Directorate-General for Agriculture
and Rural Development

Expert Group for Technical Advice on Organic Production

EGTOP

FINAL REPORT

on

Plant Protection (IX)

The EGTOP adopted this technical advice at the plenary meeting
of 14 December 2023

About the setting up of an independent expert panel for technical advice

Regulation (EU) 2018/848[1] requires that authorisation of products and substances used in organic production may only be authorised if they comply with the principles, criteria and objectives of organic production described in that Regulation. The Commission has decided that when taking decisions on these authorisations it will take account of scientific advice by a group of independent experts. For that purpose the Commission has set up the Expert Group for Technical Advice on Organic Production by Commission Decision 2021/C343/03 of 4 August 2021.

EGTOP

The Group's tasks are:

(a) to assist the Commission in evaluating technical matters of organic production, including products, substances, methods and techniques that may be used in organic production, taking into account the objectives and principles laid down in Regulation (EU) 2018/848 and additional policy objectives with regard to organic production;

(b) to assist the Commission in improving existing rules and developing new rules related to Regulation (EU) 2018/848;

(c) to stimulate an exchange of experience and good practices in the field of technical issues related to organic production.

EGTOP Permanent Group

MICHELONI Cristina (Chair), OUDSHOORN Frank Willem (Vice-Chair), BLANCO PENEDO Maria Isabel (Vice-Chair), AUTIO Sari, BESTE Andrea, BOURIN Marie-Christine, GORACCI Jacopo, KOESLING Matthias, KRETZSCHMAR Ursula, MALUSÁ Eligio, SPEISER Bernhard, VAN DER BLOM Jan, WÄCKERS Felix

Contact

European Commission
DG Agriculture and Rural Development
Directorate B: Sustainability
Unit B4 – Organic Farming
Office L130
B-1049 Brussels
Functional mailbox: AGRI-B4@ec.europa.eu

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

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0848&from=EN

ACKNOWLEDGMENTS

Members of the Group are acknowledged for their valuable contribution to this technical advice. The members are:

Permanent Group members:
MICHELONI Cristina (Chair), OUDSHOORN Frank Willem (Vice-Chair), BLANCO PENEDO Maria Isabel (Vice-Chair), AUTIO Sari, BESTE Andrea, GORACCI Jacopo, KOESLING Matthias, KRETZSCHMAR Ursula, MALUSÁ Eligio, SPEISER Bernhard, VAN DER BLOM Jan, WÄCKERS Felix

Sub-Group members:
OUDSHOORN Frank Willem (Chair), SPEISER Bernhard (Rapporteur), AUTIO Sari, BESTE Andrea, MALUSÁ Eligio, MICHELONI Cristina, VAN DER BLOM Jan, WÄCKERS Felix

External experts:
None

Observers:
DRUKKER Bastiaan

All declarations of interest of Permanent Group members are available at the following webpage:

http://ec.europa.eu/agriculture/organic/home_en

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The Expert Group for Technical Advice on Organic Production (EGTOP) was requested to advise on the use of several substances with plant protection effects in organic production. The Group discussed whether the use of these substances and methods is in line with the objectives and principles of organic production, and whether they should be included in Reg. (EU) 2021/1165.

With respect to Annex I to Reg. (EU) 2021/1165, the Group recommends the following:

- Entry 'Pheromones and other semiochemicals': The present restriction 'only in traps and dispensers' should be complemented with the following text: 'microcapsules shall be biodegradable and shall not be applied to edible parts of the crop'.
- The introductions to Annex I and to the sub-chapters of Annex I refer to the authorization of pesticides pursuant to Regulation (EC) No 1107/2009. The Group recommends minor editorial amendments to clarify that these references apply only when pesticides *are used within the EU*.

With respect to Annex VI to Reg. (EU) 2021/1165, the Group recommends the following:

- In Annex VI, a similar introduction as in Annex I should be added, which is tailored for production outside the EU. This introduction should refer to the substances listed in Annexes I and VI, and it should refer to the approval of the *third country where the pesticides are used*.
- Some micro-organisms used outside the EU are different from those used within the EU (different species and/or strains). For ecological reasons and out of considerations of fairness, organic farmers outside the EU should not be restricted to using only microbial biocontrol agents which are approved in the EU. If the recommendations regarding the introductions to Annex I and VI are followed (see previous bullet points), no further action is required with respect to the use of micro-organisms in third countries.
- As a case study for the use of micro-organisms outside the EU, the Group evaluated the use of Cryptophlebia leucotreta granulovirus (CrleGV). The Group concluded that the use of baculoviruses, in general, is completely in line with the principles of organic farming. The Group will automatically accept new products based on specific baculovirus isolates, once these are registered as plant protection products in EU countries or third countries that produce for the EU market. If the recommendations regarding the introductions to Annex I and VI are followed (see previous bullet points), no further action is required with respect to the use of baculoviruses in third countries.
- Regarding the use of plant extracts outside the EU, the Group does not recommend any changes in Annex VI at the moment. The Group concluded each plant extract should be listed individually in Annex VI. As a consequence, a dossier should be provided for each extract. In the case of home-made, traditional plant extracts, the Group is willing to evaluate also dossiers where some information is missing. The Group encourages applicants to provide all the available information, and to complement it with a summary on the 'history of safe use'. The Group suggests that dossiers for Annex VI should be accepted not only from certifiers, but also from non-profit actors in the organic sector (e.g. ColeAD, giz). Regarding *Capsicum annuum* extract, *Swinglea glutinosa* extract, thyme and peppermint oil, the information provided until now is insufficient for a full evaluation, and the Group advises to submit dossiers for each extract.

1. BACKGROUND

Several Member States and a certifying body have submitted dossiers under Article 16(3)(b) of Regulation (EU) 2018/848 concerning the possible amendment of Annex I, II and VI to Commission Implementing Regulation (EU) 1165/2021 and in general, on their compliance with the above mentioned legislation.

- Portugal asked for clarification regarding the use of micro-encapsulated pheromones.
- The International Biocontrol Manufacturers' Association (IBMA) provided a list of micro-organisms and plant extracts that are approved for use outside the EU, but not (not yet) within the EU. IBMA asked for authorisation of such micro-organisms and plant extracts in organic production in third countries.
- Ecocert asked for authorisation of Cryptophlebia leucotreta granulovirus (CrleGV) in organic production in third countries.

