicable

a) Entries in red boxes indicate that the substance is approved/authorised; entries in blue boxes indicate that the substance/product is not approved/not authorised; b) Based on Reg. (EC) 1107/2009; c) Before 2021, the residue definition for enforcement implemented in Regulation (EC) No 396/2005 was 'spirotetramat and its 4 metabolites spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat'

Table D.2: Occurrence in plant commodities, honey and other apiculture products

	Substance	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Max concentration in residue trials performed according to the critical GAP per crop	Max concentration in untreated crops	% findings in conventional commodities analysed between 2020–2022:	% findings in organic commodities analysed between 2020–2022:	Range of median concentrations in conventional commodities analysed between 2020–2022 (>5 findings per commodity)	Range of median concentrations in organic commodities analysed between 2020–2022 (>5 findings per commodity)
1	Fosetyl-Al	Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)	Fosetyl	10 mg/kg in hops (dried)	0.57 mg/kg in grapes	- 0.19% >MRL - 17.31% ≤MRL and ≥LOQ - 82.5% <LOQ	- 0% >MRL - 3.95% ≤MRL and ≥LOQ - 96.05% <LOQ	Unprocessed: 0.27 mg/kg in stone fruits to 2.5 mg/kg in bulb vegetables	Unprocessed: 0.057 mg/kg in cereals to 0.28 mg/kg in berries and small fruits
			Phosphonic acid and its salts	368 mg/kg in hops (dried)	24 mg/kg in potato tubers			Processed: 1.6 mg/kg in fruiting veg. to 29.4 mg/kg in hops (dried)	Processed: 0.57 mg/kg in berries and small fruits
			Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)	504 mg/kg in hops (dried)	NA				
2	Glyphosate	Glyphosate	Glyphosate	175 mg/kg in cereal straw	14.9 mg/kg in hay	- 0.41% >MRL - 1.21% ≤MRL and ≥LOQ - 98.38% <LOQ	- 0% >MRL - 0.09% ≤MRL and ≥LOQ - 99.91% <LOQ	Unprocessed: 0.034 mg/kg in stone fruits to 0.27 mg/kg in dried pulses	Unprocessed: None
								Processed: 0.03 mg/kg in berried and small fruits to 0.073 mg/kg in cereals	Processed: Not quantified
3	Cypermethrin	Cypermethrin (cypermethrin including other mixtures of constituent isomers (sum of isomers)) (F)	Cypermethrin (sum of isomers)	4.9 mg/kg in trefoil and vetch forage	0.06 mg/kg in winter wheat	- 0.05% >MRL - 0.93% ≤MRL and ≥LOQ - 99.02% <LOQ	- 0% >MRL - 0.09% ≤MRL and ≥LOQ - 99.91% <LOQ	Unprocessed: 0.01 mg/kg in miscellaneous fruits and fruiting vegetables to 0.067 mg/kg in leaf vegetables, herbs and edible flowers	Unprocessed: None



Findings of not authorised substances in organic products

	Substance	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Max concentration in residue trials performed according to the critical GAP per crop	Max concentration in untreated crops	% findings in conventional commodities analysed between 2020–2022:	% findings in organic commodities analysed between 2020–2022:	Range of median concentrations in conventional commodities analysed between 2020–2022 (>5 findings per commodity)	Range of median concentrations in organic commodities analysed between 2020–2022 (>5 findings per commodity)
								Processed: 0.04 mg/kg in berries and small fruits to 0.094 mg/kg in leaf vegetables, herbs and edible flowers	Processed: None
4	Imidacloprid	Imidacloprid	Imidacloprid	1.4 mg/kg in fruiting vegetables	0.37 mg/kg in maize (whole plant)	- 0.05% >MRL - 0.70% ≤MRL and ≥LOQ - 99.26% <LOQ	- 0% >MRL - 0.06% ≤MRL and ≥LOQ - 99.94% <LOQ	Unprocessed: 0.012 mg/kg in brassica vegetables (excluding brassica roots and brassica baby leaf crops) to 0.03 mg/kg in bulb vegetables	Unprocessed: None
								Processed: 0.006 mg/kg in citrus fruits to 0.025 mg/kg in fruiting vegetables and leaf vegetables, herbs and edible flowers	Processed: Not quantified
5	Boscalid	Boscalid	Boscalid	52.7 mg/kg in cereal straw	0.44 mg/kg in black currant	- 0.01% >MRL - 10.51% ≤MRL and ≥LOQ - 89.48% <LOQ	- 0% >MRL - 0.44% ≤MRL and ≥LOQ - 99.56% <LOQ	Unprocessed: 0.014 mg/kg in pulses (dried) to 1.8 mg/kg in hops (dried)	Unprocessed: 0.003 mg/kg in root and tuber vegetables, leaf vegetables, herbs and edible flowers to 0.086 mg/kg in berries and small fruits
								Processed: 0.004 mg/kg in honey to 5.5 mg/kg in hops (dried)	Processed: None



