Products for crop and animal health

Basic Admission Criteria

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1. Introduction

This document is published by the Research Institute of Organic Agriculture (FiBL) and EASY-CERT services GmbH organic inputs evaluation (EASY-CERT). It describes the criteria that need to be fulfilled in order for products for crop health[1] and animal health[2] to be included in any of the FiBL and EASY-CERT Input Lists. Additional criteria may apply for products to be included in a national list or a list of a private association for organic farming. The document will be updated whenever necessary. The most recent version, which is available on the websites of FiBL (www.input-list.com) and EASY-CERT (www.betriebsmittelbewertung.at), is the only valid version. Annex I of Reg. (EU) 2021/1165 was primarily elaborated in the context of plant protection. However, the same Annex I governs also the range of substances which may be used for the control of animal parasites.

The Basic Admission Criteria

EU organic farming is governed by a basic Regulation (Reg. (EU) 2018/848 as amended) plus the implementing regulation (Reg. (EU) 2021/1165 as amended). The Basic Admission Criteria, developed by FiBL and EASY-CERT, are a competent interpretation of this legislation, enabling a standardised evaluation of inputs for organic farming in Europe and a harmonised, cross-border approach. They provide the basic requirements that must be met for products to be included in any of the FiBL and EASY-CERT Input Lists.

Since national legislation is nevertheless relevant with regard to the categorization of certain products, there may be national differences in the conformity of individual products, due to applicable national legislation.

Scope of products included

Annex I of Reg. (EU) 2021/1165 covers products for plant protection including basic substances. FiBL and EASY-CERT Input Lists cover a broader scope of products and include also products such as beneficials (macrobial biocontrol agents), adjuvants and other products used in the context of crop health, as well as products against parasites on livestock.

[1] In this document, the term 'products for crop health' refers to plant protection products, basic substances, beneficials and adjuvants.

[2] In this document, the term 'products for animal health' refers to products for use against animal parasites, such as poultry mites, stable flies etc. Veterinary drugs are not subject to an additional evaluation.

Safeguard clause

In addition to the requirements in this document as well as in the general business contract, FiBL and EASY-CERT reserve the right to exclude substances or products from all categories if the evaluation team considers that their use does not comply with the objectives and principles of organic production according to Reg. (EU) 2018/848 Art. 4 and Art. 5, or if there is evidence 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).

2. Products for crop health: Compositional requirements

2.1 Requirements for plant protection products

Background

Pesticidal active substances are explicitly mentioned and regulated in Annex I of Reg. (EU) 2021/1165.

Requirements

- Active substances contained in plant protection products are restricted to those listed in Annex I of Reg. (EU) 2021/1165.
- Regarding co-formulants, see separate section below.
- The product is neither a genetically modified organism (GMO[3]) itself, nor does it contain any such organism, nor was it produced "from", or "by" a GMO. For materials with an increased GMO risk[4], the respective template confirming their GMO-free status must be provided.
- Materials of marine origin (Chitosan hydrochloride, Laminarin) are restricted to sustainable sources[5]. FiBL and EASY-CERT provide a specific form[6] to declare conformity of such materials with the applicable requirements.

2.2 Requirements for basic substances

Background

Basic substances for use in organic production are regulated in Annex I of Reg. (EU) 2021/1165. The authorised uses can be found in the respective review reports (available for download from the EU Pesticides Database[7]).

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[3] GMO, as defined in Article 3 and 11 of the Regulation (EU) No 2018/848

[4] See GMO-Risk List on www.input-list.com and www.betriebsmittelbewertung.at/en/

[5] Marine chitosan hydrochloride shall derive from organic aquaculture or from sustainable fisheries, as defined in Article 2 of Regulation (EU) No 1380/2013 of the European Parliament and of the Council; Laminarin shall be obtained from Kelp grown in organic aquaculture or collected in n a sustainable way in accordance with point 2.4 of Part III of Annex II to Regulation (EU) 2018/848.

[6] See Declaration on sustainability for materials sourced from aquatic environment on www.input-list.com and www.betriebsmittelbewertung.at/en/

[7] https://ec.europa.eu/food/plants/pesticides/eu-pesticides-database_en

Requirements

- Basic substances are allowed for the authorized uses, if they are explicitly mentioned in Annex I of Reg. (EU) 2021/1165.

