Directorate-General for Agriculture
and Rural Development

Expert Group for Technical Advice on Organic Production
EGTOP

FINAL REPORT

on

Cleaning and Disinfection (III)

The EGTOP adopted this technical advice at the plenary meeting
of 2 – 4 December 2024

About the setting up of an independent expert panel for technical advice

Regulation (EU) 2018/848[1] requires that authorisation of products and substances used in organic production may only be authorised if they comply with the principles, criteria and objectives of organic production described in that Regulation. The Commission has decided that when taking decisions on these authorisations it will take account of scientific advice by a Group of independent experts. For that purpose, the Commission has set up the Expert Group for Technical Advice on Organic Production by Commission Decision 2021/C343/03 of 4 August 2021.

EGTOP

The Group's tasks are:

(a) to assist the Commission in evaluating technical matters of organic production, including products, substances, methods and techniques that may be used in organic production, taking into account the objectives and principles laid down in Regulation (EU) 2018/848 and additional policy objectives with regard to organic production;

(b) to assist the Commission in improving existing rules and developing new rules related to Regulation (EU) 2018/848;

(c) to stimulate an exchange of experience and good practices in the field of technical issues related to organic production.

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[1] 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). ELI: http://data.europa.eu/eli/reg/2018/848/2024-12-01

ACKNOWLEDGMENTS

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All declarations of interest of Permanent Group members are available at the following webpage:

http://ec.europa.eu/agriculture/organic/home_en

TABLE OF CONTENTS

EXECUTIVE SUMMARY

According to Article 24 of the Regulation (EU) 2018/848 the Commission may authorise certain products and substances for use in organic production, and shall include any such authorised products and substances in restrictive lists, for the following purposes:

(e) as products for the cleaning and disinfection of ponds, cages, tanks, raceways, buildings or installations used for animal production;

(f) as products for the cleaning and disinfection of buildings and installations used for plant production, including for storage on an agricultural holding;

(g) as products for cleaning and disinfection in processing and storage facilities.

Article 24 mentions cleaning and disinfection together. The Group points out that disinfectants are regulated under the Biocidal Products Regulation, Regulation (EU) 528/2012[2], and cleaning products are regulated under the Regulation (EC) 648/2004[3] on Detergents. The Group recommends thus to determine the criteria for biocidal and cleaning products separately.

Within this mandate the Group was requested:

(1) to agree on the criteria for evaluation of substances for cleaning and disinfection to be applied to all fields of organic production where the use of such agents is necessary to maintain a high level of food hygiene. The Group consented on the following criteria:

a. The cleaning and disinfection product which contains the substance under evaluation is evaluated in terms of environmental and health hazards, which are documented in the evaluation report of the biocidal active substance.

b. The substance is evaluated on its GMO status. It is evaluated if the substance contains GMOs. If so, the substance is rejected. The information should be taken from the dossier of the applicant, in case of doubt, this needs to be proven with certificate of analysis, provided by accredited laboratory.

c. The substance is evaluated on its GMO status. It is evaluated if the substance is made by or from GMOs. If so, the substance is rejected. The information should be taken from the dossier of the applicant (where applicable showing the manufacturing flowchart and clearly stating that it is NOT made by or from GMOs).

d. The substance should not be used in form of nanoparticles; therefore, substances are excluded which contain "nano" in their substance name. This can be checked also on the ECHA homepage. In case of a nanomaterial, the substance is rejected.

e. The substance needs to be approved as a biocidal active substance under Biocidal Product Regulation (EU) No 528/2012 (BPR) or should be in the review program according to the list of biocidal active substances on the ECHA homepage. Depending on the intended use the substance needs to be approved or under assessment for product types PT1, PT2, PT 3, PT4 or PT5.

f. According to the ECHA database, substances are excluded that are

- PBT Persistent, Bioaccumulative and Toxic
- vPvB Very Persistent, Very Bioaccumulative
- SVHC Substances of Very High Concern (carcinogenic, mutagenic, toxic to reproduction, endocrine disrupting chemicals)

(2) to make a proposal for a negative list of substances with unwanted properties based on the above defined criteria.

This list will contain biocidal active substances approved under Biocidal Product Regulation (EU) No 528/2012 (BPR) which are complying with the exclusion criteria and will thus be rejected in organic production. This

[2] 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). ELI: http://data.europa.eu/eli/reg/2012/528/2024-06-11

[3] Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1–35). ELI: http://data.europa.eu/eli/reg/2004/648/2015-06-01

comprises substances that are GMOs, made from or by GMO, "nano" materials or substances which are listed as PBT, vPbB or SVHC.

- Glutaraldehyde

(3) to carry on some worked examples of evaluation of prioritized dossiers submitted by the Member States on products for cleaning and disinfection based on the criteria agreed. The Group found that the prioritized dossiers fall into three categories: green- accepted, yellow- not applicable (no biocidal active substance according to criteria (e) and red- negative list.

- Hydrogen peroxide (DK)
- Sodium percarbonate (hydrogen peroxide released from sodium percarbonate, DK)
- Sodium hydroxide (NL)
- Glutaraldehyde (SE)
- Chlorine dioxide (NO)
- Calcium hypochlorite (FR)
- Peracetic acid (FR)
- Formic acid (FR)
- Sodium hypochlorite (FR)
- Iodophors (FR)
- Dipotassium peroxodisulfate + potassium peroxomonosulfate (SE)
- Fatty acid potassium salt (SE)
- Methane sulfonic acid (probably GER, the request was made by BASF Ludwigshafen)

(4) to schedule the work for evaluating the rest of the substances on the Commission priority list.

The Group agreed on the working schedule shown in

Table 1.

Table 1: Working schedule for the remaining criteria and substances to evaluate.

Year(s)	Subjects, tasks
2025	**General aspects** EGTOP: operational criteria for assessing environmental and human health aspects - covered in this report EGTOP: recommendations clarifying the terminology in Annex IV (clear distinction between biocidal active substances, other substances and 'products') – covered in this report
2025	**Cleaning agents for all uses** EGTOP: recommendations for regulating products other than biocides in Annex IV
2025	**Active substances for livestock production and aquaculture** EGTOP: recommendations for completing Annex IV, Part A and recommendations for deleting Annex IV, Part D
2025	**Active substances for plant production** EGTOP: recommendations for completing Annex IV, Part B (?) Based on national legislation and current practice, no dossiers required
2025 – 26 2027	**Active substances for food processing, from the priority list, with food contact** Member states: submit substance dossiers EGTOP: evaluate substances EGTOP: recommendations for completing Annex IV, Part C.1 (food contact)
2027 – 28 2029	**Active substances for food processing, from the priority list, without food contact** Member states: submit substance dossiers EGTOP: evaluate substances EGTOP: recommendations for completing Annex IV, Part C.2 (without food contact)

Year(s)	Subjects, tasks
	Active substances for food processing, not from the priority list
2028 – 29	Member states: submit substance dossiers
	EGTOP: evaluate substances
2030	EGTOP: recommendations for completing Annex IV, Part C

For the preparation of its report the Group was invited to examine technical dossiers provided to the Commission by the Member States and suggest amendments to the Annex IV to Commission Implementing Regulation (EU) 2021/1165[4]. The so far suggested amendments are presented in chapter 3.6.