Findings of not authorised substances in organic products

	Substance	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Max concentration in residue trials performed according to the critical GAP per crop	Max concentration in untreated crops	% findings in conventional commodities analysed between 2020–2022:	% findings in organic commodities analysed between 2020–2022:	Range of median concentrations in conventional commodities analysed between 2020–2022 (>5 findings per commodity)	Range of median concentrations in organic commodities analysed between 2020–2022 (>5 findings per commodity)
6	Tebuconazole	Tebuconazole	Tebuconazole	21 mg/kg in hops	0.16 mg/kg in spring barley	- 0.05% >MRL - 4.57% ≤MRL and ≥LOQ - 95.38% <LOQ	- 0% >MRL - 0.15% ≤MRL and ≥LOQ - 99.85% <LOQ	Unprocessed: 0.013 mg/kg in oilseeds and oil fruits to 0.069 mg/kg in berries and small fruits Processed: 0.011 mg/kg in stone fruits to 0.07 mg/kg in fruiting vegetables	Unprocessed: 0.023 mg/kg in pome fruits to 0.025 mg/kg in bulb vegetables Processed: None
7	Folpet	Folpet (sum of folpet and phthalimide, expressed as folpet) (R)	Folpet and phthalimide expressed as folpet	192 mg/kg in hops (dried)		- 0.02% >MRL - 0.69% ≤MRL and ≥LOQ - 99.29% <LOQ	- 0.02% >MRL - 0.21% ≤MRL and ≥LOQ - 99.77% <LOQ	Unprocessed: 0.017 mg/kg in root and tuber vegetables up to 0.032 mg/kg in brassica vegetables (excluding brassica roots and brassica baby leaf crops)	Unprocessed: None
			Folpet	74 mg/kg in hops (dried)	0.39 mg/kg in table grapes			Processed: 0.18 mg/kg in berries and small fruits	Processed: 0.073 mg/kg in berries and small fruits
			Phthalimide	6.9 mg/kg in cereal straw	0.32 mg/kg in table grapes				
8	Pirimiphos-methyl	Pirimiphos-methyl (F)	Pirimiphos-methyl	3.6 mg/kg in cereals	NA	- 0.02% >MRL - 0.63% ≤MRL and ≥LOQ - 99.35% <LOQ	• 0% >MRL • 0.1% ≤MRL and ≥LOQ • 99.9% <LOQ	Unprocessed: 0.017 mg/kg in pulses (dried) to 0.035 mg/kg in cereals Processed: 0.035 mg/kg in cereals	Unprocessed: None Processed: None