2. TERMS OF REFERENCE

The Expert Group for Technical Advice on Organic Production (EGTOP) is mandated to examine the questions and dossiers mentioned above, in the light of the most recent technical and scientific information available. It shall conclude whether the substances and production methods are in line with the objectives, criteria and principles as well as the general rules laid down in Regulation (EU) 2018/848 and, hence, can be authorised for use in organic production under the EU organic legislation. The Group is invited to suggest amendments in Annexes I and VI to the Regulation (EU) 2021/1165.

3. CONSIDERATIONS, CONCLUSIONS AND RECOMMENDATIONS

3.1 Plant protection (Annex I of Reg. 2021/1165)

3.1.1 Micro-encapsulated pheromones

Introduction

Portugal (PT), in concert with France (FR) and Spain (SP), has made a request to the Commission to change the disposition of pheromones in micro-encapsulated formulations (CS) concerning their applicability to organic farming.
Currently, in the Annex I of the Regulation (EU) 2021/1165, specific conditions for pheromones are stated as to limit their use only in traps and dispensers. Based on the new micro-encapsulated formulation technologies available for pheromones today, PT suggests amending the specific conditions and suggests the following formulations:

- "Only in traps & dispensers whatever the mode of application"
- "Absence of contact of the pheromones and other semiochemicals with edible crops whatever the mode of application"

FR interprets the EU and OECD guidances available in a way that micro-encapsulated formulations (CS) fulfil the definition of passive dispensers, and thus could fulfil the present requirements of organic legislation.

Authorization in general production

Most of the currently authorised pheromones are pooled under the term 'Straight chain lepidopteran pheromones' (SCLP). Currently, 30 individual SCLP are authorised in the EU (18 acetates, 8 alcohols and 4 aldehydes). The renewal of the approval of SCLP as low risk active substances was recently decided in the EU, with expiration date of 30.8.2037 (Reg. 2022/1251). Instead of dealing with each single substance, it was decided to group them according to the similarities in their chemical structures – acetates, alcohols, and aldehydes.

The conditions of use of SCLP substances are not expected to lead to the presence of residues in food or feed commodities that may pose a risk to the consumer and, therefore, no MRLs are required. They are therefore included in Annex IV to Regulation (EC) No 396/2005 (Reg. 2023/1719).

Plant protection products containing SCLP as active substances are authorized in many EU countries in all three climatic zones, depending on their specific activity on certain lepidopteran pest species and crops cultivated in each country.

Two substances which do not belong to the group of SCLP are also approved as pheromones: lavandulyl senecioate and rescalure. Lavandulyl senecioate is used to control the vine mealybug *Planococcus ficus* in vine cultivations and rescalure against red scale *Aonidiella aurantia* in citrus. Both active substances have product authorisations in Southern Member States. Both active substances have only one application per season allowed. For the moment, there are no CS formulations on the market for these active substances.

Authorization in organic production

Currently, pheromones and other semiochemicals are allowed in the organic production with the specific condition that limits their use only in traps and dispensers. This is in line with the 'non-contact clause' of Art 24.3(c)ii of Reg. 2018/848 (see chapter Reflections and conclusions).

There are currently two interpretations of CS nature regarding this restriction:

- one interpretation claims that micro-capsules can be considered as tiny dispensers and are therefore *already allowed*.
- the other interpretation considers only retrievable devices such as twist ties, ropes or coils, where the active pheromone is not in contact with the crop, to be dispensers. This interpretation reflects the most common formulations, which are in use since 1997, when this restriction was included in the regulation.

The Group strongly recommends that a uniform interpretation is applied throughout the EU. If necessary, the wording must be adapted to facilitate uniform interpretation.

Agronomic use, technological or physiological functionality for the intended use

Semiochemicals are substances or mixtures of substances emitted by plants, animals, and other organisms that evoke a behavioral or physiological response in individuals of the same or other species. They are pest-specific, affecting often only one species or a small group of related species from the same genus. They act by modifying behavior of species when released in air compartment (non-lethal mode of action). Plant protection products (PPP) based synthetic pheromones/semiochemicals which are identical or near-identical to natural pheromones/semiochemicals have been developed and authorized in the EU market to control pests for crop protection in different sectors in agriculture. Due to their specificity and their very low toxicity to non-target organisms, these biocontrol products have very limited negative side-effects on the environment favouring a sustainable and ecofriendly pest management.

Mode of action: sex pheromones can be used in a range of distinct mating disruption strategies that vary in compound used (full pheromone vs single/partial compound) and application type (blanket application versus point source). The modes of action of the different strategies include:

- *camouflage*: hiding the pest by using a blanket application of the full pheromone;
- *sensory imbalance*: confusing the pest by applying a blanket application of part of the full pheromone;
- *false trail* (including traps): Providing "false mates" by applying point sources of the full pheromone;
- *desensitization*: reducing responses to the mate by satiating the receptors through prolonged exposure to the full pheromone either as a blanket or point application.

Traditional methods of application: pheromone dispensers are reviewed by Klassen et al. (2023). Several techniques of application of pheromones/semiochemicals-based PPP exist:

- *passive devices*: pheromones released from a passive device (as reservoirs / extruded dispensers; so-called vapour-releasing products or 'VP formulations'). This is the oldest, most simple and most common method of application. The dispenser can be made of common plastic that should be removed from the fields or of biodegradable materials that do not require removal. The biodegradable dispensers degrade in 1.5 – 2 years. The Group does not know what proportion of dispensers currently used in the EU is biodegradable.
- *active devices*: pheromones/semiochemicals released from an active device (aerosol type; so-called aerosol dispensers or 'AE formulations'). It implies the use of more technological devices that are collected and partly re-used in the following years. They are often connected to and combined with weather forecasts, temperature and wind sensors and/or pest forecasting models that allow to modulate pheromones/semiochemicals emissions according to momentary need. They are available since few years and not yet for all applications. The advantage is a lower amount of pheromones used, a monitored emission, reduced work load and no waste of plastic (the dispensers parts) in the fields, as they are collected.

Micro-encapsulation: micro-encapsulation technologies have been developed for the preparation of capsules suspension (CS) products intended to be diluted with water and sprayed over crops (so-called 'CS formulations'). These specific technologies allow a full encapsulation of the active substances in solid microparticles preventing any contact of the active substances with edible parts of the crops even if the capsule itself is in contact with the crops. The EU Guidance Document (Sante 2016) defines this technology as follows: "The *active ingredient is formulated as a microencapsulation. Suspension of the concentrate in water and spraying into the field distribute millions of microdispensers that subsequently behave as passive dispensers*". Although the active substance itself is volatile and will be evaporated from the crop, the Group does not know whether and how fast the co-formulants will be degraded.

