FiBL Europe

Products for crop and animal health

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 products for crop health[1] and animal health[2] 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.

Annex I of Reg. 2021/1165 was primarily elaborated in the context of plant protection. However, the same Annex governs also the range of substances which may be used for the control of animal parasites.

The European Input List – a private standard

The European Input List is a private standard. It is based on the relevant EU legislation (in particular Reg. 2021/1165). However, it also comprises additional criteria and interpretations, which were set by FiBL, in order to ensure compliance with the objectives and principles of organic production.

Scope of products included

Annex I of Reg. 2021/1165 covers products for plant protection including basic substances. Additionally, the European Input List covers a broader scope of products and includes 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 domestic animals.

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 substances or products from all product categories 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).

[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.

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. 2021/1165.

Requirements

- Active substances in Plant Protection Products are restricted to those listed in Annex I of Reg. 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", "by" or "involving" any GMO.
- Synthetic nano-particles[4] are not allowed.
- Materials of marine origin (chitosan hydrochloride, laminarin) are restricted to sustainable sources. FiBL provides a specific form to declare conformity of such materials with the applicable requirements.

2.2 Requirements for basic substances

Background

Basic substances are regulated in Annex I of Reg. 2021/1165. The authorised uses can be found in the review reports (download from the EU Pesticides Database[5]).

Requirements

- Basic substances are allowed, if they are explicitly mentioned in Annex I of Reg. 2021/1165.

[3] GMO, as defined in Article 3 and 11 of the Regulation (EU) No 2018/848
[4] definition of nanoparticles:
https://ec.europa.eu/environment/chemicals/nanotech/faq/definition_en.htm
[5] https://ec.europa.eu/food/plants/pesticides/eu-pesticides-database_en

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. Adjuvants have traditionally been used in combination with plant protection products but to some extent, they are also used in combination with foliar fertilizers, plant strengtheners or other crop management tools.

Adjuvants are generally allowed, if used in combination with plant protection products (Reg. 2018/848, Art. 9(3)(b)). To ensure consistency with the objectives and principles of organic production, the European Input List has developed admission criteria for adjuvants.

Requirements

- Safety for humans and the environment has to be demonstrated, either with a registration as spreaders / stickers or adjuvants, or with data on toxicity and biodegradability for the product.
- The main ingredient(s) should be of natural origin, identical to a natural substance or derived from a natural substance. Other materials are evaluated case by case (see section on co-formulants).
- Adjuvants (to be mixed with plant protection products), may not contain unacceptable co-formulants mentioned in Reg. 2021/383.

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. 2021/1165 allows all pheromones, if they are used in traps or dispensers. Furthermore, it lists 'hydrolysed proteins except gelatine' and diammonium phosphate for use as attractants. Other components of trapping systems such as coloured panels, sticky traps, glues etc. are not regulated by Reg. 2021/1165.

Requirements

- All pheromones are acceptable, when used in traps or dispensers.
- Attractants: Hydrolysed proteins (excluding gelatine) and diammonium phosphate 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. However, materials with a negative impact on humans or the environment may be excluded case by case. For example, pheromone aerosol sprayers may not contain gases which affect the earth's ozone layer.

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. 2018/848, Art 6(d) and Annex II, Part I, 1.10.1. Beneficials are regulated very differently across the EU. There is no EU legislation, but some member states have national legislation. 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.

To ensure consistency with the objectives and principles of organic production, the European Input List has developed admission criteria for beneficials.

Requirements

- The species must be native in the country of the list. Exceptionally, other species may be accepted, if the applicant demonstrates that there is no risk of ecological damage.
- 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 co-formulants

Background

In this document, materials other than active substances are referred to as 'co-formulants'. Under the EU organic legislation, co-formulants are generally allowed, if used in combination with plant protection products (Reg. 2018/848, Art. 9(3)(a)). To ensure consistency with the objectives and principles of organic production, the European Input List has developed admission criteria for co-formulants which take into account effects on human health and/or the environment (including, but not limited to the list of substances that may not be present as co-formulants in plant protection products according to Reg. 2021/383) as well as the risk of causing residues.