Findings of not authorised substances in organic products

	Substance	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Max concentration in residue trials performed according to the critical GAP per crop	Max concentration in untreated crops	% findings in conventional commodities analysed between 2020–2022:	% findings in organic commodities analysed between 2020–2022:	Range of median concentrations in conventional commodities analysed between 2020–2022 (>5 findings per commodity)	Range of median concentrations in organic commodities analysed between 2020–2022 (>5 findings per commodity)
9	Azoxystrobin	Azoxystrobin	Azoxystrobin	34 mg/kg in herbal infusions	0.64 mg/kg in wild chamomile	- 0.1% >MRL - 4.48% ≤MRL and ≥LOQ - 95.51% <LOQ	- 0% >MRL - 0.22% ≤MRL and ≥LOQ - 99.78% <LOQ	Unprocessed: 0.013 mg/kg in root and tuber vegetables to 0.263 mg/kg in hops (dried)	Unprocessed: 0.026 mg/kg in brassica vegetables (excluding brassica roots and brassica baby leaf crops)
								Processed: 0.007 mg/kg in oilseeds to 0.13 mg/kg in leaf vegetables, herbs and edible flowers	Processed: None
10	Fluopyram	Fluopyram (R)	Fluopyram	25.2 mg/kg in herbal infusions	0.034 mg/kg in parsley	- 0.02% >MRL - 7.90% ≤MRL and ≥LOQ - 92.08% <LOQ	- 0% >MRL - 0.21% ≤MRL and ≥LOQ - 99.79% <LOQ	Unprocessed: 0.008 mg/kg in bulb vegetables to 0.054 mg/kg in berries and small fruits	Unprocessed: 0.006 mg/kg in fruiting vegetables
								Processed: 0.014 mg/kg in oilseeds to 0.068 mg/kg in fruiting vegetables	Processed: None
11	Lambda-cyhalothrin	Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers) (F)	Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)	3.6 mg/kg in leaf hops (dried)	0.06 mg/kg in olives	- 0.08% >MRL - 2.26% ≤MRL and ≥LOQ - 97.66% <LOQ	- 0% >MRL - 0.04% ≤MRL and ≥LOQ - 99.96% <LOQ	Unprocessed: 0.01 mg/kg in root and tuber vegetables to 0.034 mg/kg in leaf vegetables, herbs and edible flowers	Unprocessed: Not quantified
								Processed: 0.02 mg/kg in oilseeds and oil fruits to 0.041 mg/kg in leaf vegetables, herbs and edible flowers	Processed: None



Findings of not authorised substances in organic products

	Substance	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Max concentration in residue trials performed according to the critical GAP per crop	Max concentration in untreated crops	% findings in conventional commodities analysed between 2020–2022:	% findings in organic commodities analysed between 2020–2022:	Range of median concentrations in conventional commodities analysed between 2020–2022 (>5 findings per commodity)	Range of median concentrations in organic commodities analysed between 2020–2022 (>5 findings per commodity)
12	Acetamiprid	Acetamiprid (R)	Acetamiprid	1.9 mg/kg in leaf vegetables, herbs and edible flowers	0.05 mg/kg in grape vines	- 0.12% >MRL - 6.79% ≤MRL and ≥LOQ - 93.08% <LOQ	- 0.02% >MRL - 0.26% ≤MRL and ≥LOQ - 99.72% <LOQ	Unprocessed: 0.007 mg/kg in root and tuber vegetables to 0.062 mg/kg in leaf vegetables, herbs and edible flowers Processed: 0.007 mg/kg in oilseeds and oil fruits to 0.034 mg/kg in leaf vegetables, herbs and edible flowers	Unprocessed: 0.015 mg/kg in pome fruits to 0.134 mg/kg in berries and small fruits Processed: Not quantified
13	Chlormequat	Chlormequat (sum of chlormequat and its salts, expressed as chlormequat chloride)	Chlormequat (sum of chlormequat and its salts, expressed as chlormequat chloride)	55 mg/kg in cereal straw	0.735 mg/kg in spring barley straw	- 0.11% >MRL - 4.24% ≤MRL and ≥LOQ - 95.64% <LOQ	- 0.07% >MRL - 0.56% ≤MRL and ≥LOQ - 99.37% <LOQ	Unprocessed: 0.082 mg/kg in cereals Processed: 0.064 mg/kg in cereals to 0.12 mg/kg in fruiting vegetables	Unprocessed: 0.035 mg/kg in cereals Processed: None
14	Pendimethalin	Pendimethalin (F)	Pendimethalin	0.76 mg/kg in leaf vegetables, herbs and edible flowers	0.23 mg/kg in fennel seed	- 0.01% >MRL - 1.07% ≤MRL and ≥LOQ - 98.93% <LOQ	- 0% >MRL - 0.25% ≤MRL and ≥LOQ - 99.75% <LOQ	Unprocessed: 0.002 mg/kg in citrus, pome, stone fruits, berries and small fruits to 0.021 mg/kg in bulb vegetables	Unprocessed: 0.002 mg/kg in brassica vegetables (excluding brassica roots and brassica baby leaf crops), leaf vegetables, herbs and edible flowers