Spraying techniques are widely used by farmers to apply pesticides on crops for different purposes (fungicides, insecticides, herbicides, etc...). Micro-encapsulated pheromones can be applied with standard spraying equipment, while conventional pheromone dispensers have to be applied manually.

Necessity for intended use, known alternatives

From the submitted dossier it is unclear where (which crop/pest) these microcapsules should be used, and what their advantage compared to traditional dispensers would be.

The alternatives already in use are the common passive dispensers (in plastic, to be collected after use, or in bio-degradable materials that do not need to be collected) and the active AE technologies (see description above).

The use of mating disruption is already very common in several crops (both organic and non-organic). The dossier does not specify in which crops or under which circumstances the use of micro-encapsulated pheromones may offer advantages over the use of conventional pheromone dispensers. However, the Group considers that these advantages may exist, e.g. in cases where a high density of dispensers on a large surface is required or where it is desirable to apply dispensers in places that are difficult to reach by hand.

Aspects of international harmonization / market distortion

In Annex I of Reg. 2021/1165, the concept of dispensers is not defined. The interpretation of what a dispenser is, and more specifically whether microcapsules can be considered as dispensers, differs among the EU Member States.

This issue must be solved to guarantee equal opportunities throughout the EU and beyond, in the case of imports. The Group recommends to amend the wording in Annex I in a way that allows only one interpretation.

Origin of raw materials, methods of manufacture

The CS formulations are produced by commercial PPP industry. In the dossier provided by the applicant, there was a lack of information about the production of CS formulations. Choudhury et al. (2021) give an overview of micro-encapsulation techniques in food processing, but it is not quite clear if this is directly applicable also for the formulation of micro-encapsulated pheromones. However, the dossier states that encapsulants can be either polymeric or non-polymeric materials like cellulose, ethylene glycol, and gelatin. One of the pheromone industry companies producing CS formulations explains that those formulations are comprised of two primary components: the species-specific sex pheromone used to disrupt mating (the active ingredient or AI) and the matrix that protects it. The “matrix” is a mixture of inert ingredients chemically engineered to protect the pheromone from environmental factors while ensuring consistent release over time (Suterra, 2023). However, it does not give any information about the chemical composition of those matrices, and therefore, it is impossible to assess their possible impact on the environment or human and animal health.

In the evaluation process under the Regulation 1107/2009, a growing emphasis is put on the co-formulants of plant protection products. Beyond the active substances, the composition and (eco)toxicological profile of co-formulants in plant protection products are often not well known. EFSA (2022) extracted information on co-formulants from pesticide active substances dossiers for which a peer review output was issued between January 2019 and March 2022, in which a total of 182 co-formulants were found.

Concerning semiochemicals/pheromones as CS formulation, the applicant does not provide any information about the co-formulants in CS formulations. Although the active substance SCLPs are low risk, it is not obvious that all products containing these active substances, even in the CS formulation, would also be classified as low risk products. Without knowing the properties of the other ingredients, it is impossible to judge if the CS products containing semiochemicals/pheromones are low risk. Such evaluations take place in the Member States during the product authorization. Currently, the guidance and criteria for low risk products are not clear and harmonization is required by the Member States.

Environmental issues, use of resources, recycling

Direct spraying of CS formulation would benefit the environment by not leading to plastic waste pollution and by saving resources compared to “physical” dispensers devices if made from non-degradable plastics. Nevertheless, the use of biodegradable passive dispensers or AE tools produces less waste and does not require any mechanical distribution (tractor passages, fuel, soil compaction).

Environmental impact depends on the material used to produce the microcapsules. However, as far as there is no information about the composition of CS formulations, including the environmental profiles of co-formulants, their environmental exposure cannot be judged by the Group. For example, the Group would like to know whether

these products would meet the criteria for 'microplastic-free' (according to the draft proposal to restrict intentionally added microplastics of the European Commission of August 30, 2022).

The Group is not in a position to evaluate the environmental impact and biodegradability of the micro-capsules.

Animal welfare issues

Not relevant.

Human health issues

The operator exposure to spray application of micro-encapsulated formulation should be compared to the spreading of traditional dispensers. In the human health risk assessment of SCLPs, two representative formulations were considered, one CS formulation for spray application and a traditional macro-dispenser formulation. According to the EFSA conclusion on SCLPs, the risk to operators, workers, bystanders and consumers from the use of SCLPs could not be finalised. However, the remaining data gaps do not lead to any critical areas of concern and the active substances could therefore be classified as low risk (EFSA, 2021). Both uses may require appropriate personal protective equipment for operators to be required at MS level, where necessary.

From the consumer exposure point of view, it is critical whether the product is sprayed directly on the edible parts of the crop or not. As a conclusion of the EFSA risk assessment, there is no need to set any MRLs to SCLPs. Traditional trap and dispenser uses are not directly in contact with the crop. However, in the absence of information about the composition of co-formulants (e.g. on the degradability of microencapsules), the exposure of consumers cannot be excluded if the product is sprayed on edible parts of the crop even several applications per growth season.

Food quality and authenticity

Microcapsules differ from traditional dispensers and traps in the fact that the microcapsules and their pheromone are applied directly onto the crop. Once applied, they remain on the crop from where the pheromones are released over time.

Traditional use and precedents in organic production

Pheromones are traditionally used in EU organic production and were authorized since 1991, when the first organic regulation entered into force (Reg. 2092/91, Annex I B). In 1997, their use was limited to "in traps and dispensers" (Reg. 1488/97).

Pheromone solutions currently registered at EU level target mainly the grape, fruit and vegetable sectors and are mainly hanging passive 'physical' dispensers as reservoirs and extruders and aerosols. The mating disruption solutions are manufactured by a limited number of companies and only three of them are EU-based manufacturers. Only 4 sprayable products are registered at EU level, of which only one from an EU based manufacturer.

According to Eurostat, in the EU, the volume of insect attractants straight chain lepidopteran pheromones (SCLPs) sold, is around 350 tonnes (average for 2016 – 2021). In value, IBMA indicates that pheromone markets represent 51,13 million € (2019), growing by 110% on 2016 – 2019 period.

No information on the authorization of semiochemicals/pheromones as CS formulations in organic farming outside the EU was provided by the applicant.

