

**EGTOP/2020**



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Quality, Research & Innovation, Outreach  
**B.4. Organics**

**Expert Group for Technical Advice on Organic Production**

**EGTOP**

**Criteria for evaluation of products for cleaning and disinfection  
FinalReport**

The EGTOP discussed this technical report at the plenary meeting of 14 June, 2021 and finalised it at the plenary meeting of 16 June 2021.

Criteria for evaluation of products for cleaning and disinfection  
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***About the setting up of an independent expert panel for technical advice***

With the Communication from the Commission to the Council and to the European Parliament on a European action plan for organic food and farming adopted in June 2004, the Commission intended to assess the situation and to lay down the basis for policy development, thereby providing an overall strategic vision for the contribution of organic farming to the common agricultural policy. In particular, the European action plan for organic food and farming recommends, in action 11, establishing an independent expert panel for technical advice. The Commission may need technical advice to decide on the authorisation of the use of products, substances and techniques in organic farming and processing, to develop or improve organic production rules and, more in general, for any other matter relating to the area of organic production. By Commission Decision 2017/C 287/03 of 30 August 2017, the Commission set up the Expert Group for Technical Advice on Organic Production.

***EGTOP***

The Group shall provide technical advice on any matter relating to the area of organic production and in particular it must assist the Commission in evaluating products, substances and techniques which can be used in organic production, improving existing rules and developing new production rules and in bringing about an exchange of experience and good practices in the field of organic production.

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The report of the Expert Group presents the views of the independent experts who are members of the Group. They do not necessarily reflect the views of the European Commission. The reports are published by the European Commission in their original language only.

[http://ec.europa.eu/agriculture/organic/home\\_en](http://ec.europa.eu/agriculture/organic/home_en)

Criteria for evaluation of products for cleaning and disinfection  
Report

**ACKNOWLEDGMENTS**

Members of the EGTOP Group are acknowledged for their valuable contribution to this technical advice.

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All declarations of interest of Permanent Group members are available at the following webpage: [www.organic-farming.europa.eu](http://www.organic-farming.europa.eu)

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## EXECUTIVE SUMMARY

The Group made the following conclusions:

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.

Most of the considerations hereinafter reported are based on the previous reports delivered by EGTOP (i.e. Aquaculture Part B, adopted in 2014<sup>1</sup>; Cleaning and disinfection, adopted in 2016<sup>2</sup>). Indeed, in the group's opinion, the arguments reported in those documents are still valid and contribute effectively to outline a complete overview over the complex issue of the hygiene management and cleaning and disinfection.

The promotion of a responsible and ecological approach to cleaning and disinfection is the basis for a proper evaluation process of products to be used for cleaning and disinfection in the organic production. Such approach can be summarized as follows:

1. Limit harmful microbial populations as much as possible with non-chemical methods.
2. Reduce microbial risks through conditions which do not favour growth of microbial species of concern.
3. Use chemical biocides (disinfectants) only when other methods are not sufficient.
4. Carefully clean before disinfection, to minimise the quantities of biocides (disinfectants) needed.
5. Avoid using substances which cause environmental concerns or residues in food or feed.
6. Ensure through training proper application of preventive measures, cleaning and (biocides) disinfectants, as well as management of waste water and detergents.

The substances currently listed in Annex VII of Regulation (EC) 889/2008 serve one or several of three purposes: disinfection, descaling and cleaning. However, a number of substances from Annex VII serve multiple purposes (often to unequal degrees)<sup>3</sup>. Provided that these uses are in line with the horizontal legislation (biocides and detergents) it may be unpractical to list the substances which may be used for each purpose (i.e. disinfectants and cleaners in separate lists), in particular when also under the organic rules no distinction would be made. The Group, therefore, recommends keeping the expression 'cleaning and disinfection' in the Annex VII of the Reg. (EC) 889/2008. In any case, substances with biocidal function should be clearly identified in the Annex and their use in organic farming must be compliant with the Biocidal Products Regulation (BPR) (EU) 528/2012 and the cleaning products with the Regulation (EC) No 648/2004 on detergents.

Co-formulants improve characteristics such as the product's appearance, shelf-life, effectiveness or user-friendliness. The composition of preparations is adapted to the intended use of each product and co-formulants often are not declared on product labels. It is therefore not possible for farmers, certifiers, etc. to select products based on their co-formulants. However, in the Group's opinion, specific measures to exclude a limited number of co-formulants with undesirable properties, would be appropriate.