Findings of not authorised substances in organic products

	Substance	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Max concentration in residue trials performed according to the critical GAP per crop	Max concentration in untreated crops	% findings in conventional commodities analysed between 2020–2022:	% findings in organic commodities analysed between 2020–2022:	Range of median concentrations in conventional commodities analysed between 2020–2022 (>5 findings per commodity)	Range of median concentrations in organic commodities analysed between 2020–2022 (>5 findings per commodity)
								Processed: 0.014 mg/kg in fruiting vegetables to 0.123 mg/kg in leaf vegetables, herbs and edible flowers	Processed: None
15	Spirotetramat	Spirotetramat and spirotetramat-enol (sum of), expressed as spirotetramat (R) ^{a)}	Spirotetramat and spirotetramat-enol expressed as spirotetramat	21.8 mg/kg in herbal infusions from leaves and herbs	0.36 mg/kg in pear fruit	- 0.01% >MRL - 5.5% ≤MRL and ≥LOQ - 94.49% <LOQ	- 0% >MRL - 0.09% ≤MRL and ≥LOQ - 99.91% <LOQ	Unprocessed: 0.014 mg/kg in root and tuber vegetables to 0.094 mg/kg in hops (dried)	Unprocessed: None
			Spirotetramat and spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat	23.3 mg/kg in herbal infusions from leaves and herbs				Processed: 0.011 mg/kg in citrus fruits	Processed: Not quantified
			Spirotetramat	17 mg/kg in herbal infusions from leaves and herbs					
			Spirotetramat-enol expressed as spirotetramat	10 mg/kg in herbal infusions from leaves and herbs					
			Spirotetramat-ketohydroxy expressed as spirotetramat	8.2 mg/kg in herbal infusions from leaves and herbs					



Findings of not authorised substances in organic products

	Substance	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Max concentration in residue trials performed according to the critical GAP per crop	Max concentration in untreated crops	% findings in conventional commodities analysed between 2020–2022:	% findings in organic commodities analysed between 2020–2022:	Range of median concentrations in conventional commodities analysed between 2020–2022 (>5 findings per commodity)	Range of median concentrations in organic commodities analysed between 2020–2022 (>5 findings per commodity)
			Spirotetramat-monohydroxy expressed as spirotetramat	0.35 mg/kg in leaf vegetables, herbs and edible flowers					
			Spirotetramat-enol-glucoside expressed as spirotetramat	7.7 mg/kg in herbal infusions from leaves and herbs					
16	Cyprodinil	Cyprodinil (R) (F)	Cyprodinil	8.9 mg/kg in leaf vegetables, herbs and edible flowers	0.16 mg/kg in barley straw	- 0.01% >MRL - 5.73% ≤MRL and ≥LOQ - 94.26% <LOQ	- 0% >MRL - 0.18% ≤MRL and ≥LOQ - 99.82% <LOQ	Unprocessed: 0.009 mg/kg in cereals to 0.082 mg/kg in berries and small fruits	Unprocessed: 0.012 mg/kg in stone fruits to 0.052 mg/kg in berries and small fruits
								Processed: 0.019 mg/kg in berries and small fruits to 0.16 mg/kg in fruiting vegetables	Processed: None
17	Chloridazon	Chloridazon (sum of chloridazon and chloridazon-desphenyl, expressed as chloridazon) (R)	Sum of chloridazon and chloridazon-desphenyl, expressed as chloridazon	1.79 mg/kg in leaf vegetables, herbs and edible flowers	-	- 0.01% >MRL - 0.18% ≤MRL and ≥LOQ - 99.82% <LOQ	- 0% >MRL - 0.06% ≤MRL and ≥LOQ - 99.94% <LOQ	Unprocessed: 0.018 mg/kg in leaf vegetables, herbs and edible flowers to 0.02 mg/kg in root and tuber vegetables	Unprocessed: None
			Chloridazon and its glycoside	0.47 mg/kg in leaf vegetables, herbs and edible flowers				Processed: Not quantified	Processed: Not quantified
			Chloridazon-desphenyl	0.93 mg/kg in leaf vegetables, herbs and edible flowers					