Authorised use in organic farming outside the EU / international harmonization of organic farming standards

The clarification of the status of these flowable passive dispensers products at European level would give a harmonization of interpretation between all Member States and would prevent market distortion compared to other manually applied biodegradable and non-biodegradable plastic dispensers. However, such a harmonized interpretation should preferably take place as part of the 'borderline issues' (SANCO 6621-99) in the context of Reg. 1107/2009 and not cover only organic agriculture.

Other relevant issues

Currently it is discussed to extend the interpretation of semiochemicals to other groups than the straight chain lepidopteran pheromones that are currently approved in the EU to cover also other groups of arthropods than lepidopterans. So probably in the future there will be a need for further consideration of larger groups of this kind of chemicals.

The Group is aware that there are different formulations of microcapsules, some of which may not be biodegradable. Therefore, the Group proposed to restrict microcapsules to biodegradable materials.

Reflections and conclusions

The Group still has questions regarding the following aspects:

Necessity: it is not clear to the Group in which crops/trellising systems or under which circumstances the application of micro-encapsulated pheromones has a significant advantage over traditional application methods.

Pros and Cons, labour: the Group acknowledges that there might be situations where the application of micro-encapsulated formulations is preferable to traditional dispensers, and vice versa, but the dossier does not report clear examples. For example in the EFSA conclusions for SCLP, the GAP described for the representative formulation of the micro-encapsulated formulation involves several applications over one season, whereas for the traditional dispenser and AE, there is often only one application per season (fruit production and viticulture). In vegetables, there may be multiple applications of traditional dispensers.

Plastic pollution: the environmental benefit of micro-encapsulated pheromones is not clear to the Group. Traditional dispensers may result in plastic contamination. However, this is only the case if they are not re-collected after use. The industry has started to develop traditional dispensers made from biodegradable materials (for example based on non-GM corn starch). Besides, the active dispensers are all collected after use and parts are re-used the year after. With respect to micro-encapsulated pheromones, the Group thinks that only biodegradable should be considered for authorisation.

Food quality: traditional dispensers prevent direct contact of pheromones / semiochemicals with the crops, while micro-encapsulated pheromones / semiochemicals are applied directly to the crops. As the micro-capsules retain the pheromones for some time, there is at least the potential of contamination of the edible parts of the crop with pheromones / semiochemicals.

The term ‘pheromones and other semiochemicals’ is very broad and includes also synthetically produced substances that deviate slightly from the natural form. For substances that are not identical to their natural form, Art. 24.3(c)(ii) of Reg. 2018/848 requires that the conditions for use preclude any direct contact with the edible parts of the crop. In view of the consumer perspective, the Group proposes to apply this precautionary measure to all pheromones and semiochemicals.

The Group emphasises that the use of pheromones / semiochemicals is in most cases preferable to the use of insecticides with a toxic mode of action. Thus, the Group welcomes further developments in this area. If a better understanding of the formulation, the benefits of micro-encapsulated pheromones and of the absence of negative effects become evident in the future, the Group is willing to re-evaluate this mode of application. Further information on the components and biodegradability of micro-capsules should be provided by the applicants.

Some Member States apparently interpret that micro-encapsulated pheromones are authorised by the current list, while other Member States consider them as not allowed. The Group sees micro-encapsulated pheromones as dispensers. However, after the spraying application, the micro-capsule may get into contact with the edible crop parts and as a result, the consumer may be exposed to the product and the pheromones. In the Group’s opinion, this is in contradiction with consumer expectancies.

Recommendations

The Group advises keeping the requirements for traditional dispensers unchanged and add a statement concerning micro-encapsulated pheromones. Suggested amendment in red, underlined:

Number and part of Annex	CAS	Name	Specific conditions and limits
255A and others	-	Pheromones and other semiochemicals	Only in traps and dispensers. Microcapsules shall be biodegradable and shall not be applied to edible parts of the crop.

3.2 Products for use in third countries (Annex VI of Reg. 2021/1165)

The International Biocontrol Manufacturers' Association (IBMA) has compiled a list of micro-organisms and plant extracts that are approved for use outside the EU, but not (not yet) within the EU (see Annex I to this report). In the near future, EU-accredited organic certifiers operating in third countries may not accept the use of these products any more. This means that organic farmers in third countries cannot use these products, if they intend to export into the EU, and are therefore certified according to the EU organic regulation.

The reason for this is that the rules for import of organic products change from the principle of 'equivalence' to the principle of 'compliance'. The problem is similar to the use of ethylene for flower induction of pineapple which the Group has previously described (EGTOP report on Plant Protection VIII and Fertilisers VI, chapter 3.3.1). The problem varies in different countries. For simplicity, the issue is explained here only for micro-organisms, but it is analogous for plant extracts.

- In third countries that do not have an equivalence agreement with the EU, certifiers currently have the possibility to accept the use of any microbial strain by referring to the principle of 'equivalence'. After this transition from equivalence to compliance, EU-accredited certifiers may only allow those microbial strains which are approved as active substances under EU legislation.
- In third countries that have an equivalence agreement with the EU (i.e. USA, New Zealand, Costa Rica or Switzerland), any microbial strain can be authorised under their national standards and may continue to be allowed in the future, without compromising export into the EU.

The Group was asked to evaluate whether EU-accredited organic certifiers operating in third countries should accept the use of micro-organisms and plant extracts from the above-mentioned list prepared by IBMA.

3.2.1 Reference to pesticide approval under general legislation

Introduction

This chapter discusses whether there is a need to amend the introduction to Annex I, and/or to include a similar introduction to Annex VI.

Authorisation of plant protection products

In the EU, the authorisation of plant protection products is regulated at different levels. Active substances are authorised at EU level. The principles and procedures of the authorisation process are governed by Reg. (EC) 1107/2009. The active substances which have been approved, are given in Reg. (EU) 540/2011. Plant protection products are their uses are approved at Member State level, and each EU member state has a register of approved plant protection products, specifying the details of use.

Outside the EU, the authorisation of plant protection products may be organised differently.

Reference to plant protection legislation in Annex I

In the EU, plant protection legislation (as described above) applies in all cases where a plant protection product is placed on the market. From this point of view, it seems unnecessary to repeat it in Annex I of Reg. 2021/1165. However, when these requirements are repeated in the organic regulation, organic inspectors are made aware of them, and will check them during the organic inspection. This results in a much higher level of enforcement, and thus ensures much better that only approved products are used, and that these products are used correctly.