The European Input List does not want to restrict the use of co-formulants to certain substances, as this would limit the potential for innovations in this field. Instead, it applies a scheme based on the following principles:

- Natural substances should be used in preference, but other materials may be accepted, provided that the applicant can demonstrate their need and that they are not harmful to the user or the environment.

Requirements

- All co-formulants must explicitly be declared towards the evaluation team.
- Where a synthetic co-formulant is used, the applicant might be asked to demonstrate that the desired effect cannot be achieved with a natural substance.
- If synthetic co-formulants are necessary, the applicant might be asked to demonstrate that they are added in the lowest possible amounts.
- Co-formulants must not be harmful to humans or the environment. FiBL reserves the right to request additional information, particularly on environmental fate and on residues in soil and/or crops. If the applicant fails to demonstrate the need to use a co-formulant, or if he fails to demonstrate that the co-formulant does not cause residues in crops or animal products and has no unacceptable effects on human health and the environment, the product will be rejected.
- The following substances are not accepted as co-formulants:
  - EDTA; HEEDTA; DTPA; [o,o] EDDHA; [o,p] EDDHA; [o,o] EDDHMA; [o,p] EDDHMA; EDDCHA; EDDHSA; HBED and other poorly biodegradable chelating agents;
  - Alkylphenols and their ethoxylates (e.g. NPE, OPE) and other substances classified as endocrine disruptors;
  - 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. 2021/383 may not be present in any products, including products that are not subject to registration as plant protection products.
  - Piperonyl butoxide (PBO): In line with the EGTOP recommendations[6], the European Input List requires that products do not contain PBO in all cases.
- Manufacturers are free to choose those co-formulants which they consider to be most appropriate. The EPA's old list 4, and the 'Safer Choice' database may be consulted for orientation purposes. Substances authorized for use in food are normally accepted.
- Co-formulants must not act as plant nutrients (e.g. ammonium compounds) and must not have a plant protection / biocidal effect (e.g. preservatives).

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. 2018/848, Annex II, Part II, 1.5.1.7, the active substances listed in Annex I of Reg. 1165/2021 can be used for the elimination of insects and other pests in buildings and other installations where livestock is kept.

Kieselgur (diatomaceous earth) is a natural deposit of the shells of certain micro-algae called 'diatoms' and consists mainly of amorphous silicium dioxide ('silica'). It can be used as an insecticide/acaricide in food storage and in stables. There are other insecticides with a similar composition, similar mode of action but synthetic origin, called 'pyrogenic silica'. Because of the similarity, there is some uncertainty in the organic sector whether pyrogenic silica is allowed. The European Input List interprets Annex I of Reg. 2021/1165 in such a way that kieselgur is allowed, while pyrogenic silica is not allowed.

Requirements

- The composition including co-formulants must fulfill the same requirements as mentioned above for plant protection products / beneficials.
- Pyrogenic silica is not allowed.

[6] See EGTOP report on plant protection products (II).

- The national registration requirements must be respected.
- Piperonyl butoxide (PBO): In line with the EGTOP recommendations[7], the European Input List requires that products do not contain PBO in all cases.

3.2 Products for use on animals

Background

Products for control of parasites by direct application on animals are not covered by Reg. 2021/1165. To ensure consistency with the objectives and principles of organic production, the European Input List covers 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 European Input List requires products to comply with relevant general EU and national regulations. 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. The following table describes the most important requirements for different product groups.

Product group	Requirement
Crop and animal health	
Adjuvants	Where applicable, the product must be registered in the country of listing.
Trapping and mating disruption systems	Where applicable, the product must be registered 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 registered in the country of listing.

[7] See EGTOP report on plant protection products (II).

Crop health	
Plant protection products	The product must be registered 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].
Animal health	
Products against animal parasites (for use in stables; for use on animals)	The product must be registered / notified as a biocide (or possibly as a veterinary drug[9] in the case of products for use on animals) in the country of listing.

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

[9] Veterinary drugs are not subject to an additional evaluation.