

Products for cleaning, disinfection and hygiene

Basic admission criteria for the European Input List

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1. Introduction

This document describes the criteria that need to be fulfilled in order for cleaning, disinfection and hygiene products to be included in the European Input List. Additional criteria may apply for products to be included in a national list or a list of a private association. This document will be updated whenever necessary. The most recent version, which is available on the project website (www.inputs.eu), is the only valid version.

This document is based on the relevant EU legislation. EU organic farming is governed by a 'framework regulation' plus an 'implementing regulation'. By 1 January 2022, both of the current regulations will be repealed by new regulations¹. For the time being, this document provides references to the old as well as the new organic legislation. However, it also comprises additional criteria, which were set by FiBL, in order to ensure compliance with the objectives and principles of organic production. These criteria take into account effects on human health and/or the environment as well as the risk of causing residues. Furthermore, the scope of uses is broader than the one covered by the EU organic legislation.

2. Requirements concerning the composition

This chapter describes a set of requirements which are applied either to the components of a product or to the product as a whole. Not all requirements apply to all product types. Tab. 1 explains which requirements apply to which types of products.

¹ Reg. (EC) 834/2007 repealed by Reg. (EU) 2018/848; Reg. (EC) 889/2007 repealed by Reg. (EU) 1165/2021

Table I: Overview showing which requirements apply to which products (yes = applies; no = does not apply).

Requirement	Product for use in ...				
	Livestock buildings and installations, aquaculture	Milking facilities	Crop production	Processing	Animal care
Active substances in Annex VII (see section 2.1)	yes	no	no	no	no
Exclusion of unwanted substances (see section 2.2)	yes	yes	yes	yes	yes
Exclusion of substances with unwanted properties (see section 2.3)	yes	yes	yes	yes	yes ²
Refined assessment of impact on the aquatic environment (see section 2.3.1)	yes	yes	yes	yes	no

2.1 Allowed active substances

Background

The EU organic legislation contains a list of substances for cleaning and disinfection (Annex VII of Reg. 889/2008³). The European Input List has adopted this list. However, formaldehyde is a substance of very high concern⁴ and is therefore prohibited by several organic farming associations.

In line with the interpretation of EGTOP⁵, the European Input List applies Annex VII only to active substances. Note: In certain countries (e.g. Austria, The Netherlands), national legislation specifies which active substances may be used in organic crop

² with exceptions, see chapter 2.4

³ For the time being, the substances that were authorized under the old regulation (Annex VII of Reg. 889/2008) may continue to be used under the new organic regulation (see Article 5(4) of Reg. 2021/1165).

⁴ It is classified as toxic and carcinogenic, and suspected to be mutagenic, see <https://echa.europa.eu/nl/substance-information/-/substanceinfo/100.000.002>.

⁵ Expert Group for Technical Advice on Organic Production

production. Where this is the case, this legislation is taken into account by the complementary national admission criteria.

Annex VII applies in different ways, depending on the field of use. For cleaning and disinfection of *buildings and installations for livestock production*, section 1 of Annex VII applies. For cleaning and disinfection of *milking facilities and teats*, Annex VII of Reg. 889/2008 allows all substances. For cleaning and disinfection in *crop production and processing facilities*, Annex VII of Reg. 889/2008 contains no provisions at the moment. Thus, the European Input List does not apply Annex VII of Reg. 889/2008 for such products. For cleaning and disinfection in *aquaculture*, section 2 of Annex VII of Reg. 889/2008 applies. At the moment, however, the European Input List does not include such products and has therefore not developed a policy for such products.

Application of requirements

The requirements concerning active substances are applied

- to all products for use in buildings and installations for livestock production, but
- not to products for other uses.

Requirements

- All components which are active substances must be listed in section 1 of Annex VII of Reg. 889/2008.

2.2 Prohibition of unwanted substances

Background

Commercial products for cleaning and disinfection contain not only active substances, but also a wide range of other substances (so-called co-formulants). Because the EU organic legislation does not regulate these components, the team of the European Input List has developed its own policy, taking into account other legislation and expertise

such as REACH⁶, EU Ecolabel⁷, the EU Detergents Regulation⁸ and the EGTOP reports on cleaning and disinfection⁹.

Safeguard clause

In addition to the requirements outlined in this document, as well as in the General Business contract, the European Input List reserves the right to exclude all substances or products from all categories if there is a reasonable scientific suspicion that they could have serious adverse effects on human health and/or the environment (e.g. carcinogenic, mutagenic, toxic to reproduction, endocrine disrupting, toxic to aquatic organisms, low biodegradability, persistent).