Reflections and conclusions

Annex I aims at two different goals: (i) to define the range of active substances to be used, and (ii) to remind that plant protection products must be used in accordance with the conditions under which they were approved.

Range of active substances: this is the core of organic production rules and unequivocal rules are important. For organic production within the EU, the tables in Annex I define what is allowed. Organic production outside the EU should use the same substances wherever possible. However, the Group acknowledges that agronomic conditions and pests outside the EU may necessitate the use of other substances. Annex VI defines what can be used outside the EU. As an example, certain uses of ethylene are included in Annex I. As the use in pineapples is not included in Annex I, the Group has recommended to include this particular use in Annex VI.

Conditions of use: authorisations of plant protection products are always granted under a set of conditions sometimes based on nationally defined risk mitigation measures e.g. for reducing the drift to surface waters. These measures specify the crops, maximum dosage, maximum number of applications, period/crop growth stage when treatments can be made, pre-harvest interval, personal protective equipment etc. Such conditions may depend on crops and regional conditions, and are therefore set at Member State level. From an ecological point of view, it is important that these conditions are respected. Regarding uses outside the EU, the Group emphasises that conditions should also be set in the local context. Conditions that make perfect sense within the EU may be inappropriate outside the EU and vice versa. In the Group's opinion, the only viable solution is to rely on pesticide approval of the country where the product is used.

Introduction to Annex I: the introduction to Annex I provides a reference to the conditions of use which is useful for production within the EU. However, the text is tailored to the regulatory situation in the EU, and cannot be applied outside the EU. The Group would welcome a comparable text that achieves the same result under the multiple situations outside the EU and proposes an analogous text as introduction to Annex VI.

Introduction to the chapter of basic substances: in most third countries, there is no legally defined category of basic substances. Therefore, the Group sees no need for an analogous text in Annex VI.

Introduction to the chapter of low risk active substances: the Group assumes that most third countries do not distinguish active substances from low risk active substances in the same way as the EU. Therefore, the Group does not propose an analogous text for Annex VI.

Chapter of micro-organisms: the Group sees a need for an analogous text in Annex VI (see recommendations below).

Introduction to the chapter of active substances not included in any of the above categories: the Group sees a need for an analogous text in Annex VI (see recommendations below).

Recommendations for Annex I

The Group recommends to slightly amend the introduction to Annex I, to make clear which parts of the text apply only for production within the EU. Proposed amendment for the Introduction to Annex I:

black = existing text

red, underlined = new text

ANNEX I

Active substances contained in plant protection products authorised for use in organic production as referred to in point (a) of Article 24(1) of Regulation (EU) 2018/848

The active substances listed in this Annex may be contained in plant protection products used in organic production as set out in this Annex. Within the EU, these plant protection products shall be authorised pursuant to Regulation (EC) No 1107/2009. These plant protection products shall be used in compliance with the conditions set out in the Annex to Implementing Regulation (EU) No 540/2011 and in accordance with the conditions specified in the authorisations granted by the Member States where they are used. More restrictive conditions for use in organic production are specified in the last column of each table below.

In accordance with Article 9(3) of Regulation (EU) 2018/848, safeners, synergists and co-formulants as components of plant protection products, and adjuvants that are to be mixed with plant protection products shall be allowed for use in organic production, provided that they are authorised pursuant to Regulation (EC) No 1107/2009. The substances in this Annex may only be used for the control of pests as defined in Article 3(24) of Regulation (EU) 2018/848.

[...]

3. Micro-organisms

Within the EU, all micro-organisms listed in Parts A, B and D of the Annex to Implementing Regulation (EU) No 540/2011 may be used in organic production, provided that they are not from GMO origin and only when used in accordance with the uses, conditions and restrictions set in the relevant review reports[3]. Micro-organisms including viruses are biological control agents that are considered as active substances by Regulation (EC) No 1107/2009.

Recommendations for Annex VI

In addition, the Group recommends to introduce a similar introduction to Annex VI, which is tailored for production outside the EU. Proposed amendment for the Introduction to Annex VI:

black = existing text

blue = text existing in Annex I, but new in Annex VI

red, underlined = new text

ANNEX VI

Products and substances authorised for use in organic production in certain areas of third countries pursuant to Article 45(2) of Regulation (EU) 2018/848

The active substances listed in Annexes I and VI may be contained in plant protection products used in organic production as set out in these Annexes. These plant protection products shall be applied in compliance with the authorisations granted by the country where they are used. More restrictive conditions for use in organic production are specified in the last column of the tables in Annex I and VI.

In accordance with Article 9(3) of Regulation (EU) 2018/848, safeners, synergists and co-formulants as components of plant protection products, and adjuvants that are to be mixed with plant protection products shall be allowed for use in organic production, provided that they are authorised by the country where they are used. The substances in this Annex may only be used for the control of pests as defined in Article 3(24) of Regulation (EU) 2018/848.

[...]

3. Micro-organisms

All micro-organisms authorised by a third country may be used in organic production, provided that they are not from GMO origin and only when used in accordance with the uses, conditions and restrictions set by the third country where they are used. Micro-organisms including viruses are biological control agents that are considered as active substances by Regulation (EC) No 1107/2009.

4. Active substances not included in any of the above categories

The active substances as approved by a third country and listed in Annexes I and VI may be used as plant protection products in organic production only when they are used in accordance with the uses, conditions set by the third country where they are used and taking into account the additional restrictions, if any, in the last column of the tables in Annex I and VI.

3.2.2 Use of micro-organisms in organic production outside the EU

Introduction

This chapter discusses the use of micro-organisms for plant protection purposes (so-called microbial biocontrol agents) under EU organic production rules outside the EU.

Annex I contains a number of microbial biocontrol agents (species and strain) that are in use outside the EU, but not approved under Reg. 1107/2009. This table is extracted from the list provided by IBMA, but some entries in the original list were not incorporated in this list, either because the species and/or strain were not specified, or because the strain is approved under Reg. 1107/2009. The table contains 4 bacteria, 6 fungi and 3 viruses. 9 species are used as insecticides, and 4 as fungicides. For the purpose of this chapter, this table serves as a useful illustration of the issue. However, the Group assumes that this list is far from being complete.

Listing policy for microbial biocontrol agents in organic legislation and standards

In the first version of EU organic regulation dating from 1992, *Bacillus thuringiensis* and granulosis viruses were explicitly mentioned. In 1997, this was replaced by a *single, generic entry covering all micro-organisms*. This generic entry for micro-organisms has remained until the present day (although minor changes in wording and conditions were made over time).

