

Products for crop and animal health

Basic admission criteria for the European Input List

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Table of Contents

| | |
|---|----------|
| 1. Introduction | 1 |
| 2. Products for crop health: Compositional requirements | 2 |
| 2.1 Requirements for plant protection products | 2 |
| 2.2 Requirements for basic substances | 2 |
| 2.3 Requirements for adjuvants..... | 2 |
| 2.4 Requirements for trapping and mating disruption systems..... | 3 |
| 2.5 Requirements for beneficials..... | 4 |
| 2.6 Requirements for co-formulants | 4 |
| 3. Products for animal health: compositional requirements..... | 6 |
| 3.1 Products for use in stables | 6 |
| 3.2 Products for use on animals..... | 7 |
| 4. Compliance with general legislation | 7 |

I. Introduction

This document describes the criteria that need to be fulfilled in order for products for crop health¹ and animal health² 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 only ‘pesticides – plant protection products’. By contrast, the European Input List covers a broader scope of products and includes also products such as basic substances, beneficials (macrobial biocontrol agents), adjuvants and other products used in the context of crop health, as well as products against parasites on domestic animals.

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 explicitly excluded.

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.

2.2 Requirements for basic substances

Background

Basic substances are regulated in Annex I of Reg. 2021/1165. For those basic substances which are food and have plant or animal origin, there is a single entry in Annex II which authorises all these substances collectively. Other basic substances (i.e. not of plant/animal origin or not food, for example sodium hydrogen carbonate) are only authorised, if they are explicitly mentioned in Annex II.

Requirements

- Basic substances which are food and have plant or animal origin are allowed.
- Other basic substances are allowed, if they are explicitly mentioned in Annex I of Reg. 2021/1165.

2.3 Requirements for adjuvants

Background

In this document, the term 'adjuvant' summarizes 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

- The main ingredient(s) must be of natural origin or listed in Annex I or Annex II of Reg. 2021/1165. In case of substances listed in Annex I, these substances must not have a pesticidal effect.
- Safety for humans and the environment has to be demonstrated (e.g. registration as adjuvant / spreader/sticker in a European country or with data on toxicity and biodegradability).
- Regarding 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. 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 an exceptionally 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 threaten 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 the species cannot form permanent populations in the wild.

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 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 flexible 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

- Where a synthetic co-formulant is used, the applicant must demonstrate that the desired effect cannot be achieved with a natural substance.
- If synthetic co-formulants are necessary, the lowest possible amounts must be used.
- Co-formulants must not be harmful to the user or the environment. Endocrine disruptors (including potential endocrine disruptors) are not accepted. This applies to all alkylphenols and their ethoxylates, including nonylphenol and dodecylphenol. EDTA is not allowed as co-formulant. 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.
- 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.
- Co-formulants must not act as plant nutrients (e.g. ammonium compounds) and must not have a plant protection / biocidal effect (e.g. preservatives).
- Preservatives may be used in products in the lowest effective concentration but must be explicitly declared to the evaluation team.
- **Note on piperonyl butoxide (PBO):** The legal status of PBO has changed over time and varies across the EU. In line with the EGTOP recommendations³, the European Input List requires that products do not contain PBO in all cases.

³ See EGTOP report on plant protection products (II).

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 products listed in Annex II, 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 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 must fulfill the same requirements as mentioned above for plant protection products / beneficials.
- Pyrogenic silica is not allowed.
- The national registration requirements must be respected.
- **Note on piperonyl butoxide (PBO):** The legal status of PBO has changed over time and varies across the EU. In line with the EGTOP recommendations⁴ and with the policy for plant protection products (see above), the European Input List requires that products do not contain PBO in all cases.

⁴ See EGTOP report on plant protection products (II).

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 includes only products that comply with the relevant EU and national legislation. Because such products are mostly regulated / registered at a national level, compliance with general legislation is checked during evaluation for inclusion of products into the national lists associated with the European Input List. Compliance with general legislation is primarily in the responsibility of the applicant companies. However, if national 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 | |
| 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. |
| 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 ⁵ . |
| 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 ⁶ in the case of products for use on animals) in the country of listing. |

⁵ See EU pesticides database >Search active substances > Type: Basic substance

⁶ Veterinary drugs are not subject to an additional evaluation.