In the Group' opinion, the use of ecolabelled<sup>4</sup> products should be preferred to other products,

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<sup>1</sup> [EGTOP reports on organic production | European Commission \(europa.eu\)](#)

<sup>2</sup> [EGTOP reports on organic production | European Commission \(europa.eu\)](#)

<sup>3</sup> However, this approach may not be consistent with horizontal rules and in order to clearly describe their function(s), consideration may have to be given to list substances in separate lists, while the same substance may be included in several lists if found appropriate.

<sup>4</sup> Reg. (EC) 66/2010 on the EU Ecolabel

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where possible. In the new structure for Annex VII ecolabelled products should be included in the basic lists, while non-ecolabelled cleaning products should be included in the restricted lists.

In consideration of the classification of substances according to their hazard with respect to human health and/or the environment, laid down in the Regulation (EC) 1272/2008, as well as the provisions on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), laid down in the Regulation (EC) 1907/2006, a list of substances is drawn up that should be excluded from a positive list of the EU organic regulation.

The approach of the critical dilution volume (CDV), developed by the Commission Decision (EU) 2017/1217, is applied to ensure that only products with low eco-toxicity and good biodegradability in aquatic environments are allowed in the organic regulation.

Tensioactives must have an ultimate biodegradability greater than 60% within 28 days and anaerobic biodegradability greater than 60%. In the long term, this criteria of biodegradability should be extended to all the other substances, step by step.

The Group fully supports the new structure of Annex VII previously proposed by EGTOP, where for some non-controversial substances (i.e. basic list), the organic regulation should not add further restrictions beyond those already included in the general legislation and product authorization. While, all the substances and products for cleaning and disinfection, which may be used for limited purposes, which must be specified, should be included in a restricted list.

According to the feedback received so far by Member States, a priority list of substances to be evaluated, which is made up of five groups, has been agreed.

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## **1. TERMS OF REFERENCE**

In light of the most recent technical and scientific information available to the experts, as well as on the basis of the previous EGTOP Reports “Aquaculture – Part B 2014” and “Cleaning and disinfection 2016”, and considering the suggestions received by MSs and FiBL, the Group is requested:

- To agree on a responsible and ecological approach to cleaning and disinfection strategies within organic operations. On such basis, to provide appropriate criteria for evaluation of products for cleaning and disinfection.
- To conceive the criteria for evaluation of products for cleaning and disinfection in order to be applied to all fields of organic production (stables and livestock buildings, bee-keeping facilities, aquaculture, plant production, water irrigation systems, etc.), as well as to post-harvest applications (storage, processing, transport) and to milking facilities.
- To carry on some worked examples of evaluation of products for cleaning and disinfection based on the above defined criteria.
- To endorse a priority list of substances to be fully evaluated, while a list of substances already evaluated for other purposes will get a “bridging” evaluation.
- To schedule the work for evaluating the substances on the priority list and, if necessary, select experts to be involved in the substance assessment.

## 2. CONSIDERATIONS AND CONCLUSIONS

### 2.1. General consideration

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.

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 taken into account for the evaluation of cleaning and disinfection substances.

Furthermore, as already pointed out in a previous EGTOP report, 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 the next EGTOP will deemed appropriate to reinforce the criteria defined in this report (see point 2.4).

However, most of the considerations hereinafter reported are taken from the previous reports delivered by EGTOP (i.e. Aquaculture Part B, adopted in 2014; Cleaning and disinfection, adopted in 2016). Indeed, in the group's opinion, the arguments reported in those documents are still valid in a general way and contribute effectively to outline a complete overview over the complex issue of the hygiene management and cleaning and disinfection.

Finally, it should be noted that the process of evaluation and approval of substances will require a significant effort in terms of work of expert staff in the different topics. This is why any delays in the preparation of dossiers relating to the substances to be authorized pursuant to Article 24 of the Regulation (EU) 2018/848 might hinder the entire process of evaluation and approval of these substances.

This report has been revised at the light of comments and suggestions provided to the Commission by Member States and several stakeholders.

### 2.2. Terminology

The following terminology will be used in the context of this report.