The Codex Alimentarius Guidelines, the IFOAM Basic Norms and the National Organic Program of the USA all allow the use of microbial biocontrol agents. None of these standards lists individual species or strains.

Use of micro-organisms for plant protection

The number of microbial strains that may be used for plant protection has grown fast over the last decades. New uses for microbial pest/disease control are developed continuously. A wide range of micro-organisms may be used for plant protection, including fungi, bacteria, viruses and occasionally also other biological taxa. Within a given species, there may be multiple strains with different properties. The number of species and strains used for plant protection grows continuously. Under EU pesticides legislation, every microbial strain is considered as a separate 'active substance' and must undergo separate approval. Annex II A of this report provides an overview over the microbial biocontrol agents currently approved in the EU. In total, 71 strains are authorised (21 bacteria, 41 fungi and 9 viruses). In addition, approval is pending for another 26 strains (8 bacteria, 14 fungi and 4 viruses).

In organic production, micro-organisms were authorised since the beginning of the EU organic legislation in 1992. As they are living organisms, their use is considered to be in line with organic production principles (as long as they are not from GMO origin). In general, microbial biocontrol agents have very little side-effects on non-target organisms, so that their use is often preferable to other authorised natural substances with a toxic mode of action authorised in organic production such as spinosad, pyrethrins or azadirachtin. Furthermore, micro-organisms are a fully renewable resource and can be potentially produced in unlimited quantities. This contrasts with some plant extracts and products of mineral origin, for which the availability of raw materials can be limited.

Reasons for authorising microbial strains outside the EU that are not approved in the EU

For a number of reasons, microbial strains may be used outside the EU that are not approved in the EU:

- *Different crops and their pests/diseases*: outside the EU, crops are grown that cannot be grown and/or have no relevance in the EU. Biocontrol agents for use on such crops will not be registered in the EU.
- *Foreign pests/diseases*: outside the EU, there are pests/diseases which are inexistent in Europe. In many cases, there is a risk that they might be spread to Europe, but this has not (yet) happened. As long as such pests/diseases have not arrived in Europe, biocontrol agents for use against such pests/diseases will not be registered in the EU.
- *Speed and costs of approval procedures*: when a new microbial strain is simultaneously submitted for registration in the EU and outside the EU, it is likely that approval outside the EU will be granted faster than in the EU (Sundh and Eilenberg, 2021). Since registration costs are very high in the EU, certain strains and products are not submitted for approval in the EU, while they are registered outside the EU.

- *Strains adapted to local conditions*: individual microbial strains may differ in their tolerance to environmental conditions such as heat, cold, dryness or wetness. Thus, individual strains may be adapted for use in certain climatic or geographical regions.
- *Native strains*: some countries outside the EU have started to implement policies which favour the use of locally derived microbial strains over the strains that have been obtained on other continents.

Considerations and conclusions

- When new microbial biocontrol agents are approved for use in the EU, they can automatically also be used in organic production since 1997. The Group is not aware that this has ever been questioned. Also for the 26 species for which approval is pending, the Group expects that their future use in organic farming will not meet any opposition.
- For ecological reasons and out of considerations of fairness, the Group considers it important that organic farmers outside the EU are not restricted to using microbial biocontrol agents which are approved in the EU. Where locally adapted strains of microbial biocontrol agents are available, organic farmers outside the EU should be given the opportunity to use these.
- Organic food produced with the use of microbial biocontrol agents not authorised in the EU but authorised in the country of use should be able to be certified according to the EU organic legislation, and imported into the EU as organic.
- The case study on *Cryptophlebia leucotreta* granulovirus (see chapter 3.2.3) provides a good illustration for the need to allow microbial strains outside the EU which are not allowed in the EU.
- The entry 'micro-organisms' in Annex I is sufficiently broad to cover also the use of locally adapted microbial strains outside the EU.
- Use of locally adapted strains is at the moment limited by the reference to EU pesticide approval. The Group has recommended a solution for this problem in the previous chapter (chapter 3.2.1).

Recommendations

If the recommendations in the previous chapter ("reference to pesticide legislation"; chapter 3.2.1) regarding reference to pesticide approval are followed, no further action is required with respect to the use of micro-organisms in third countries.

3.2.3 Case study: use of Cryptophlebia leucotreta granulovirus (CrleGV) outside the EU

Introduction

Cryptophlebia leucotreta granulovirus (CrleGV) is a microbiological insecticide, specific against *Thaumatotibia leucotreta,* ('False Codling Moth', FCM, formerly known as *Cryptophlebia leucotreta*). This pest does not occur in EU countries and was placed on the list of priority quarantine pests in 2019 (Reg. 2019/1702). It has been detected and irradicated in several EU countries in the (recent) past[2]. The request refers to the authorisation for use in organic crops in non-EU countries, from which the harvest is imported as organic produce into the EU.

Authorization in general production

CrleGV is not registered as phytosanitary product in any country of the EU, as the pest is currently not present in any EU country.

[2] see EPPO Global Database, https://gd.eppo.int/taxon/ARGPLE

Authorization in organic production

Since CrleGV is not registered in the EU, it is not allowed in organic production in the EU.

Agronomic use, technological or physiological functionality for the intended use

FCM affects a wide range of agricultural crops, like citrus, ornamentals (mainly roses), cotton, avocado, pomegranate, bean, grape, macadamia, corn, pepper, stone fruit, tea, and many others. It is considered as one of the key pests in these crops in several countries. This means that there is a clear need for non-chemical control methods.

CrleGV belongs to the family of baculoviruses, which are highly specific pathogens of arthropods, in most cases limited to a very narrow range of species, or even only one species, as is the case for CrleGV. This specificity turns the specific baculoviruses into perfect biological control agents, since they have no side-effect on non-target organisms, like arthropod natural pest enemies, mammals or birds. Since it concerns a living organism, a virus, the product does not leave any synthetic residues. Neither do they produce any toxins. They are unable to enter plant tissues, to infest them or to multiply on plant surfaces. They degrade rather quickly through the effect of UV light, but may persist in the soil from where they can infest populations of the sensitive insect species (Williams, 2023).

Necessity for intended use, known alternatives

Being a quarantine pest in Europe, successful management of FCM at origin is critical to enable import of the produce into the EU.

Other control methods that may be allowed in organic farming are pheromone mating disruption and/or the use of microbiological insecticides based on *Bacillus thuringiensis.* In the Group's opinion, it is important that several alternative methods of control are available, to complement each other.