[4] 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, 16.7.2021, p. 13–48). ELI: http://data.europa.eu/eli/reg_impl/2021/1165/2023-11-15

1. BACKGROUND

Several Member States have inquired about the applicability of cleaning agents and disinfectants in organic production and submitted dossiers under Article 24(1) (e-g) of Regulation (EU) 2018/848 concerning the possible amendment of Annex IV to Regulation (EU) 2021/1165 and in general, on their compliance with the above-mentioned legislation. Nonetheless, the use of cleaning and disinfectant products in organic production must be compliant with the Biocidal Products Regulation (EU) No 528/2012 and the Regulation (EC) No 648/2004 on Detergents.

In 2016, EGTOP outlined an 'ecologically responsible approach to cleaning and disinfection', that aims to achieve a high level of microbial safety while minimising the use of disinfectants, minimising impacts on operator and environmental safety and achieving the lowest possible levels of residues in organic foods.

In 2021, EGTOP further elaborated this approach and recommended a hierarchy of choices for the use of cleaning products. Ecolabeled cleaning products should be used preferentially and be included in the basic list without the additional checking for further criteria. In case of special needs, also non-ecolabeled cleaning products should be allowed to use when they are in line with criteria for detergents that will be defined at a later stage by EGTOP. With respect to livestock production, EGTOP made several recommendations on disinfectant uses in livestock production, plant production, food processing.

The Commission has created a consolidated list of the cleaning agents and disinfectants prioritized by the Member States. The EGTOP 2021 ranked them in five groups (substances prioritised by two or more Member States, without objections, not covered by authorisations in organic production in the EU; substances prioritised by one Member State, without objections, not covered by authorisations in organic production in the EU; substances prioritised by one or more Member State, without objections, already covered by authorisations in organic production in the EU; substances prioritised by one or more Member States but deprioritised/objected by one or more Member States; and substances not prioritised by Member States). This list of substances gives the background of a stepwise procedure of evaluation by the EGTOP Subgroup Cleaning Agents and Disinfection.

FiBL and BLQ conducted a study funded by the German Bundesministerium für Ernährung und Landwirtschaft to make recommendations for the development of EU legal requirements on cleaning and disinfection products in the organic food processing and storage (RuDi[5]). Before the RuDi project, IFOAM also conducted practical work to assess the potential implementation of positive or negative lists of Cleaning & Disinfection substances, pointing out the need to define clear conformity criteria, applicable at Cleaning & Disinfection product level, that would be applicable to any type of organic operators. The results of this IFOAM project were considered and evaluated in the RuDi project.

Therefore, the Group is requested to prepare a report with technical advice on the matters included in the terms of reference. The current EGTOP Subgroup Disinfection and Cleaning agents builds its work on the approaches and recommendations agreed in above mentioned reports.

2. TERMS OF REFERENCE

Considering the most recent technical and scientific information available to the experts, the Group is requested:

(5) to agree on the criteria for evaluation of substances for cleaning and disinfection to be applied to all fields of organic production where the use of such agents is necessary to maintain a high level of food hygiene.
(6) to make a proposal for a negative list of substances with unwanted properties based on the above defined criteria.
(7) to carry on some worked examples of evaluation of prioritized dossiers submitted by the Member States on products for cleaning and disinfection based on the criteria agreed:

i. Hydrogen peroxide (DK)
ii. Sodium percarbonate (hydrogen peroxide released from sodium percarbonate, DK)
iii. Sodium hydroxide (NL)
iv. Glutaraldehyde (SE)
v. Chlorine dioxide (NO)

[5] RuDi Final Report: https://orgprints.org/id/eprint/52648/1/Schlussbericht%20gesamt.pdf

vi. Calcium hypochlorite (FR)
vii. Peracetic acid (FR)
viii. Formic acid (FR)
ix. Sodium hypochlorite (FR)
x. Iodophors (FR)
xi. Dipotassium peroxodisulfate + potassium peroxomonosulfate (SE)
xii. Fatty acid potassium salt (SE)
xiii. Methane sulfonic acid (probably GER, the request was made by BASF Ludwigshafen)

(8) to schedule the work for evaluating the rest of the substances on the Commission priority list.

For the preparation of its report the Group was invited to examine technical dossiers provided to the Commission by the Member States and suggest amendments to the Annex IV to the Regulation (EU) 2021/1165.

3. CONSIDERATIONS, CONCLUSIONS AND RECOMMENDATIONS

3.1 GENERAL CONSIDERATIONS REGARDING THE EVALUATION CRITERIA FOR INCLUSION / EXCLUSION

According to Article 24 of the Regulation (EU) 2018/848 the Commission may authorise certain products and substances for use in organic production, and shall include any such authorised products and substances in restrictive lists, for the following purposes:

(e) as products for the cleaning and disinfection of ponds, cages, tanks, raceways, buildings or installations used for animal production;

(f) as products for the cleaning and disinfection of buildings and installations used for plant production, including for storage on an agricultural holding;

(g) as products for cleaning and disinfection in processing and storage facilities.

Article 24 mentions cleaning and disinfection together. The Group points out that disinfectants are registered biocides, while cleaning agents (detergents) are not. Disinfectants exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.