Application of requirements

The requirements concerning unwanted substances are applied

- to all products groups.

Requirements

- The substances listed in Table 2 are not allowed in the products.

⁶ REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

⁷ COMMISSION DECISION (EU) 2017/1217 of 23 June 2017 establishing the EU Ecolabel criteria for hard surface cleaning products.

⁸ REGULATION (EC) No 648/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on detergents

⁹ EGTOP report on cleaning and disinfection (2016); Criteria for evaluation of products for cleaning and disinfection, Draft Report (2020)

Table 2: Unwanted substances.

A) Unwanted tensides
<ul style="list-style-type: none">• Alkylphenoethoxylate (APEO)• Fluorosurfactants• Poorly biodegradable quaternary ammonium compounds (QAC's)
B) Unwanted acids (including their salts)
<ul style="list-style-type: none">• Phosphoric acid and its salts (phosphates) (small amounts up to maximum 1% are tolerated in all products; use in products for dairy equipment is allowed)• Phosphoric acid esters• Phosphonic acids (H_3PO_3) and their salts are excluded (exception: organophosphonic acids and their salts e.g. HEDP, DTPMP, ATMP, PBTC are permitted up to maximum 1%)• Phosphonic acid ester / Polyphosphonates• Phthalic acid esters / Phthalates• Persistent long-chain polycarboxylic acids (short-chain, such as ascorbic acid, tartaric acid, citric acid, are permitted)• Boron-containing acids• Methoxyacetic acid (exception: in glycolic acid permitted up to maximum 0.6 %)• Methyl methanesulphonate (MMS) (exception: in methanesulphonic acid up to maximum 0.001 %)

C) Unwanted other components

- Biphenyl-2-ol
- Electrolyte water
- Other chlorine releasing substances / Active chlorine
- Chlorine dioxide
- Diethanolamine
- Monoethanolamine
- Ortho-, Meta- and Para-Phenylenediamine (PPD / PDA)
- Chlorofluorocarbons
- Triclosan
- Perchlorates
- Ethylenediaminetetraacetic acid (EDTA), Diethylenetriaminepentaacetic acid (DTPA), Nitrilotriacetic acid (NTA) and their salts, as well as other comparable synthetic chelating agents
- Formaldehyde-releasing substances
- Ammonia and ammonia-releasing substances
- Synthetic nanoparticles (< 0.3 µm), in particular silver nanoparticles
- Enzymes of GMO origin (note: enzymes of non-GMO origin are allowed)
- Bromine compounds

2.3 Exclusion of substances with unwanted properties

Background

Substances are classified with certain hazard statements according to Reg. 1272/2008. This indicates their hazards with respect to human health and the environment. Many substances with unwanted properties have been categorized as 'unwanted substances' by the European Input List (see above). As an additional safeguard, the European Input List also excludes other substances that are classified with the hazard statements shown in Tab. 3.

Application of requirements

The requirements concerning substances with unwanted properties are applied to all product categories.

Requirements

- Components which are classified with one of the hazard statements relating to human health (given in Table 3A) are excluded.
- Products which are classified with one of the hazard statements relating to impact on the aquatic environment (given in Table 3B) are only accepted, if a refined assessment of the product at use concentrations shows that the CDV is below the values given in section 2.3.1.
- The evaluation team may exceptionally allow a component that is classified with H 317, H 334 or H 372, if (i) the risk for the user is minimized by the mode of application and (ii) there are no suitable alternatives.
- Exceptions for *natural plant extracts and oils*:
 - the hazard statements H317, H410 and H411 are not taken into account
 - all other hazard statements are only taken into account for components that make up at least 5 % in the formulation.
- Exceptions for *enzymes*: the hazard statements H317, H334, H410 and H411 are not taken into account.
- Exception for *substances explicitly mentioned in Annex VII of Reg. 889/2008*: hazard statements are not taken into account.

Table 3: Hazard statements defining unwanted properties in the context of the European Input List.

A) Hazard statements relating to human health					
H300	H310	H317	H330	H334	H340
H350	H350i	H360	H360F	H360D	H360FD
H360Fd	H360Df	H370	H372		
B) Hazard statements relating to impact on the aquatic environment					
H410	H411				

2.3.1 Refined assessment of impact on the aquatic environment

Background

For the refined assessment of impact on the aquatic environment, the European Input List applies the approach of the 'critical dilution volume' (CDV), which was developed for the EU Ecolabel¹⁰. Whereas all previously described criteria apply to individual components of products, the CDV applies to the product as a whole. This approach takes into account the chronic aquatic toxicity, degradation and concentration of each component as well as the proportions of the components in the product and the use concentrations of the product. For more explanations, see the summary in Annex I or the full description in the EU-Ecolabel.