Findings of not authorised substances in organic products

	Substance	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Max concentration in residue trials performed according to the critical GAP per crop	Max concentration in untreated crops	% findings in conventional commodities analysed between 2020–2022:	% findings in organic commodities analysed between 2020–2022:	Range of median concentrations in conventional commodities analysed between 2020–2022 (>5 findings per commodity)	Range of median concentrations in organic commodities analysed between 2020–2022 (>5 findings per commodity)
			Chloridazon-desphenyl, expressed as chloridazon	1.41 mg/kg in leaf vegetables, herbs and edible flowers					
18	Pyriproxyfen	Pyriproxyfen (F)	Pyriproxyfen	0.47 mg/kg in citrus fruits	-	- 0.01% >MRL - 1.57% ≤MRL and ≥LOQ - 98.42% <LOQ	- 0% >MRL - 0.07% ≤MRL and ≥LOQ - 99.93% <LOQ	Unprocessed: 0.004 mg/kg in leaf vegetables, herbs and edible flowers to 0.038 mg/kg in miscellaneous fruits	Unprocessed: 0.052 mg/kg in citrus fruits
								Processed: 0.024 mg/kg in citrus fruits	Processed: Not quantified
19	Fludioxonil	Fludioxonil (R) (F)	Fludioxonil	11.42 mg/kg in leaf vegetables, herbs and edible flowers	0.45 mg/kg in lettuce	- 0.02% >MRL - 9.03% ≤MRL and ≥LOQ - 90.95% <LOQ	- 0.01% >MRL - 0.2% ≤MRL and ≥LOQ - 99.79% <LOQ	Unprocessed: 0.015 mg/kg in stem vegetables to 0.171 mg/kg in citrus fruits	Unprocessed: None
								Processed: 0.021 mg/kg in berries and small fruits to 0.112 mg/kg in citrus fruits	Processed: None
20	Difenoconazole	Difenoconazole	Difenoconazole	12 mg/kg in herbal infusions from flowers, leaves and herbs	0.64 mg/kg in witloof leaves	- 0.003% >MRL - 4.69% ≤MRL and ≥LOQ - 95.31% <LOQ	- 0% >MRL - 0.17% ≤MRL and ≥LOQ - 99.83% <LOQ	Unprocessed: 0.014 mg/kg in stone fruits to 0.083 mg/kg in leaf vegetables, herbs and edible flowers	Unprocessed: None



Findings of not authorised substances in organic products

	Substance	Residue definition for monitoring applicable from 2020–2022	Residues to monitor based on the residue definition for monitoring from 2020–2022	Max concentration in residue trials performed according to the critical GAP per crop	Max concentration in untreated crops	% findings in conventional commodities analysed between 2020–2022:	% findings in organic commodities analysed between 2020–2022:	Range of median concentrations in conventional commodities analysed between 2020–2022 (>5 findings per commodity)	Range of median concentrations in organic commodities analysed between 2020–2022 (>5 findings per commodity)
								Processed: 0.017 mg/kg in berries and small fruits, oilseeds and oil fruits to 0.227 mg/kg in leaf vegetables, herbs and edible flowers	Processed: None
21	Deltamethrin	Deltamethrin (<i>cis</i> -deltamethrin) (F)	<i>cis</i> -deltamethrin	7 mg/kg in herbal infusions from flowers, leaves and herbs, fruit spices, bud spices and flower pistil spices	0.024 mg/kg in apricot fruit	- 0.06% >MRL - 1.96% ≤MRL and ≥LOQ - 97.98% <LOQ	- 0.01% >MRL - 0.06% ≤MRL and ≥LOQ - 99.93% <LOQ	Unprocessed: 0.013 mg/kg in fruiting vegetables to 0.075 mg/kg in pulses (dried) Processed: 0.019 mg/kg in oilseeds and oil fruits to 0.037 mg/kg in miscellaneous fruits	Unprocessed: None Processed: None

NA – not applicable

a) Before 2021, the residue definition for enforcement implemented in Regulation (EC) No 396/2005 was 'spirotetramat and its 4 metabolites spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy, and spirotetramat-enol-glucoside, expressed as spirotetramat'

Table D.3: Environmental transfer of residues to plants^{a)}

	Substance	Residue definition for monitoring applicable from 2020 to 2022	Residues to monitor based on the residue definition for monitoring from 2020 to 2022	Natural occurrence	Persistence in soil	Uptake from soil	Transfer from water used for irrigation (unlikely/ cannot be excluded)	Transfer from drift	Medium-range air transfer	Possible sources of residue release in the environment (other than plant protection)
1	Fosetyl-Al	Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)	Fosetyl	No	Not persistent, DT ₉₀ <1d High persistence, DT ₉₀ >1000d	No	Unlikely	Plausible	Cannot be excluded	NA
			Phosphonic acid,	No		Yes	Data gap			Use as fertiliser, plant strengthener, manure, and for soil amendments
			Phosphonic acid precursor compounds (salts, esters and organic phosphonates)	Yes						
2	Glyphosate	Glyphosate	Glyphosate	No	Moderate persistence, DT ₉₀ 192d	No for organic crops	Cannot be excluded	Not completely excluded	Cannot be excluded	Runoff from railway tracks, urban areas, road and infrastructure management or use in private gardens for weed control noting weed control in all these situations is plant protection according to the legislation in place