Within this mandate the following starting points were defined and agreed within the Group:

(1) The mandate refers to Article 24(1)(g) of the Regulation (EU) 2018/848 and Regulation (EU) 2021/1165 Annex IV Parts C and D (Products for cleaning and disinfection (C&D) in processing and storage facilities).
(2) The criteria for disinfection products used on materials & objects intended to come into contact with foodstuffs will be defined. The aim is to develop a list of criteria for the evaluation of the active substance of the disinfectants, as the active substance is always indicated on the product label. Contrary, the co-formulants are not indicated on the product label and there is a large variety of biocidal products containing different co-formulants in different countries. Therefore, the Group considered it impossible to evaluate all co-formulants in those products individually. Instead, three options are suggested (1) the same exclusion criteria can be applied to co-formulants as for biocidal active substances in general, (2) further criteria could be elaborated for co-formulants in a later stage or (3) they can be assessed with the criteria for cleaning products or (4) to see if the exclusion criteria for co-formulants in plant protection products could be used.
(3) The criteria for cleaning products will be defined in a later stage by EGTOP, maybe with the same approach for active substances and co-formulants as for the disinfectants.
(4) The suggested criteria are checked for feasibility by evaluating the substances of the priority list that the member states applied for.
(5) Based on legal reasons a positive list of substances is demanded. However, the Group thinks that from a technical point of view, a positive list is not feasible. This is further discussed in the chapter 3.1.5.
(6) The suggested criteria should be easily accessible and understandable for both users and manufacturers of disinfectants so that allowed and forbidden active substances and thus disinfection products are rapidly recognized.

3.1.1 Legal situation

Points (e), (f) and (g) of Article 24(1) of Regulation (EU) 2018/848 set out the possibility for the Commission to authorise products and substances for use in organic production, and in particular for cleaning and disinfection.

Points (a) and (b) of Article 24(3) set out the minimum criteria, to be evaluated as a whole, that such products must respect for being authorised, making reference to Chapter II of that Regulation.

Article 24(5) sets out conditions for the authorisation.

Finally, Article 24(6) empowers the Commission to add further criteria (through a Delegated Act adopted in accordance with the procedure in Article 54) for the authorisation of products and substances referred to in paragraphs 1 of that Article, therefore also on cleaning and disinfection products and substances.

The Terms of Reference described in Chapter 2 of this report, therefore, mandate EGTOP to provide its technical advice in setting the criteria for the authorisation of active substances and co-formulants in detergents and biocides.

Opinion of the Group regarding the legal situation

In the described relevant organic regulations, products and substances are not clearly differentiated. In Regulation (EU) 2018/848 the term "products and substances" is used, whereas in the Regulation (EU) 2021/1165 in the title is used the same term, however, in Article 5 only the term "products" appear. However, especially with view on the list in Part C of Annex IV, it is recommended to focus on easy clearly identifiable substances instead of products with unknown co-formulants or changing formulations. The recommendations propose a wording which is more appropriate.

Neither in the Regulation (EU) No 528/2012 on biocides nor in the Regulation (EC) No 648/2004 on detergents there is any obligation for the companies to reveal the complete composition of their products, including all co-formulants. The only exceptions are: for medical purposes in accordance with Article 9(3) of Regulation (EC) No 648/2004 on detergents and Annex VII, Parts C and D of that Regulation; for classification purposes according to Regulation (EC) No 1272/2008[6] on classification, labelling and packaging of substances and mixtures (CLP).

Furthermore, it should be noted that the Regulation does not explicitly specify whether a restrictive list must be a positive or negative list. Additionally, Annex IV, Part D of Regulation (EU) 2021/1165 provides the following requirement: *'The following products or products containing the following active substances, as listed in Annex VII to Regulation (EC) No 889/2008, cannot be used as biocidal products: caustic soda…'*. Consequently, a list of excluded substances (negative list) appears to be a feasible approach.

The Group discussed whether it was technically feasible to establish a "positive" or "negative" list. The "negative" list could represent a major simplification of the sector, reducing technical difficulties and delays for new products, improving the competitiveness of European companies, allowing the same consumer protection as a "positive" list.

3.1.2 Ecologically responsible approach to cleaning and disinfection

The Group has previously outlined the principles of an ecologically responsible approach to cleaning and disinfection (see EGTOP report on Cleaning and Disinfection I, chapter 4.1.2; EGTOP report on Cleaning and Disinfection II, chapter 2.3). The Group sees no need to repeat this in the present report but emphasizes once more the importance of an ecologically responsible approach, which is also the base for the priorities, approach and criteria described in this report.

3.1.3 Priorities and working schedule

The Group was requested to schedule the work for evaluating the rest of the substances on the Commission priority list.

In the consolidated priority list of substances created by the Commission, there are almost 1300 entries, of which 39 substances are prioritized by two or more Member States (MS), without objections and not covered by

[6] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1–1355). ELI: http://data.europa.eu/eli/reg/2008/1272/2024-12-10

authorizations in organics. Furthermore, 77 substances are prioritized by one MS, without objections and not covered by authorizations in organics. 102 substances are already covered by authorizations in organics and prioritized by one or more MSs. 335 substances are prioritized by one or more MSs but deprioritized or objected by one or more MSs, and 742 substances are not prioritized by the industry. Due to the expected impossibly high workload, the Group decided to approach the mandate by creating exclusion criteria (see Chapter 3.1.5) instead of evaluating the substances one by one, and testing the criteria in a case study for a set of biocidal substance dossiers available (see Chapter 3.3).

Based on the priorities given above, the Group proposes the following, tentative schedule for handling the substances from the priority list as well as other pending issues in the field of cleaning and disinfection.

Table 2: Tentative schedule of tasks.

Year(s)	Subjects, tasks
2025	**General aspects** EGTOP: operational criteria for assessing environmental and human health aspects - covered in this report EGTOP: recommendations clarifying the terminology in Annex IV (clear distinction between biocidal active substances, other substances and 'products') – covered in this report
2025	**Cleaning agents for all uses** EGTOP: recommendations for regulating products other than biocides in Annex IV
2025	**Active substances for livestock production and aquaculture** EGTOP: recommendations for completing Annex IV, Part A and recommendations for deleting Annex IV, Part D
2025	**Active substances for plant production** EGTOP: recommendations for completing Annex IV, Part B (?) Based on national legislation and current practice, no dossiers required
2026 - 27	**Active substances for food processing, from the priority list, with food contact** Member states: submit substance dossiers EGTOP: evaluate substances EGTOP: recommendations for completing Annex IV, Part C.1 (food contact)
2027 – 28 2029	**Active substances for food processing, from the priority list, without food contact** Member states: submit substance dossiers EGTOP: evaluate substances EGTOP: recommendations for completing Annex IV, Part C.2 (without food contact)
2028 – 29 2030	**Active substances for food processing, not from the priority list** Member states: submit substance dossiers EGTOP: evaluate substances EGTOP: recommendations for completing Annex IV, Part C