**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 contains at least one substance which is

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classified as a biocidal active ingredient, 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<sup>5</sup>. The Regulation (EU) 528/2012<sup>6</sup> 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

**Cleaning<sup>7</sup>:** Cleaning is the removal of ‘dirt’. 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.

**Co-formulants:** substances other than active substances in products are referred to as ‘co-formulants’, sometimes also referred to as ‘formulating agents’ or as ‘inert ingredients’.

**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<sup>8</sup> 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 in order to protect human health (e.g. skin allergies) and avoid overuse of detergents.

**Disinfection<sup>9</sup>:** 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.”

**Ecolabel:** The Regulation (EC) 66/2010 ‘EU Ecolabel’ provides detailed criteria, as well as the related assessment and verification requirements for the voluntary labelling of various products. The aim of the regulation is the minimisation of the environmental impact.

**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 Council<sup>10</sup>.

**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

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<sup>5</sup> See for the complete definition in Regulation (EU) 528/2012

<sup>6</sup> OJ L 167, 27.6.2012, p.1.

<sup>7</sup> Article 2(3) of Regulation (EC) 648/2004: ‘Cleaning’ has the meaning defined by EN ISO 862

<sup>8</sup> OJ L 104, 8.4.2004, p 1.

<sup>9</sup> Definition used in the ECHA guidance document on efficacy of biocides :

[https://echa.europa.eu/documents/10162/23036412/bpr\\_guidance\\_assessment\\_evaluation\\_part\\_vol\\_ii\\_part\\_bc\\_en.pdf/950efefa-f2bf-0b4a-a3fd-41c86daae468](https://echa.europa.eu/documents/10162/23036412/bpr_guidance_assessment_evaluation_part_vol_ii_part_bc_en.pdf/950efefa-f2bf-0b4a-a3fd-41c86daae468)

<sup>10</sup> OJ L 396, 30.12.2006, p.1.

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.

### 2.3. A responsible and ecological approach

The ecological and responsible approach to cleaning and disinfection, for all kind of possible applications from farm to fork, is about finding the right balance between the need for sufficient cleaning and disinfection and the requirement to strictly limit the use of chemically produced external inputs in organic production. Important elements of this approach are: i) achieving a high level of safety, ii) limiting the use of biocides (disinfectants) to what is strictly necessary, iii) reducing to the minimum environmental impacts of disinfection and iv) achieving the minimal risk levels of residues in organic products (food and feed).

There is not a single solution which fits all the above elements. In addition, such approach need to be adapted to the specific conditions of individual operations, in the context of an integrated hygiene plan, which must be implemented by well-trained staff.

Long-term microbiological safety also includes minimisation of the risk of micro-organisms building up resistance against control methods. 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 too.

There are numerous methods for reducing microbial populations that do not involve the use of chemical disinfectants (non-chemical methods), such as easy-to-clean design of buildings and installations, appropriate organisation of processes and working schedules, tidy working habits, choice of high quality raw materials, etc. Washing, cleaning and hot water/steam are of particular importance in most situations. Finally, such an approach is only successful, if it is implemented by well-trained staff. Physical disinfection technologies may complement this approach in some situations. Physical methods are the basis of good hygiene, and of primary importance for preventing contamination and limiting growth of microbial populations.

Non-chemical methods sometimes have complex modes of action. For example, well aerated soil in poultry ranges may reduce the levels of pathogens that are found in organic poultry houses, probably due to alterations of the soil microflora (e.g. biological mode of action mediated by management practices).

Chemical methods of disinfection should only be used as a complement to the non-chemical methods. Indeed, cleaning and disinfection are only parts of systems assuring food and feed safety. Control of the factors affecting growth of micro-organisms is also important. Of these, temperature, pH (acidity) and water activity are the most relevant factors. These factors also determine which micro-organisms are best adapted and may predominate in the microbiota. They usually are harmless, or even part of the desired flora on fermented foods. Therefore, cleaning and disinfection methods should always be more effective against pathogenic micro-organisms than against those micro-organisms involved in fermentations or in spoilage of the food (spoilage symptoms warn the consumer from eating food that could be hazardous as a

consequence of e.g. time and temperature abuse).

There are many examples showing that colonisation of a biotope by harmless micro-organisms may also reduce the risk of growth of pathogenic contaminants. Examples are antagonists to *Listeria monocytogenes* present on the surface microbiota of certain surface-ripened cheese, human skin and large intestine, where the autochthonous strains inhibit colonisation by pathogens, or compost with antagonistic effects on plant pathogens.