Findings of not authorised substances in organic products

	Substance	Residue definition for monitoring applicable from 2020 to 2022	Residues to monitor based on the residue definition for monitoring from 2020 to 2022	Natural occurrence	Persistence in soil	Uptake from soil	Transfer from water used for irrigation (unlikely/ cannot be excluded)	Transfer from drift	Medium-range air transfer	Possible sources of residue release in the environment (other than plant protection)
3	Cypermethrin	Cypermethrin (cypermethrin including other mixtures of constituent isomers (sum of isomers)) (F)	Cypermethrin (sum of isomers)	No	Moderate persistence, DT ₉₀ 104d	No	Unlikely	Plausible	Cannot be excluded	Biocidal use, veterinary medicine use, occurrence in organic fertilisers (manure)
4	Imidacloprid	Imidacloprid	Imidacloprid	No	High persistence, DT ₉₀ 956d	No	Unlikely	No, unless organic crops in the vicinity to crops for which emergency authorisations apply	Cannot be excluded	Biocidal use, veterinary medicine use (domestic animals), other uses (REACH registrations)
5	Boscalid	Boscalid	Boscalid	No	Very high persistence, DT ₅₀ 746d	Yes	Cannot be excluded	Plausible	Cannot be excluded	Occurrence in organic fertilisers
6	Tebuconazole	Tebuconazole	Tebuconazole	No	Medium persistence, DT ₉₀ 304d	No	Unlikely	Plausible	Cannot be excluded	Biocidal use, occurrence in organic fertilisers (manure)
7	Folpet (sum)	Sum of folpet and phthalimide expressed as folpet	Folpet	No	Moderate persistence, DT ₉₀ 99.8d	No	Unlikely	Plausible	Cannot be excluded	Biocidal use, occurrence in organic fertilisers (manure)
			Phthalimide	Yes	Low persistence, DT ₉₀ 24d	No	Unlikely			Other uses (REACH registrations)
8	Pirimiphos-methyl	Pirimiphos-methyl	Pirimiphos-methyl	No	NA	NA	Unlikely	Unlikely but dust	Unlikely	Other uses (REACH registration), cross-



Findings of not authorised substances in organic products

	Substance	Residue definition for monitoring applicable from 2020 to 2022	Residues to monitor based on the residue definition for monitoring from 2020 to 2022	Natural occurrence	Persistence in soil	Uptake from soil	Transfer from water used for irrigation (unlikely/cannot be excluded)	Transfer from drift	Medium-range air transfer	Possible sources of residue release in the environment (other than plant protection)
								drift during drilling is not excluded		contamination from treated storage facilities (which is plant protection when it is plant products that are stored)
9	Azoxystrobin	Azoxystrobin	Azoxystrobin	No	High persistence, DT ₉₀ 870d	No	Cannot be excluded	Plausible	Cannot be excluded	Biocidal use, occurrence in organic fertilisers
10	Fluopyram	Fluopyram (R)	Fluopyram	No	Very high persistence, DT ₉₀ 1370d	Yes	Cannot be excluded	Plausible	Cannot be excluded	Occurrence in organic fertilisers
11	Lambda-cyhalothrin	Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers) (F)	Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)	No	Moderate persistence, DT ₉₀ 158d	No	Unlikely	Plausible	Unlikely based on the available limited air monitoring	Biocidal use, veterinary medicine use (bovine species), other uses (REACH registration)
12	Acetamiprid	Acetamiprid (R)	Acetamiprid	No	Very low to moderate persistence, DT ₉₀ 43d	No	Unlikely	Plausible	Cannot be excluded	Biocidal use, occurrence in organic fertilisers
13	Chlormequat	Chlormequat (sum of chlormequat and its salts, expressed as chlormequat chloride)	Chlormequat (sum of chlormequat and its salts, expressed as chlormequat chloride)	No	Moderate persistence, DT ₉₀ 134d	No	Unlikely	Plausible	Data gap but might be anticipated for aerosols formed at the time of spraying	NA
14	Pendimethalin	Pendimethalin (F)	Pendimethalin	No	High persistence, DT ₉₀ 621d	No	Unlikely	Not completely excluded	Yes, also long-range transfer	NA