3.1.4 Approach towards formulated products and cleaning agents

Disinfection is usually carried out with formulated biocidal products ('disinfectants'). These products contain at least one biocidal active substance, and usually one or several co-formulants. The EU biocides legislation requires that the active substances are shown on the product label. Therefore, organic farmers and certifiers can easily verify whether the active substances shown on the label comply with the list of active substances given in the organic regulation (Annex VII to Regulation (EC) No 889/2008[7] and/or Annex IV to Regulation (EU) 2021/1165). By contrast, there is no obligation for companies to disclose co-formulants, which means that it would be very difficult for the organic sector (organic farmers as well as certifiers) to assess any criteria which are based on co-

[7] Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 250, 18.9.2008, p. 1–84). ELI: http://data.europa.eu/eli/reg/2008/889/2022-01-01

formulants. This situation is very similar to co-formulants in plant protection products, where all co-formulants except those included in the Annex III of the Regulation (EC) No 1107/2009[8] are explicitly allowed (see Regulation (EU) 2018/848, Art. 9(3)(a)). The Group suspects that in many EU member states, co-formulants are also generally allowed in biocidal products. To ensure transparency and harmonized interpretation across the EU, the Group recommends that this policy is explicitly stated in Annex IV to Reg. 2021/1165. A proposal is made in the chapter 'Recommendations' below.

Cleaning is also usually carried out with formulated products. Although many biocidal products have a certain cleaning effect, appropriate cleaning procedures must be established and carried out before the disinfection process. Cleaning products are not categorized as biocidal products but managed according to the Regulation (EC) 648/2004 on detergents. Whenever a detergent product claims biocidal function, it must also comply with the biocidal products regulation. The components of cleaning agents can be similar to the co-formulants of biocidal products. The main active components of cleaning agents are usually surfactants, which lower the surface tension between water and oil and are thus able to solubilize substances which are not water soluble. There is no obligation for companies to disclose the components of cleaning agents for any other purposes than classification and labelling, which means that it would be very difficult for the organic sector (organic farmers as well as certifiers) to assess any criteria which are based on the components of cleaning agents. In line with Article 5 of Reg 2021/1165, cleaning products are still allowed that were authorized for use in organic production under Regulation (EC) No 834/2007 or under national law prior to the date of application of Regulation (EU) 2018/848. Thus, the Group agreed to prioritise the work on the exclusion criteria for cleaning products in 2025. In the meantime, the Group strongly recommend the use of ecolabeled products, wherever possible. A proposal is made in the chapter 3.6 below.

While most of this report is focused on disinfection in food processing, the approach towards formulated products and cleaning agents applies to all uses, including cleaning of machines, housing, barns etc. and should therefore be placed at the beginning of Annex Reg. 2021/1165, Annex IV (see proposal in the chapter 3.6 below). Until the Commission has taken decisions on these, the products available today should be available for organic production based on the previous legislation, including appropriate transition periods.

3.1.5 Criteria for evaluating biocidal active substances

In the Group's opinion, a responsible and ecological approach to cleaning and disinfection strategies, within organic operations, should form the basis to provide appropriate criteria for the evaluation of cleaning and disinfection products. At the same time, all the general principles of the Regulation (EU) 2018/848 (i.e. the prohibition for use of GMOs, ionising radiations, nanoparticles, etc.), should be considered for the evaluation of cleaning and disinfection substances.

Furthermore, as already pointed out in previous EGTOP reports, cleaning and disinfection is a complex matter not fully addressed so far, especially in reference to processing and storage. This is why the Group welcomes any effort that EGTOP will deem appropriate to reinforce the criteria defined in this report. The Group is aware that the legal framework for food safety is always the top priority. The criteria have thus to be set in a way that food safety for organic as well as conventional production is always assured. Especially considering that most of the companies are producing organic and conventional products, it is emphasised that the possibility of having only one cleaning system is highly recommended by the Group. Separate cleaning and disinfection processes for organic and conventional products are costly, time-consuming and prone to error and can be technically not advised. Nevertheless, as the organic regulation aims at "substantially contributing to a non-toxic environment" (Article 4(d) of Regulation (EU) 2018/848), Cleaning & Disinfection procedures at mixed facilities should be designed to reduce as much as possible their impact on the environment.

The present mandate (Chapter 2) covers criteria for substances used under regular conditions, except if the use of a substance is 'directly legally required', in the meaning of being directly required by provisions of European Union law or provisions of national law compatible with European Union law, or if no alternative substance is available which fulfils the set criteria and would suffice hygienic requirements for specific applications in food processing (e.g. mandatory use, set out by EU or national laws, of products and/or substances for cleaning and disinfections in relation to pathogens like Salmonella spp or Listeria spp).

[8] 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 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1–50). ELI: http://data.europa.eu/eli/reg/2009/1107/2022-11-21

For the evaluation criteria the Group agreed on the following:

- distinguishing between the biocidal active substance (1) and co-formulants/ cleaning substances (2) leading to 2 options in the first step of the decision tree
- taking into consideration the results of the RuDi project and the IFOAM one
- substances are evaluated for a certain period of time, and need to be re-evaluated after that time to consider changes in the evaluated properties
- a negative list should only contain clearly identified substances (incl. CAS numbers) not substance Groups
- Criteria on product specific exceptions might need to be developed.
- There is a list of approved biocidal active substances (so called "Union list" under Biocidal Product Regulation (EU) No 528/2012[9]) available which could serve as the basis of a "positive list" (the entrance point). Substances not approved due to risks or non-efficacy and substances not further supported by any manufacturer would be on the "negative list" by default. For substances on the positive list the additional criteria as mentioned above will be required.

Focusing in a first step to define criteria for suitable disinfectant (biocide) the following requirements need to be respected:

- Legally, only disinfectants with an approved biocidal active substance listed in the EU under BPR, Regulation (EU) No 528/2012 or active substances in the review program for relevant product types, according to the list of biocidal active substance on ECHA homepage[10], are allowed. This is a requirement already stated under Regulation (EU) 2018/848 and Regulation (EU) 2021/1165, Art. 5.
- High level of food hygiene needs always to be maintained (independent of the quality conventional or organic).
- The criteria should assure not to harm the environment and human health respecting Regulation (EU) 2018/848.
- A list of substances in Regulation (EU) 2021/1165 Annex IV Part C is legally demanded (negative or positive list)

Considering the defined preconditions the Group proposes the following criteria for the evaluation of products to be used for disinfection in processing and storage facilities of organic production:

(1) The cleaning and disinfection product which contains the substance under evaluation is evaluated in terms of environmental and health hazards, which are documented in the evaluation report of the biocidal active substance.

Explanation: This information is summarized and might be useful at a later stage.