The ecological and responsible approach to cleaning and disinfection is a typical example of 'good organic practice', which is primarily the responsibility of each individual organic operator. The full development of such an approach would require further scientific basis for supporting policy. The outcome might be a set of guidelines for different situations.

### ***2.3.1. Summary of criteria for a responsible and ecological approach to cleaning and disinfection***

The promotion of a responsible and ecological approach to cleaning and disinfection is the basis for a proper evaluation process of products to be used for cleaning and disinfection in the organic production. Such approach can be summarized as follows:

1. Limit harmful microbial populations as much as possible with non-chemical methods.
2. Reduce microbial risks through conditions which do not favour growth of microbial species of concern.
3. Use chemical biocides (disinfectants) only when other methods are not sufficient.
4. Carefully clean before disinfection, to minimise the quantities of biocides (disinfectants) needed.
5. Avoid using substances which cause environmental concerns or residues in food or feed.
6. Ensure through training proper application of preventive measures, cleaning and (biocides) disinfectants, as well as management of waste water and detergents.

The Group is concerned about the potential use and impact of the presence of manufactured nano-particles in cleaning and disinfection products. As Regulation (EU) 2018/848 requires the exclusion of food containing, or consisting of, engineered materials but does not mention their use as cleaning and disinfection products, there is the need of an in-depth assessment of such aspect.

## **2.4. Evaluation criteria for cleaning and disinfection products**

### ***2.4.1. Need for a range of authorised substances***

The main targets of disinfection are fungi, bacteria, viruses, protozoa and algae, as well as certain parasites in the case of livestock production and aquaculture. Most disinfectants have a broad activity against these organisms. Therefore, the choice of disinfectant does not depend much on its species-specific activity, but mainly depends on whether the object to be treated tolerates the disinfectant (e.g. alcohols are aggressive to certain plastics, acids and alkaline substances are caustic, hypochlorite and hydrogen peroxide are corrosive to certain materials, etc.). Thus, many disinfectants, which would theoretically be effective, cannot be used in practical situations, because they would harm the installations, equipment, machinery or tools, or raise concern about safety, or risk for the environment. For this reason, organic operators need to have a choice of available disinfectants, which allow them to treat all materials in most situations.

#### **2.4.2. *Disinfection, descaling and cleaning***

The substances currently listed in Annex VII of Regulation (EC) 889/2008 serve three purposes: disinfection, descaling and cleaning. However, a number of substances from Annex VII serve multiple purposes (often to unequal degrees), so that (provided that these uses are allowed under the horizontal rules) it may be unpractical to list the substances which may be used for each purpose (i.e. disinfectants and cleaning products in separate lists). The Group, therefore, recommends keeping the expression ‘cleaning and disinfection’ in the Annex VII of the Regulation (EC) 889/2008.

Nonetheless, the use of biocidal products, in organic farming, must be compliant with the Biocidal Products Regulation (BPR) (EU) 528/2012. Indeed, disinfectants are the substances of major concern in organic production, because they are toxic to micro-organisms and, sometimes, also to other organisms. In the Group’s opinion, the highest priority should be attributed to a clear regulation of active substances for as many uses as possible. Substances from Annex I to the Biocidal Products Regulation should be preferred or authorized as a group. Descaling can be seen as a special case of cleaning, where the ‘dirt’ to be removed consists mainly of calcium carbonate, and is not subject to biocide legislation. The presence of lime scale may interfere with the functioning of tubes, pipes or taps, but may also facilitate the deposition of other dirt particles, with subsequent microbial growth. Thus, descaling is also important for microbial safety. In the Group’s opinion, a clear regulation of descaling agents in relation to different uses would be also desirable.

In the Group’s opinion, cleaning is an essential step in hygiene management, and good cleaning reduces the need for use of disinfectants. Water, steam, potassium and sodium soap are an extremely limited range of cleaning agents and are not sufficient to guarantee good cleaning under all conditions. Nevertheless, it is strongly recommended the use of substances which degrade rapidly and completely and leave no residues. QACs (Quaternary ammonium compounds) and hypochlorite are widely used, but the Group has concerns that contamination incidents may be caused by their use, just as it may be by use of these compounds as disinfectants.