Origin of raw materials, methods of manufacture

Baculoviruses are natural pathogens of arthropods, isolated from wild populations, which are not genetically modified. Insect viruses can only be multiplied in living cells. This occurs by mass-rearing the host, infecting them with the virus and isolating the virus from the dead remains of the insects. The virus can be conserved at low temperatures in a watery suspension.

Environmental issues, use of resources, recycling

No issues.

Animal welfare issues

Test on mammalian cell cultures as well as on mutagenicity, teratogenicity and carcinogenicity all gave negative results (Krieg, 1976).

Human health issues

No issues (OECD, 2023).

Food quality and authenticity

The use of CrleGV has no effect on food quality and/or authenticity.

Traditional use and precedents in organic production

Since the target pest, *Thaumatotibia leucotreta,* does not occur in Europe, the virus CrleGV has no traditional use within the EU. Outside the EU, it has been used under equivalence rules. Other baculovirus based products are authorised and widely used in European organic agriculture, e.g. *Cydia pomonella* granulosis virus (CpGV), or *Spodoptera exigua* Multinuclear Polyhedrosis Virus (SeMNPV).

Authorised use in organic farming outside the EU / international harmonization of organic farming standards

In South Africa, Israel, Kenya, Mozambique and Namibia CrleGV based products are already well established and integrated and organic control strategies for FCM control, mostly in citrus and rose production.

Other relevant issues

No other issues

Reflections and conclusions

The Group considers that the use of baculoviruses, in general, is completely in line with the principles of organic farming. Because of this, the Group sees no necessity to evaluate, and will automatically accept for authorisation in organic farming, new products based on specific baculovirus isolates, once these are registered as plant protection products in EU countries or in third countries that produce for the EU market.

Recommendations

If the recommendations in the chapter 3.2.1 regarding reference to pesticide approval are followed, no further measures are needed with respect to the use of CrleGV.

3.2.4 Use of plant extracts outside the EU

Introduction

This chapter discusses the use of plant extracts under EU organic production rules outside the EU. This chapter is based on the list of 5 plant extracts provided by IBMA. However, plant extracts have traditionally been used in agriculture, and the Group suspects that there might be a large number of plant extracts concerned, many of which are not covered by this list.

Listing policy for plant extracts in organic legislation and standards

Plant extracts were always *individually mentioned* in the EU organic regulation (with the exception of 'plant oils', which were collectively mentioned for some time, but are meanwhile mentioned individually again). In the first version of EU organic regulation dating from 1992, the following plant extracts were mentioned:

- 'preparations of basis of pyrethrins extracted from *Chrysanthemum cinerariaefolium*, containing possibly a synergist'
- 'preparations from *Derris elliptica'* (aka rotenone)
- 'preparations from *Quassia amara'*
- 'preparations from *Ryania speciosa'*.

Out of these four active substances, only pyrethrins are still authorised today, but a number of new substances has been added: laminarin, lupin seed extract, garlic extract, azadirachtin, citronella, clove, rape seed, spearmint, orange and tea tree oil. In addition, a number of plant-based basic substances is also authorised.

The Codex Alimentarius Guidelines and the IFOAM Basic Norms also mention allowed plant extracts individually. By contrast, the National Organic Program of the USA has a more generic approach. It considers all plant extracts as 'non-synthetic' and therefore allowed, except for those which are explicitly prohibited.

Use of plant extracts for plant protection

Plant extracts are relatively simple to prepare on-farm, and have traditionally been used in agriculture. In organic production, some plant extracts were authorised since the beginning of organic legislation. As they are derived from living organisms, their use is considered to be in line with organic production principles (as long as they are not from GMO origin).

Some plant extracts such as pyrethrins or azadirachtin are widely used, potent insecticides, but they have side-effects on non-target organisms. Other plant extracts such as rotenone and tobacco extract were once authorised for organic production, but were later withdrawn due to safety concerns.

Some plant extracts are authorised as active substances, while others are approved as basic substances.

Use of plant extracts outside the EU that are not approved in the EU

Only a very limited number of plant extracts are currently authorised in the EU. By contrast, the Group suspects that a wide range of plant extracts is in use outside the EU, particularly in traditional agricultural production systems. However, the Group has no overview on the nature of these extracts, their hazards and their agronomic value. In the following, the few substances that were on the list are briefly discussed.

- *Capsicum annuum* (cayenne) extract: Cayenne extract was applied as a basic substance. However, this application was not approved as an active substance. The Group is not aware of an application as a 'regular pesticide'.
- *Swinglea glutinosa* extract is approved for use in some countries of South and Central America. A request for approval in the EU is pending, but approval is not expected by the end of 2024.
- A product containing thyme and peppermint oil is approved for use in some countries of Central America and Africa. These two oils are not approved in the EU.

Finally, the list contains two products which the Group sees as different formulations of azadirachtin (which is approved in the EU).

Other issues

The Group considers that there are similar issues with the use of plant materials and extracts in animal husbandry.

Considerations and conclusions

- In the EU organic regulation (Annex I to Reg. 2021/1165 and its precursors), plant extracts were always *individually* mentioned (with few exceptions for plant oils). For reasons of fairness, the Groups thinks that they should also be listed individually in Annex VI.
- As a consequence, inclusion in Annex VI should be requested separately for each plant extract, and a dossier should be provided in each case:
  - for plant extracts which are industrially produced and commercially distributed, the dossier should contain the same information as the dossiers for inclusion in Annex I. By contrast, the Group is aware that for home-made, traditional plant extracts, not all this information may be available. In this particular case, the Group is willing to evaluate also dossiers where some information is missing. The Group encourages applicants to provide all the available information, and to complement it with a summary on the 'history of safe use';
  - the Group suggests that dossiers for Annex VI should be accepted not only from certifiers, but also from non-profit actors in the organic sector (e.g. ColeAD, giz);
  - potential applicants are reminded that Annex VI inclusion is *only* necessary for plant extracts that are *classified as pesticides*. Plant extracts used for fertilisation or as biostimulants ('plant strengtheners') are generally allowed in Annex II ('products and by-products of plant origin'), so there is no need for a request or a dossier.

- Regarding the plant extracts mentioned by IBMA (*Capsicum annuum* extract, *Swinglea glutinosa* extract, thyme and peppermint oil), the information provided in the list is insufficient for a full evaluation. Therefore, the Group cannot make a recommendation regarding the possible listing in Annex VI at the moment. The Group advises to submit requests, as described above.