(2) The substance is evaluated on its GMO status. It is evaluated if the substance contains GMOs. If so, the substance is rejected. The information should be taken from the dossier of the applicant, in case of doubt, this needs to be proven with certificate of analysis, provided by accredited laboratory.

(3) The substance is evaluated on its GMO status. It is evaluated if the substance is made by or from GMOs. If so, the substance is rejected. The information should be taken from the dossier of the applicant (where applicable showing the manufacturing flowchart and clearly stating that it is NOT made by or from GMOs).

Explanation: The importance of (2) and (3) is given by the fact that the use of GMOs is prohibited in the Regulation (EU) 2018/848 in Article 11: "Prohibition of the use of GMOs". However, it is not clearly stated that it also includes cleaning and disinfection products. However, several standards for household care products, e.g. Ecocert, Ecogarantie, NCP or the BNN only accept GMO-free products. At the moment the likelihood of biocides produced by using GM-technologies is low, but as can be seen in the sector of cleaning agents, GM-technologies can raise rapidly in importance. Due to the fast developments in this field, the suspected products should be first approved according to the GMO legislation before they could be considered for approval as biocides.

[9] https://echa.europa.eu/de/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/union-authorisation

[10] https://echa.europa.eu/de/information-on-chemicals/biocidal-active-substances

(4) The substance should not be used in form of nanoparticles; therefore, substances are excluded which contain "nano" in their substance name. This can be checked also on the ECHA homepage. In case of a nanomaterial, the substance is rejected.

Explanation: The organic regulation clearly refuses the presence of engineered nanoparticles in organic processed food (Regulation (EU) 2018/848, Article 7(e): "the exclusion of food containing, or consisting of, engineered nanomaterials"). Disinfectants in form of nanoparticles are not a relevant field yet, according to the Group. However, if available, these substances can be identified by the "nano" in their name as they are listed in the ECHA list. Thus, the Group identified this as a clear exclusion criteria for biocides used for disinfection in processing and storage facilities of organic production.

(5) The substance needs to be approved as a biocidal active substance under Biocidal Product Regulation (EU) No 528/2012 (BPR) or should be in the review program according to the list of biocidal active substances on the ECHA homepage. Depending on the intended use the substance needs to be approved or under assessment for product types PT1, PT2, PT 3, PT4 or PT5.

Explanation: By default, substances within PT4 are expected to be the most relevant for the organic food processing as these are intended for disinfection of materials that come into contact with food or feed. However, also hand disinfection (PT1), disinfection of water without direct contact to food or feed (falling under PT2), disinfection for veterinary hygiene or disinfection of drinking water (PT5) might play a role in food processing. Thus, the respective product types were not excluded.

The Group decided that biocides in approval process should not be generally excluded, as substances are applied for approval e.g. in PT4 but are still pending (in the frame of the review program). Products containing these substances are marketable at least until the decision is taken in the frame of BPR. The Group concludes that if they are excluded from the positive list by default, this might result in a lack of important and desirable substances in view of their hazard profile, such as for example Ethanol. The Group recommends accepting biocides in the approval process and already on the market if they fulfil the other criteria.

(6) According to the ECHA database, substances are excluded that are

- PBT Persistent, Bioaccumulative and Toxic
- vPvB Very Persistent, Very Bioaccumulative
- SVHC Substances of Very High Concern (carcinogenic, mutagenic, toxic to reproduction, endocrine disrupting chemicals)

Explanation: The database to decide on these criteria is the ECHA homepage, where the candidates for PBT, vPvB and SVHC[11] [12] are listed.

The exclusion of PBT, vPvB and SVHC provides a transparent, easily verifiable (database: ECHA) approach to avoid substances of very high concern in cleaning and disinfectant products (C&D) to be used in organic processing. The exclusion of PBT/vPvB/SVHC is feasible for organic processors and C&D producers.

Example: Glutaraldehyde is approved in PT4 → no nanomaterial → but is a SVHC (candidate list) → exclusion!

Properties which are not included in the criteria (they might be included partially or stepwise at a later stage, if necessary):

CLP classification (based on Regulation (EC) No 1272/2008): The Group decided on not considering the hazard classification of the product according to the Classification, Labelling and Packaging Regulation for the evaluation of the substances as the outcome of the RuDi project was that the CLP as criterion is quite complex, as the hazard statements to exclude are not easy to choose. Furthermore, the substance is only part of the formulation in the final product as available in the market. Depending on the concentration of the active substance it will have a different CLP classification than the substance and therefore the CLP of the active substance does not reflect the hazards of the final products. Additionally, the hazards of the substances according to the CLP are well-known and accessed in detail under BPR, so that suitable risk management and safety measures may lead to sufficient control of the hazards. On the other hand, guided from the organic principles, not to harm the environment and the human health,

[11] https://echa.europa.eu/de/candidate-list-table

[12] https://echa.europa.eu/de/pbt

it is considered as very important, but at the moment seen as too difficult to accomplish while assuring sufficient food safety: due to the intended effect of disinfectants, there will be few if not any biocidal active substances without CLP classification for human health and/or the environment available.

- The proposal is to keep the CLP classification as information in the evaluation criteria to have them present in the document. Whether or not the CLP classification could be already addressed in the dossiers of the applicants is still to be discussed. At regular re-evaluations of the substances, also the CLP classification need to be validated, as they can change due to new data.

The critical dilution volume (CDV) estimates the impact of a product on aquatic systems. It is used for example in the EU-Ecolabel for hard surface cleaning products. The method of the critical dilution volume is also not feasible here, because the CDV approach was developed for cleaning agents, not for biocides. When applied to disinfectants, there is a risk that important products could be excluded.

Chemically synthesised substances are not (also not partly) reason for restriction or exclusion. The reason is that many highly efficient biocidal substances are chemically synthesised substances and thus too important for food safety to exclude them. However, it should be stated that, wherever possible, substances of natural origin are preferred, i.e. plant based or mineral materials, over materials originating from chemical synthesis.

- No exclusion of chemically synthesized substances, however the Group highly recommend the use of chemically synthesized substances only where urgently needed and no other alternatives are available. This is based on the Article 24(3)(b), where products or substances from natural sources are preferred, but not obligatory. Due to food safety reasons, there is a need for many biocidal active substances, which can only be produced by chemical synthesis.

The evaluation of the substances regarding "treated by **ionized radiation**" is not considered in the criteria, as the treatment with ionized radiation is considered as an alternative to the use of biocides and therefore not relevant to the evaluation of the biocidal active substances. Furthermore, no reliable database is known to evaluate this criterion.

- The Group is convinced that no substances will appear that are produced by ionized radiation. In any case, it is forbidden to use ionic radiation as an alternative to disinfecting chemicals in organic disinfection.