#### **2.4.3. *Co-formulants of commercial products***

Co-formulants improve characteristics of the products such as the product’s appearance, shelf-life, effectiveness or user-friendliness. For example, stabilisers are needed to increase shelf-life, thickeners improve the adherence time to treated surfaces, foam suppressers are needed for use in high-pressure cleaners, buffers and sequestrants (chelating agents) reduce the corrosiveness towards surfaces and prevent deposition of scale. Surfactants are particularly important. On one hand, they are the primary constituents of cleaning products, which make particles such as oil and wax water-soluble. On the other hand, they may be ingredients of disinfectant products where they lower the surface tension of water, which results in a better wetting of the surfaces and also of dirt particles and microorganisms. In this way, the efficacy and effectivity of the active substance is increased. Finally, surfactants may have a negative impact on microbial cell membranes and may thus contribute to the reduction of micro-organisms.

The composition of products is adapted to the intended use of each product and co-formulants often are not declared on product labels. It is therefore not possible for farmers, certifiers, etc. to select products based on their co-formulants. However, in the Group’s opinion, specific measures to exclude a limited number of co-formulants with undesirable properties, would be appropriate. The group therefore recommends the Commission to plan, for the coming years, the setting of criteria to define acceptable co-formulants and the process to assess and verify their presence in order to allow operators and certification bodies to identify clearly which

formulated product will be allowed in organic production.

#### **2.4.4. Ecolabelled cleaning products**

The Regulation (EC) 66/2010 ‘EU Ecolabel’ provides detailed criteria for the voluntary labelling of various products. Detailed criteria for the labelling of certain types of cleaners are laid down by Commission Decision (EU) 2017/1217 of 23 June 2017. In order to be awarded the EU Ecolabel, a cleaning product, which fall within the product group ‘hard surface cleaning products’, shall comply with the criteria, as well as the related assessment and verification requirements, set out in the Annex to the Commission Decision (EU) 2017/1217.

The aim of the EU ecolabel is the minimisation of the environmental impact and is in line with the objectives and principles of organic production in terms of environment. Therefore, from an environmental point of view, it is advisable to use ecolabelled cleaning products. However, the Group is aware that ecolabelled products may not cover all cleaning needs of organic production.

In the Group’ opinion, the use of ecolabelled products should be preferred to other products, where possible. In the new structure for Annex VII, highlighted in the paragraph 2.5, ecolabelled products should be included in the basic lists, while non-ecolabelled cleaning products should be included in the restricted lists. The Group considers that other labelling schemes, who have at least the same requirements for environment and health of the EU ones (e.g. the Nordic Swan ecolabel), after being evaluated by EGTOP, might be put on the basic list as well.

#### **2.4.5. Prohibition of unwanted substances**

In consideration of the classification of substances according to their hazard with respect to human health and/or the environment, laid down in Regulation (EC) 1272/2008, the following substances<sup>11</sup> cannot be considered for the inclusion in a positive list of the EU organic regulation:

- Active substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1A or 1B.
- Active substances that meet the criteria required to be classified as respiratory sensitizers.

In consideration of the provisions on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), laid down in the Regulation (EC) 1907/2006, the following substances cannot be considered for the inclusion in a positive list of the EU organic regulation:

- Active substances which are designated as substances with endocrine disrupting properties in accordance with Article 57(f) and Article 59(1) of the above mentioned Regulation.
- Active substances that meet the criteria for designation as very Persistent and very Bio-accumulative substances.
- Active substances that meet two of the criteria required to be considered a Persistent,

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<sup>11</sup> For biocidal active substances, another approach, for simplification and in view of the horizontal rules, would be to consider to avoid allowing actives substances which meets the exclusion criteria set out in Article 5(1) of the BPR and active substances meeting the substitution criteria under Article 10(1) of the BPR.

The above criteria, when considering active substances, exclusion substances are covered, and partly substitution substances (respiratory sensitizer, endocrine disrupter for the environment).

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Bioaccumulative and Toxic (PBT) as referred to in Annex XIII to the above mentioned Regulation.

Products for animal care that are classified, by Regulation (EC) 1272/2008, with the hazard statements reported in the table below should not be considered for the inclusion in a positive list of the EU organic regulation (for natural plant extracts and oils present up to a maximum of 5% in the formulation, hazard statements are not taken into account).