2.3 Requirements for adjuvants

Background

In this document, the term 'adjuvant' refers to products which may be used in combination with other authorised products, for example spreaders/stickers.

As per Art. 9(3)(b) of Reg. (EU) 2018/848, adjuvants are generally allowed, if used in combination with plant protection products. To ensure consistency with the objectives and principles of organic production, the following criteria are being verified during product evaluation:

Requirements

- Safety for humans and the environment has to be demonstrated, either with a.) a valid authorization as spreaders / stickers or adjuvants with the relative competent authority of an EU country, or b.) with data on toxicity and environmental behaviour (i.e. ecotoxicity profile) for the product.
- The main ingredient(s) should preferably be of natural origin, identical to a natural substance or derived from a natural substance. Other materials are evaluated case by case.
- For co-formulants, see separate section below.

2.4 Requirements for trapping and mating disruption systems

Background

Trapping systems usually consist of a combination of an *attractant* and a *killing agent*. The attractant may be a pheromone, another volatile substance (often related to the smell of food) or a board with certain colour. The killing agent may be an insecticide, a liquid where the insect drowns or a sticky surface. Mating disruption systems usually consist of one or several pheromones and a dispensing device. Under pesticide legislation, certain pheromones or other attractants and certain killing agents are considered as active substances, while others are not. Annex I of Reg. (EU) 2021/1165 allows pheromones. Components of trapping systems such as coloured panels, sticky traps, glues etc. are not regulated by Reg. (EU) 2021/1165.

Requirements

- Pheromones, as listed in Annex I of Reg. (EU) 2021/1165 are allowed.
- If applicable, the trade product must be authorized by the competent authority in the respective country.
- Attractants: Hydrolysed proteins (excluding gelatine) and diammonium phosphate (in traps) may be used; other attractants can be authorized case by case, if they are not classified as pesticides.
- Other components of trapping or mating disruption systems such as coloured panels, sticky traps, glues and aerosol sprayers are generally allowed.
- For propellants in aerosol cans and similar, the relevant EU regulations apply, compliance therewith is the sole responsibility of the companies. However, the evaluation team reserves the right to obtain confirmation of compliance with the relevant regulations for the products concerned (e.g. chemicals belonging to the group of FCKWs and HFKW).

2.5 Requirements for beneficials

Background

In this document, the term 'beneficials' refers to animals such as predatory insects and mites, entomopathogenic nematodes etc., which are also known as 'macrobial biocontrol agents' or 'natural enemies'. Beneficials have traditionally been used for crop protection purposes in organic farming, and their use is in line with Reg. (EU) 2018/848, Art 6(d) and Annex II, Part I, 1.10.1. The use of beneficials has two very different aspects:

- The use of *suitable species* as beneficials is clearly beneficial for humans and the environment.
- By contrast, the use of *unsuitable species* might lead to uncontrolled mass-development and may ultimately threat native species. Events such as the introduction of the ladybird species *Harmonia axyridis* into Europe have to be avoided.

Requirements

Beneficials are regulated very differently across Europe. Several European Countries require beneficials to be authorized. Others do not impose any authorization requirement. Hence, the following applies:

- Where applicable, laws regarding the release of non-native animal species must be respected.
- Where applicable, the product must be registered in the country of listing (see chapter 4).

2.6 Requirements for related products

Technical materials in the category of plant protection and related products encompass products such as wound sealings, trunc paints, UV-protectants. While products containing active substances for plant protection are subject to authorization on member state level, products containing other materials are not.

Requirements

- For products subject to plant protection authorization, the respective active substance(s) need to be listed in Annex I of Reg. (EU) 2021/1165.
- For products exempted from authorization the main materials should be natural or of natural origin. If synthetic materials are being used, the products are subjected to a case-to-case evaluation.
- For co-formulants see separate section below.