The Group also reflected on the need to evaluate the **CO_2 equivalent** of the substances. The Group decided to not evaluate these properties, due to the lack of reliable information and complexity of the topic. Due to the absence of its explicit mentioning in the organic regulation, EGTOP considered not possible to set specific limits on the carbon footprint solely for disinfectants and cleaning agents to be used in organics.

Explanations about the advantages of an exclusion criteria list

The commission recommends on legal reasons to have a positive list as similar for the substances for the cleaning and disinfection of ponds, cages, tanks, raceways, buildings or installations used for animal production. On the commissions point of view a positive list is complete in itself. However, from a technical point of view, the members of the subgroup meetings recommend having clear criteria to evaluate the suitability of disinfectants and to have a negative list on unwanted substances. This is based on the following reflections and reasons:

All European frameworks (proposals for implementation of Regulation (EU) 2018/848 and already implemented private standards) for C&D products support a list of prohibited substances, as shown in Table 2. The European Input List (published by FiBL Europe) also uses a negative list, among other criteria, for the evaluation of cleaning and disinfection products. The EU Ecolabel is a voluntary ISO type I label (EN ISO 14024) for products. The criteria for the EU-Ecolabel for hard surface cleaning products aims to maintain better biodegradability and low toxicity to aquatic organism. The standard has a criterion of excluded and restricted substance (negative list) to be fulfilled by the formulation. Both IHO and AISE also recommend negative lists for the implementation of the regulation instead of a positive list. IFOAM concluded its preliminary work with stakeholders that a positive list of C&D substances could lead to a blockage of the sector and recommends a pragmatic approach based on a positive list of criteria at the C&D product level, pointing out that the negative list of substances approach seems not to be a realistic concept on a practical point of view. The RuDi project, coordinated by FiBL Germany concluded that for an EU-wide approach a brief negative list, limited to a few clearly defined problematic substances, combined with the exclusion of PBT, vPvB, and SVHC substances, would suit best to the request.

Other widely used eco-certification labels in Europe such as Ecocert or Ecogarantie, which are not only focussing on the biodegradability of household care products, but also strongly on the source of the ingredients and their production, also use strong exclusion criteria together with negative lists of forbidden substances. In addition, the National Organic Program (NOP) has successfully implemented a negative list to describe non-allowed detergents and Sanitizers for Food Contact Surfaces and Equipment in Organic Operation[13].

Table 2: Overview of different private standards or proposals for the implementation of Regulation (EU) 2018/848 and their habits regarding positive/negative lists, where 1: IHO: Industrieverband Hygiene und Oberflächenschutz; 2: AISE: International Association for Soaps, Detergents and Maintenance Products (source: results RuDI project presentation EGTOP meeting 16.9.23 Marlene Milan).

	EGTOP 2021 (Proposal for the implementation of Regulation (EU) 2018/848)	**European Input List** (Private standard for cleaning and disinfection products)	**EU Ecolabel** (Decision EU 2017/1217) (voluntary standard for cleaning products)	**IHO[1]/AISE[2]** (Proposal for the implementation of Regulation (EU) 2018/848)	**IFOAM OE** (Proposal for the implementation of Regulation (EU) 2018/848)	**RuDi** (First proposal for the implementation of Regulation (EU) 2018/848)
List of approved substances/ products (Positive list)	✓	X	X	X	X	X
Prohibited or restricted substances (Negative list)	✓	✓	✓	✓	✓	✓

The Group consents that a negative list in addition with clear criteria is manageable and will not discriminate new sustainable positive developments of cleaning and disinfectants by long examination procedures. Contrary, a positive list is not feasible with more than 1000 substances that should be evaluated, and all new substances need to be applied by the member states, proved and implemented in the annex. This procedure is very time consuming and costly. Thus, the negative list will fulfil better the overall goal not to harm environment and human health with inputs from cleaning and disinfectants. The Group decided that only clearly identified substances (incl. CAS numbers) and not substance Groups are to put on the negative list. To keep consistency, the Group proposes that the negative list Part C will be equally as the Regulation 2021/1165, Part D which is also a negative list as shown in Figure 1. Also, the Group is consent about naming it “list of exclusion criteria” instead of “negative list”.

13 https://www.ams.usda.gov/sites/default/files/media/8%20Cleaners%20and%20Sanitizers%20FINAL%20RGK%20V2.pdf

PART D

Products referred to in Article 12(1) of this Regulation

The following products or products containing the following active substances as listed in Annex VII to Regulation (EC) No 889/2008 cannot be used as biocidal products:

— caustic soda;

— caustic potash;

— oxalic acid;

— natural essences of plants with the exception of linseed oil, lavender oil and peppermint oil;

— nitric acid;

— phosporic acid;

— sodium carbonate;

— copper sulphate;

— potassium permanganate;

— tea seed cake made of natural camelia seed;

— humic acid;

— peroxyacetic acids with the exception of peracetic acid.

Figure 1: Example of a negative list in Regulation 2021/1165.

3.2 Negative list of active substances fulfilling the exclusion criteria

This list will contain substances which are complying with the exclusion criteria and will thus be rejected in organic production. This comprises substances that are “nano” materials – if found – and substances which are listed as active substance/ biocide and are listed as PBT, vPbB or SVHC.

-Glutaraldehyde

3.3 Case study: Evaluation of a set of dossiers submitted for active substances

The Group tested the criteria defined in chapter 3.1.5 on feasibility based on the evaluation of the substances which are listed in Table 3. The Group members which were evaluating the substances were consent that with the defined criteria a comprehensive and fast-forward evaluation was possible.

Table 3: Overview of the results of the first set of dossiers evaluated according to the criteria defined in chapter 3.1.3.