H300	H310	H311	H317	H330	H340	H350
H350i	H360	H360F	H360D	H360FD	H360Fd	H360Df
H362	H370	H372	H410	H411	H420	EUH070

In addition, active substances or co-formulants in the following tables are not allowed due to their toxicity and/or environmental impact:

<b>Unwanted tensides</b>
<ul style="list-style-type: none"> <li>• Alkylphenolethoxylate (APEO)</li> </ul>
<ul style="list-style-type: none"> <li>• Fluorosurfactants</li> </ul>
<ul style="list-style-type: none"> <li>• Quaternary ammonium compounds (QACs)</li> </ul>

<b>Unwanted acids (including their salts)</b>
<ul style="list-style-type: none"> <li>• Phosphates</li> </ul>
<ul style="list-style-type: none"> <li>• Phosphoric acid esters</li> </ul>
<ul style="list-style-type: none"> <li>• Phosphonic acid</li> </ul>
<ul style="list-style-type: none"> <li>• Phosphonic acid ester / Polyphosphonates</li> </ul>
<ul style="list-style-type: none"> <li>• Phthalic acid esters / Phthalates</li> </ul>
<ul style="list-style-type: none"> <li>• Persistent long-chain polycarboxylic acids (short-chain, such as ascorbic acid, tartaric acid, citric acid, are permitted)</li> </ul>

<b>Unwanted other components</b>
<ul style="list-style-type: none"> <li>• Biphenyl-2-ol</li> </ul>
<ul style="list-style-type: none"> <li>• Chlorine releasing substances / Active chlorine / Electrolyte water</li> </ul>
<ul style="list-style-type: none"> <li>• Triclosan</li> </ul>
<ul style="list-style-type: none"> <li>• Perchlorates</li> </ul>
<ul style="list-style-type: none"> <li>• Ethylenediaminetetraacetic acid (EDTA), Diethylenetriaminepentaacetic acid (DTPA), Nitrilotriacetic acid (NTA) and their salts as well as other comparable chemical-synthetic chelators</li> </ul>
<ul style="list-style-type: none"> <li>• Formaldehyde und formaldehyde-releasing substances</li> </ul>
<ul style="list-style-type: none"> <li>• Ammonia and ammonia-releasing substances</li> </ul>
<ul style="list-style-type: none"> <li>• Amino-alcohols (monoethanolamine, diethanolamine)</li> </ul>
<ul style="list-style-type: none"> <li>• Synthetic nanoparticles (&lt; 0.3 µm)</li> </ul>
<ul style="list-style-type: none"> <li>• Enzymes</li> </ul>
<ul style="list-style-type: none"> <li>• Bromine compounds</li> </ul>

#### 2.4.6. *Ecotoxicity and biodegradability*

The approach of the critical dilution volume (CDV), developed by the Commission Decision (EU) 2017/1217, is applied to ensure that only products with low eco-toxicity and good biodegradability in aquatic environments are allowed in the organic regulation.

The requirements concerning eco-toxicity and biodegradability are applied to all product groups, except for products for animal care.

The  $CDV_{\text{chronic}}$  of all-purpose undiluted cleaning products shall not exceed the concentrations of 10000 (l/l of cleaning solution).

The  $CDV_{\text{chronic}}$  is calculated for all ingoing substances (i) in the product, except micro-organisms, using the following equation:

$$CDV_{\text{chronic}} = \sum CDV(i) = 1\,000 \cdot \sum \text{dosage}(i) \cdot \frac{DF(i)}{TF_{\text{chronic}}(i)}$$

Where:

$\text{dosage}(i)$ : weight (g) of the substance (i) in the reference dose;

$DF(i)$ : degradation factor for the substance (i);

$TF_{\text{chronic}}(i)$ : chronic toxicity factor for the substance (i).

The values of  $DF(i)$  and  $TF_{\text{chronic}}(i)$  shall be as given in the most updated Part A of the Detergent ingredient database (DID) list<sup>12</sup>.

Tensioactives must have an ultimate biodegradability greater than 60% within 28 days and anaerobic biodegradability greater than 60%. In the long term, this criteria of biodegradability should be extended to all the other substances, step by step.

### 2.5. **New structure of Annex VII**

The Group fully supports previous considerations made by EGTOP, that for some non-controversial substances (i.e. basic list), the organic regulation should not add further restrictions beyond those already included in the general legislation and product authorization.