2.7 Requirements for co-formulants

Background

In this document, materials other than active substances are referred to as 'co-formulants'. As per Art. 9(3)(b) of Reg. (EU) 2021/1165, co-formulants are generally allowed, if used in combination with plant protection products. FiBL and EASY-CERT do not restrict the use of co-formulants to certain substances, as this would limit the potential for innovations in this field. However, to ensure consistency with the objectives and principles of organic production, the following requirements apply:

Requirements

- All co-formulants must explicitly be declared towards the evaluation team.
- Natural substances should be used in preference.
- Co-formulants must not be harmful to humans or the environment. The evaluation team reserves the right to request additional information, particularly on environmental fate and on residues in soil and/or crops.
- The EPA's old list 4, and the 'Safer Choice' database may be consulted for orientation purposes.
- Phosphonic acid (H_3PO_3) and its salts are excluded (exception: organophosphonic acids and their salts e.g. HEDP, DTPMP, ATMP. PBTC are evaluated case by case).
- Substances mentioned in Reg. (EU) 2021/383 may not be present in any products, including products that are not subject to registration as plant protection products.

- Co-formulants for which compliance with the principles of organic farming is questionable because they are in contradiction to the principles of organic production (e.g. easily soluble nitrogen compounds such as ammonia, urea) are evaluated case by case.
- Certain co-formulants are known for their problematic residue behaviour. In order to prevent residues in organic goods, the evaluation team reserves the right to request evidence to verify this aspect.

3. Products for animal health: compositional requirements

3.1 Products for use in stables

Background

Products against animal parasites (e.g. products against the poultry mite, products against stable flies) are included in some national input lists. According to Reg. (EU) 2018/848, active substances used for the elimination of insects and other pests in buildings and other installations where livestock is kept are regulated in Annex II, Part II, 1.5.1.7.

Requirements

- Active substances listed in Annex I of Reg. (EU) 2021/1165 are allowed.
- In terms of active substances and other natural materials than those listed in listed in Annex I of Reg. (EU) 2021/1165, such as plant oils, are evaluated case by case.
- The composition including co-formulants must fulfil the same requirements as mentioned above for plant protection products / beneficials.
- Pyrogenic silica, due to its synthetic origin, is not allowed.
- The national registration requirements must be respected.

3.2 Products for use on animals

Background

Products for control of parasites by direct application on animals are not covered by Reg. (EU) 2021/1165. To ensure consistency with the objectives and principles of organic production, the FiBL and EASY-CERT Input Lists cover also such products.

Requirements

- For products for use on animals, the same criteria apply as for products which are used in stables (see above).

4. Compliance with general legislation

The FiBL and EASY-CERT Input Lists include only products that comply with the applicable EU and national legislation. Compliance with general legislation is in the responsibility of the applicant companies. However, if evaluation teams suspect that a product does not comply with the relevant legislation, they may postpone inclusion into the list until the applicant has demonstrated legal compliance. The following table summarizes the most important requirements for different product groups. However, national evaluation teams may require compliance with additional legislation for their lists.

Product group	Requirement
Crop and animal health	
Trapping and mating disruption systems	**Where applicable, the product must be authorized in the country of listing.**
Beneficials	**Where applicable, laws regarding the release of non-native animal species must be respected. Where applicable, the product must be authorized in the country of listing.**
Crop health	
Plant protection products	**The product must be authorized as a plant protection product in the country of listing. Emergency authorizations may also be accepted.**
Basic substances	**The substance must be approved as a basic substance at EU level[8].**
Adjuvants	**Where applicable, the product must be authorized in the country of listing.**
Animal health	
Products against animal parasites (for use in stables; for use on animals)	**The product must meet the marketability requirements of the country of listing. This may include a registration / notification as a biocide. Veterinary drugs are not included into the FiBL and EASY-CERT Input Lists and hence not subject to evaluation.**

[8] See EU pesticides database >Search active substances > Type: Basic substance

5. Recommendations for use

It is the responsibility of the applicant companies to ensure that the recommendations for use of their products given on product labels, technical sheets, publications and websites are consistent with organic farming practices. If the national evaluation teams suspect that a product is intended for a use that does not comply with organic farming practices, they may postpone inclusion into the list or remove the product from the list until the applicant has amended the recommendations for use accordingly.

Impressum

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