Substance	**Evaluation of the Subgroup**
Potassium peroxomonosulfate KMPS	Biocide -> acceptable
Chlorine dioxide	Biocide -> acceptable
Polyvinylpyrrolidone iodine	Biocide -> acceptable
Sodium hypochloride	Biocide -> acceptable
Calcium hypochloride	Biocide -> acceptable

Iodine	Biocide -> acceptable
Peracetic acid	Biocide -> acceptable
Hydrogen peroxide	Biocide -> acceptable
Formic acid	Biocide -> acceptable
Dipotassium peroxodisulfate	Co-formulants/ cleaning -> not assessed
Fatty acid potassium salt	Co-formulants/ cleaning -> not assessed
Sodium percarbonate	Co-formulants/ cleaning-> not assessed
Methane sulfonic acid	Co-formulants/ cleaning-> not assessed
Glutaraldehyde	Biocide -> not acceptable (SVHC)

3.4 TRANSFERRING THE LISTS OF AUTHORISED SUBSTANCES FROM THE OLD TO THE CURRENT ORGANIC REGULATION

At present, Annex IV to Regulation (EU) 2021/1165 contains no list of authorised products or substances for cleaning and disinfection. The transitional provisions in Article 12(1) of Regulation (EU) 2021/1165 allow using the products and substances from Annex VII to Regulation (EC) 889/2008. However, these transitional provisions expire on 31 December 2025. To ensure cleaning and disinfection beyond this date, the Group proposes the following:

- Cleaning agents not containing any biocidal active substances shall be explicitly authorized in Annex IV to Regulation (EU) 2021/1165.
- The active substances listed in Annex VII to Regulation (EC) 889/2008 shall be transferred to Part A of Annex IV to Regulation (EU) 2021/1165.
- However, those substances on Annex VII to Regulation (EC) 889/2008 which are not notified as biocidal active substances shall not be transferred. These are the substances identified in Part D of Annex IV to Regulation (EU) 2021/1165, but also potassium and sodium soap, and water and steam.

This approach results in a continuation of the current practices beyond the transitional period, but presents no innovation. As an exception, the Group proposes restricting the use of formaldehyde (see next paragraph). If there are wishes to authorise new substances or to restrict or phase out currently authorised substances, dossiers should be submitted. Please note the following:

- These proposals are intended for implementation as a whole. If only part of these proposals should be implemented, this could threaten the responsible approach to hygiene management.
- The Group has not included any references to the EU biocide legislation in the proposal, although it is clear that the requirements of biocide legislation must be respected. If such references should be added, it is important to keep in mind the situation in non-EU countries also.

Note on formaldehyde

When transferring the substances, the Group noted formaldehyde. Formaldehyde is classified as toxic, carcinogenic and suspected to be mutagenic. In the Group's opinion, such a substance is not in line with the reputation of organic production.

The Group is not aware of any use of formaldehyde in organic production. If an essential need for formaldehyde should be identified during the further discussions, the Group recommends to restrict the use of formaldehyde to these particular uses.

3.5 CONCLUSIONS

The Group consents on not excluding too many substances to not endanger the sufficient availability of suitable substances for cleaning and disinfection in processing and storage facilities. The Group also consents on evaluating single substances which are clearly identifiable with CAS numbers. However, it should be noted that substances can be formulated in products in many ways, and the products can be applied in many ways, so that an individual explanation of the use of the substance by the applicant in the dossier is very important, as well necessity of the use and absence of equivalent physical ways of maintaining the hygienic requirements of organic production.

The decision to evaluate single substances and not products lead the consequence of not implementing the CLP classification in the decision. As the final formulation is not known, the properties of the substance will not reflect the properties of the product. On top, the application of the products, their used dilution and application in open or closed systems for example, can increase or lower the risks for harming human or environmental health. Therefore, the CLP classification of the substance is neglected in the exclusion criteria.

To use preferably substances of natural origin, but to also accept the use of chemically synthesized substances lead the decision finally at the manufacturer's side which is difficult to steer. For this point the Group can only give recommendations. Disinfectants are not produced specifically for organic purposes. Therefore, too strictly requiring natural origin would lead to a situation where essential chemicals disappear from the alternatives available for organic producers.

The Group recommends to the applicants to describe the necessity and importance of the substance in the dossier. The advantages of this substance compared to others in the relevant application should be explained and alternatives should be named and compared to the substance. The product and its application should be described in terms of the risk assessment and possible hazards for the environment and human and animal health. This description is the basic information to evaluate the necessity and the specific conditions of use. In case there are no alternatives with better health and environmental profile of the substance, the urgent needs could be exceptionally considered for substances that normally comply with the exclusion criteria. The applicant shall, however, provide a clear reasoning for urgency in such cases.

- The exclusion of too many substances might lead to a reduced availability of compliant biocides and thus endanger the productivity of organic processors.
- The CLP classification of the substances is not reflected in the exclusion criteria, as the CLP classification changes with dilution (e.g. formulation of the product) and the hazards differ upon the application of the product.
- The Group recommends the use of substances and products, where available, from natural origin.
- The necessity, importance and alternatives of the substances should be explained in the dossier, as well as the application of the substance or the respective product.

3.6 RECOMMENDATIONS

1. Whenever possible, the Group recommends using naturally sourced substances and products (see chapter 3.1.5).

2. The Group recommends not to approve glutaraldehyde as a disinfectant to be used in organic production.

3. The Group recommends to transfer the lists of authorised active substances from Annex VII to Regulation (EC) 889/2008 to Part A of Annex IV of Regulation (EU) 2021/1165, taking into account the provisions of Part D of Annex IV of Regulation (EU) 2021/1165. This requires the following changes ((green, underlined = recommended insertion; ~~red, strike-out~~ = recommended deletion):

- Article 5(1) of Regulation (EU) 2021/1165 should be changed as follows:

  For the purposes of point (e) of Article 24(1) of Regulation (EU) 2018/848, only the products complying with the requirements given ~~listed~~ in Part A of Annex IV to this Regulation (...)

- Article 12(1) of Regulation (EU) 2021/1165 should be deleted.

- Annex IV to Regulation (EU) 2021/1165 shall be amended as follows:

ANNEX IV

Authorised products for cleaning and disinfection referred to in points (e), (f) and (g) of Article 24(1) of Regulation (EU) 2018/848

The following products shall be allowed for cleaning:

- Cleaning agents that are not considered disinfectants

PART A

Products for the cleaning and disinfection of ponds, cages, tanks, raceways, buildings or installations used for animal production

A.1 Livestock production

- Products for cleaning and disinfection of teats
- Products for cleaning and disinfection of milking facilities
- Products for cleaning and disinfection of buildings and installations for livestock production, containing only the following biocidal active substances:
  - ~~Potassium and sodium soap~~
  - ~~Water and steam~~
  - Milk of lime
  - Lime
  - Quicklime
  - Sodium hypochlorite (e.g. as liquid bleach)
  - ~~Caustic soda~~
  - ~~Caustic potash~~
  - Hydrogen peroxide
  - ~~Natural essences of plants~~
  - Citric, peracetic, formic, lactic, oxalic and acetic acid
  - Alcohol
  - ~~Nitric acid (dairy equipment)~~
  - ~~Phosphoric acid (dairy equipment)~~
  - Formaldehyde (appropriate restrictions to be defined)
  - ~~Sodium carbonate~~