Such an approach has been previously suggested by EGTOP in the Report on organic food (2012)<sup>13</sup>, in the Report on greenhouse production (Protected Cropping) (2013)<sup>14</sup>, in the Report on plant protection products II (2014)<sup>15</sup> and in the Report on Aquaculture part B (2014)<sup>16</sup>. In analogy, the Report on cleaning and disinfection (2016) highlights that such approach can be equally applied to livestock and plant production. Nonetheless, the use of biocidal products, in organic farming, must be compliant with the Biocidal Products Regulation (BPR) (EU) 528/2012.

The proposed new structure of Annex VII is the following:

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<sup>12</sup> [https://ec.europa.eu/environment/archives/ecolabel/product/pg\\_did\\_list\\_en.htm](https://ec.europa.eu/environment/archives/ecolabel/product/pg_did_list_en.htm)

<sup>13</sup> [EGTOP reports on organic production | European Commission \(europa.eu\)](#)

<sup>14</sup> [EGTOP reports on organic production | European Commission \(europa.eu\)](#)

<sup>15</sup> [EGTOP reports on organic production | European Commission \(europa.eu\)](#)

<sup>16</sup> [EGTOP reports on organic production | European Commission \(europa.eu\)](#)

Criteria for evaluation of products for cleaning and disinfection  
Report

<b>1. Products for use in buildings and installations for livestock production, crop production, processing product, packaging, transport and storage of product.</b>
1.1 Basic list of substances and products for cleaning and/or disinfection, which may be used for all purposes authorised under general legislation:
<i>(EU Ecolabelled cleaning products may be included in this basic list)</i> ..... .....
1.2 List of substances and products for cleaning and/or disinfection, which may be used for limited purposes. In different columns, it should be specified a) for which use is authorized, b) if it is a biocide .
..... ..... .....

<b>2. Products for use in aquaculture, both in the presence or absence of animals</b>
2.1 Basic list of substances and products for cleaning and/or disinfection and for the management of aquatic ecosystems, which may be used for all purposes authorised under general legislation:
<i>(EU Ecolabelled cleaning products may be included in this basic list)</i> ..... .....
2.2 List of substances and product for cleaning and/or disinfection, which may be used for limited purposes. In different columns, it should be specified a) for which use is authorized, b) if it is a biocide.
..... ..... .....

<b>3. Products for use in aquaculture, only in the absence of animals</b>
3.1 Basic list of substances and product for cleaning and/or disinfection, which may be used for all purposes authorised under general legislation:
<i>(EU Ecolabelled cleaning products may be included in this basic list)</i> ..... .....
3.2 List of substances and product for cleaning and/or disinfection, which may be used for limited purposes. In different columns, it should be specified a) for which use is authorized, b) if it is a biocide.
..... ..... .....

## **2.6. Priority list of substances to be evaluated**

According to the feedback received so far by Member States, the priority list of substances to be evaluated is made up of five groups, as shown below:

1. Substances prioritised by two or more Member States, without objections, not covered by authorisations in organics : 39 substances.
2. Substances prioritised by one Member State, without objections, not covered by authorisations in organics : 77 substances.
3. Substances prioritised by one or more Member States, without objections, already covered by authorisations in organics: 102 substances.
4. Substances prioritised by one or more Member States but deprioritised/objected by one or more Member States: 335 substances.
5. Substances not prioritised by Member States : 742 substances.

Substances in the first and second group have higher priority and will be fully evaluated once the dossiers will be made available to EGTOP.

Substances in the third group will be examined with a simplified procedure and, in principle, could not require the preparation of a dossier by the Member States.

## **2.7. References EGTOP Report on organic food, adopted in 2012**

- EGTOP Report on greenhouse production adopted in 2013
- EGTOP report Aquaculture Part B, adopted in 2014
- EGTOP Report on plant protection products II, adopted in 2014
- EGTOP report Cleaning and disinfection, adopted in 2016
- Reg. (EC) 889/2008 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
- Reg. (EU) 2018/848 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007
- Reg. (EU) 528/2012 concerning the making available on the market and use of biocidal products
- Reg. (EC) No 648/2004 on detergents
- Reg. (EC) 66/2010 on the EU Ecolabel
- Reg. (EC) 1907/2006 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
- Commission Decision (EU) 2017/1217 establishing the EU Ecolabel criteria for hard surface cleaning products
- Reg. (EC) 1272/2008 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