Application of requirements

- The refined assessment of impact on the aquatic environment is only applied for products which are classified with one of the above hazard statements relating to the aquatic environment (table 3B).
- The refined assessment of impact on the aquatic environment is not applied to products for animal care.

Requirements

- The CDV_{chronic} for the reference dosage for undiluted products may not exceed 18 000 l/l of cleaning solution.
- The CDV_{chronic} for the reference dosage for ready-to-use products may not exceed 350 000 l/l of cleaning solution.

Definition for the reference dosage for the calculations:

- Ready-to-use products: 1 litre of the product.
- Undiluted products: highest dosage recommended for regular use (in g/l or ml/l of cleaning solution).

¹⁰ COMMISSION DECISION (EU) 2017/1217 of 23 June 2017 establishing the EU Ecolabel criteria for hard surface cleaning products

2.4 Products for animal care

Background

Animal care products¹¹ are not regulated in the EU organic legislation. Based on the objectives and principles of organic farming, the European Input List has developed separate approval criteria for these products. Animal care products are grouped into the main category of cleaning, disinfection and hygiene products. Not all national lists contain animal care products.

Application of requirements

- *Unwanted substances*: the requirements of chapter 2.2 apply.
- *Substances with unwanted properties*: the requirements of chapter 2.3 apply, with the exception of aspects relating to aquatic toxicity.
 - the hazard statements H410 and H411 are not taken into account
 - the refined assessment of impact on the aquatic environment with CDV calculation does not apply.

2.5 Products for stable hygiene, bedding materials

Background

Some national lists also contain products that are used as bedding materials or applied onto bedding materials. Such products are included in the main category of products for cleaning, disinfection and hygiene. However, these products fall into the border zone between disinfection, hygiene, parasite control, feed and fertilizers. Such products are not explicitly covered by the Annexes of Reg. 889/2008.

Application of requirements

To ensure consistency with the objectives and principles of organic production, the European Input List applies the following policy: Depending on the purpose and mode of action of an individual product, the evaluation team will decide case by case which set of the basic admission criteria is appropriate to be applied. The general legislation must be respected as applicable (e.g. the feed law). In the following, the FiBL policy is illustrated for selected types of products.

¹¹ Under the heading 'products for animal care', the European Input List groups products such as products for cleaning, disinfection and care of teats, products for the care of fur and claws.

2.5.1 Bedding materials

Bedding materials are typically composed of materials such as straw, wood chips or cellulose pellets. Such products are normally evaluated according to the criteria for fertilizers, soil conditioners and crop management tools.

2.5.2 Products for stable hygiene

Disinfectants for bedding materials and other products not classified under the category 'bedding materials' are pooled under the denomination 'products for stable hygiene'. Due to the variable nature of the products in this category, different sets of criteria may be applied in individual cases. Where possible, the criteria developed for products for cleaning, disinfection and hygiene will be applied.

3. Compliance with general legislation

The European Input List requires products to comply with relevant general EU and national regulations. In the context of cleaning, disinfection and hygiene, the following aspects are particularly relevant:

- Products with a disinfecting effect must be registered in compliance with biocide legislation.
- For products which are not registered as disinfectants, no claims of a disinfecting effect may be made.

It is the responsibility of the applicant company to comply with the general legal requirements. The European Input List reserves the right to verify the information provided by the applicant in this regard as part of its internal quality assurance. If there is insufficient evidence of compliance with general legislation, it may postpone the listing until the applicant has demonstrated legal compliance.

Annex I: Calculation of the Critical Dilution Volume (CDV)

The method for calculating the chronic Critical Dilution Volume (CDV) is explained in the EU-Ecolabel¹². The formula for calculating the CDV is as follows:

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

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 $DF(i)$ and $TF(i)$ are taken from the 'Detergent ingredient database' list (DID list).

Based on the EU-Ecolabel¹³ the following exemptions are used for the calculation of CDV:

- Hydrogen peroxide (H_2O_2): not to be included in calculation of CDV
- Peracetic acid: to be included in the calculation as 'acetic acid'.

¹² COMMISSION DECISION (EU) 2017/1217 of 23 June 2017 establishing the EU Ecolabel criteria for hard surface cleaning products

¹³ COMMISSION DECISION (EU) 2017/1219 of 23 June 2017 establishing the EU Ecolabel criteria for industrial and institutional laundry detergents