A.2 Aquaculture: Products to be used in the absence of aquaculture animals, containing only the following biocidal active substances:

- Ozone
- Sodium hypochlorite
- Calcium hypochlorite
- Calcium hydroxide
- Calcium oxide
- ~~Caustic soda~~
- Alcohol
- ~~Copper sulphate: only until 31 December 2015~~
- ~~Potassium permanganate~~
- ~~Tea seed cake made of natural camelia seed (use restricted to shrimp production)~~
- Mixtures of potassium peroxomonosulphate and sodium chloride producing hypochlorous acid

A.3 Aquaculture: Products to be used in the presence of aquaculture animals, containing only the following biocidal active substances:

- Limestone (calcium carbonate) for pH control
- Dolomite for pH correction (use restricted to shrimp production)
- Sodium chloride
- Hydrogen peroxide
- Sodium percarbonate

- Organic acids (acetic acid, lactic acid, citric acid)
- ~~Humic acid~~
- ~~Peroxyacetic acids~~
- Peracetic and peroctanoic acids
- Iodophores (only in the presence of eggs)

PART B

Products for the cleaning and disinfection of buildings and installations used for plant production, including for storage on an agricultural holding

PART C

Products for cleaning and disinfection in processing and storage facilities

~~**PART D**~~

~~Products referred to in Article 12(1) of this Regulation~~

~~The following products or products containing the following active substances as listed in Annex VII to Regulation (EC) No 889/2008 cannot be used as biocidal products:~~

- ~~caustic soda;~~
- ~~caustic potash;~~
- ~~oxalic acid;~~
- ~~natural essences of plants with the exception of linseed oil, lavender oil and peppermint oil;~~
- ~~nitric acid;~~
- ~~phosphoric acid;~~
- ~~sodium carbonate;~~
- ~~copper sulphate;~~
- ~~potassium permanganate;~~
- ~~tea seed cake made of natural camelia seed;~~
- ~~humic acid;~~
- ~~peroxyacetic acids with the exception of peracetic acid.~~

4. Minority Opinions

No minority opinions were recorded.

5. List of Abbreviations/ Glossary

The following terminology is used in the context of this report and was defined in a former EGTOP meeting.

Active substance: Means a substance or a micro-organism that has an action on or against harmful organisms (definition in Article 3(1)(c) of the Biocidal Products Regulation (EU) No 528/2012).

Biocidal activity: Cleaning and disinfection are closely related and difficult to separate. As a theoretical concept, cleaning acts by “removal”, while disinfection acts by “killing”. In practice, many cleaning substances also have some toxic effect on micro-organisms, e.g. via high or low pH, or via surface activity against membranes. While some disinfecting substances also have a cleaning effect, e.g. strong oxidisers or alcohols. Hereinafter, within this document, the Group will consider the following distinction: a) if a product intended to have a biocidal effect, it is considered as a disinfectant; b) all other products are not considered as disinfectants.

Biocide: 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, any harmful organism by any means other than mere physical or mechanical action. The Regulation (EU) 528/2012 has established a list of active substances which may be used in biocidal products and a list of active substances which are still under examination and that may still be used in biocidal products according to transitional national rules in each Member State

BPR: Biocidal Product Regulation (EU) No 528/2012.

Chemically synthesized substance or product: Contrary to naturally sourced substances or products coming from plant-based materials or minerals, chemically synthesized substances or products have their origin in petrochemicals or have been created by chemical synthesis.

Cleaning: Cleaning is the removal of dirt without damaging the surface. In the context of organic production, the primary aim is to remove micro-organisms themselves and substances which serve as substrates for microbial growth, or which provide protective environments for bacteria to survive subsequent disinfection.

CLP: Classification, labelling and packaging of substances and mixtures. Regulation (EC) No 1272/2008.

Co-formulants: A co-formulant is any non-active substance or mixture that is intentionally added.

Decontamination: is the removal of harmful micro-organisms from food and feed or, in general, from surfaces without necessarily achieving sterilisation.

Descaling: is the removal of lime scale from surfaces which are in contact with water (e.g. milking equipment, irrigation pipes).

Detergents: The Detergents Regulation (EC) No 648/2004 entered into application in October 2005. The regulation establishes common rules to enable detergents and surfactants to be sold and used across the EU, while providing a high degree of protection to the environment and human health. It stipulates that surfactants used in detergents must be fully biodegradable. In addition, it regulates how products should be labelled with ingredient and dosage information to protect human health (e.g. skin allergies) and avoid overuse of detergents.

Disinfection: According to the Codex Alimentarius 'General Principles of Food Hygiene', the term 'Disinfection' means "the reduction, by means of chemical agents and/or physical methods, of the number of micro-organisms in the environment, to a level that does not compromise the health of the environment, of the animals and the food safety or suitability."

EU Ecolabel: Under the Regulation (EC) 66/2010 'EU Ecolabel', Commission Decisions establish detailed criteria, as well as the related assessment and verification requirements for the voluntary labelling of various products, e.g. detergents and cleaning products. The aim of the regulation is the minimisation of the environmental impact. Further info on the EU Ecolabel & on the criteria for Product Groups under the Cleaning product category: EU Ecolabel - Home & EU Ecolabel - Cleaning

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals): is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. REACH is governed by Regulation (EC) 1907/2006 of the European Parliament and of the Council10.

Residue: is a substance present in or on products of plant or animal origin, water resources, drinking water, food, feed or elsewhere in the environment, and resulting from the use of a biocidal product, including such a substance's metabolites, breakdown or reaction products (definition of Article 3(1)(h) of the Biocidal Products Regulation (EU) No 528/2012).

Resistance: Micro-organisms possess a wide range of properties and mechanisms to survive in environments where disinfectants are regularly used. Nowadays, mechanisms of disinfectant action and resistance have gained renewed attention, as connections between disinfectant tolerance and antibiotic resistance have become obvious. To design safe and effective disinfection strategies, that prevent bacterial tolerance/resistance development, knowledge on how bacteria and disinfectants interact under various conditions is essential.

Sterilisation: is the procedure of making some object free of live bacteria and other microorganisms, for example by heat or chemical means.

6. REFERENCES

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

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

REGULATION (EU) No 182/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1165 of 15 July 2021 authorising certain products and substances for use in organic production and establishing their lists

REGULATION (EC) No 648/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on detergents

Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation)

Information on biocides – European Chemicals Agency (ECHA): https://echa.europa.eu/de/information-on-chemicals/biocidal-active-substances

7. ANNEX

Decision tree with the criteria elaborated by the Group.