Findings of not authorised substances in organic products

	Substance	Residue definition for monitoring applicable from 2020 to 2022	Residues to monitor based on the residue definition for monitoring from 2020 to 2022	Natural occurrence	Persistence in soil	Uptake from soil	Transfer from water used for irrigation (unlikely/ cannot be excluded)	Transfer from drift	Medium-range air transfer	Possible sources of residue release in the environment (other than plant protection)
15	Spirotetramat	Spirotetramat and spirotetramat-enol (sum of), expressed as spirotetramat (R) ^{b)}	Spirotetramat	No	Very low persistence, DT ₉₀ <1 year	No	Cannot be excluded	Plausible ^{c)}	Cannot be excluded	NA
			Spirotetramat-enol	No	Low to moderate persistence, DT ₉₀ <1 year	No	Unlikely			NA
			Spirotetramat-ketohydroxy	No	Low to moderate persistence, DT ₉₀ <1 year	No	Unlikely			NA
16	Cyprodinil	Cyprodinil (R) (F)	Cyprodinil	No	High Persistence, DT ₉₀ 944d	No	Unlikely	Plausible	Cannot be excluded	Occurrence in organic fertilisers
17	Chloridazon	Chloridazon (sum of chloridazon and chloridazon-desphenyl, expressed as chloridazon) (R)	Chloridazon	No	Medium persistence, DT ₉₀ 230d	No	Unlikely	No	Unlikely following the no renewal of the approval of the active substance and the end of the grace period for the withdrawal of product authorisations	NA
			Chloridazon-desphenyl		High Persistence, DT ₉₀ 438d		Unlikely			
18	Pyriproxyfen	Pyriproxyfen (F)	Pyriproxyfen	No	Moderate persistence, DT ₉₀ 135d	No	Unlikely	Plausible	Data gap but might be anticipated for	Biocidal use, veterinary medicine use, occurrence in organic fertilisers

Findings of not authorised substances in organic products

	Substance	Residue definition for monitoring applicable from 2020 to 2022	Residues to monitor based on the residue definition for monitoring from 2020 to 2022	Natural occurrence	Persistence in soil	Uptake from soil	Transfer from water used for irrigation (unlikely/cannot be excluded)	Transfer from drift	Medium-range air transfer	Possible sources of residue release in the environment (other than plant protection)
									aerosols formed at the time of spraying	
19	Fludioxonil	Fludioxonil (R) (F)	Fludioxonil	No	High persistence, DT ₉₀ 790d	No	Unlikely	Plausible	Cannot be excluded	Biocidal use, occurrence in organic fertilisers
20	Difenoconazole	Difenoconazole	Difenoconazole	No	High persistence, DT ₉₀ 879d	Yes	Unlikely	Plausible	Cannot be excluded	Occurrence in organic fertilisers
21	Deltamethrin	Deltamethrin (<i>cis</i> -deltamethrin) (F)	<i>cis</i> -deltamethrin	No	High persistence, DT ₉₀ 390d	No	Unlikely	Plausible	Cannot be excluded	Biocidal use, veterinary medicine use

NA – not applicable

a) Entries in red boxes indicate that the transfer from the environmental source is expected or is plausible; entries in yellow boxes indicate that transfer from the environmental source cannot be excluded; entries in blue boxes indicate a data gap;

b) Before 2021, the residue definition for enforcement implemented in Regulation (EC) No 396/2005 was 'spirotramat and its 4 metabolites spirotramat-enol, spirotramat-ketohydroxy, spirotramat-monohydroxy, and spirotramat-enol-glucoside, expressed as spirotramat';

c) According to Reg. (EU) 1107/2009 a grace period is applicable to the sale, distribution, disposal, storage and use of existing stocks of the plant protection products that contain spirotramat following the expiry date of the approval of the active substance. This period should not exceed 18 months from the expiry of the approval (from 30 April 2024).