Recommendations

At the moment, the Group does not recommend any changes in Annex VI regarding plant extracts.

4. MINORITY OPINIONS

None.

5. LIST OF ABBREVIATIONS / GLOSSARY

None.

6. REFERENCES

References for the chapter on micro-encapsulated pheromones

Choudhury, N., Meghwal, M. & Das, K. (2021). Microencapsulation: An overview on concepts, methods, properties and applications in foods. Food Frontiers. 2021; 2: 426–442.

EFSA (2021). Peer review of the pesticide risk assessment of the active substance Straight Chain Lepidopteran Pheromones (SCLPs). EFSA Journal 2021; 19(6):6656, 30 pp. https://doi.org/10.2903/j.efsa.2021.6656.

EFSA (2022). Data collection on co-formulants used in representative plant protection product formulations in the context of the EFSA peer review process for approval/renewal of approval of active substances. EFSA supporting publication 2022: EN-7547. 97 pp. https://www.efsa.europa.eu/en/supporting/pub/en-7547.

Klassen, D, Lennox, M.D., Dumont, M.J., Chouinard, G. & Tavares, J.R. (2023). Dispensers for pheromonal pest control. J Env Man 325: 116590. https://www.sciencedirect.com/science/article/pii/S0301479722021636.

SANCO 6621-99: Working document REGULATION (EC) No 1107/2009 – scope and borderline issues SANCO Doc 6621-99, latest version.

Sante (2016): Guidance Document on Semiochemical Active Substances and Plant Protection Products, SANTE/12815/2014 rev. 5.2 (European Commission, DG SANTE, 2016) https://food.ec.europa.eu/system/files/2016-10/pesticides_ppp_app-proc_guide_doss_semiochemicals-201605.pdf.

Suterra (2023). The Science of Microencapsulated Pheromone Technology. Suterra, Apr 17, 2023. https://www.suterra.com/blog/the-science-of-microencapsulated-pheromone-technology.

References for the chapter on use of micro-organisms in organic production outside the EU

Sundh, I., Eilenberg, J. (2021): Why has the authorization of microbial biological control agents been slower in the EU than in comparable jurisdictions? Pest Manag Sci 2021; 77: 2170–2178. https://onlinelibrary.wiley.com/doi/full/10.1002/ps.6177.

References for the chapter on Cryptophlebia leucotreta granulovirus

Krieg, A. (1976). Granulose- und Kernpolyeder-Viren: Hygienische Gesichtspunkte bei ihrer Produktion und Anwendung, Z. für ang. Ent. 82, 129-134. https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1439-0418.1976.tb03382.x.

OECD (2023). Guidance document on Baculoviruses as plant protection products. Series on Pesticides, No 111. ENV/CBC/MONO(2023)21. https://one.oecd.org/document/ENV/CBC/MONO(2023)21/en/pdf.

Williams, T. (2023). Soil as an Environmental Reservoir for Baculoviruses: Persistence, Dispersal and Role in Pest Control. Soil Systems 7(1): 29. DOI:10.3390/soilsystems7010029.

7. ANNEX

Annex I: Some micro-organisms used outside the EU, but not approved in the EU

Some microbial biocontrol agents (species and strain) that are in use outside the EU, but not approved under Reg. 1107/2009. This table is extracted from a list that was provided to the Group (see chapter 3.2.2). Some entries in the original list were not incorporated in this table, either because the species and/or strain were not specified, or because the strain is approved under Reg. 1107/2009.

Taxonomic group	Species	Strain	Use
bacteria	*Bacillus amyloliquefaciens*	UMAF6614	Insecticide
bacteria	*Bacillus pumilus*	CNPSo3203	Fungicide
bacteria	*Bacillus subtilis*	B-1111	Fungicide
bacteria	*Bacillus velezensis*	UMAF6639	Fungicide
fungi	*Beauveria bassiana*	CG 716	Insecticide
fungi	*Beauveria bassiana*	PL63	Insecticide
fungi	*Isaria fumusorosea*	ESALQ 1296	Insecticide
fungi	*Metarhizium anisoliae*	ESALQ E9	Insecticide
fungi	*Metharizium rileyi*	?	Insecticide
fungi	*Trichoderma harzianum*	ESALQ 1306	Fungicide
viruses	*Cryptophlebia leucotreta* Granulovirus	-	Insecticide
viruses	*Plutella xylostella* Granulovirus	-	Insecticide
viruses	*Spodoptera frugiperda* Nucleopolyhedrovirus	-	Insecticide

Annex II: Micro-organisms approved or pending in the EU

Microbial biocontrol agents (species and strain) approved under Reg. 1107/2009 (Annex II A) or for which approval is pending (Annex II B). Data extracted from the EU pesticides database on 12 November 2023.

Annex II A: approved under Reg. 1107/2009		
ID	**Group**	**Species and strain**
1018	bacteria	Bacillus amyloliquefaciens (formerly subtilis) str. QST 713
1257	bacteria	Bacillus amyloliquefaciens AH2
1333	bacteria	Bacillus amyloliquefaciens IT-45
1198	bacteria	Bacillus amyloliquefaciens MBI 600
1197	bacteria	Bacillus amyloliquefaciens strain FZB24
1078	bacteria	Bacillus amyloliquefaciens subsp. plantarum D747
1079	bacteria	Bacillus pumilus QST 2808
1278	bacteria	Bacillus subtilis strain IAB/BS03
1269	bacteria	Bacillus thuringiensis subsp. Aizawai strain ABTS-1857
1301	bacteria	Bacillus thuringiensis subsp. Aizawai strain GC-91
861	bacteria	Bacillus thuringiensis subsp. Israeliensis (serotype H-14) strain AM65-52
1270	bacteria	Bacillus thuringiensis subsp. Kurstaki strain ABTS-351
1271	bacteria	Bacillus thuringiensis subsp. Kurstaki strain EG2348
1272	bacteria	Bacillus thuringiensis subsp. Kurstaki strain PB 54
1273	bacteria	Bacillus thuringiensis subsp. Kurstaki strain SA 11
1463	bacteria	Bacillus thuringiensis subsp. Kurstaki strain SA 12
1309	bacteria	Pasteuria nishizawae Pn1
716	bacteria	Pseudomonas chlororaphis strain MA342
1084	bacteria	Pseudomonas sp. Strain DSMZ 13134
1411	bacteria	Streptomyces K61 (formerly S. griseoviridis)
1081	bacteria	Streptomyces lydicus WYEC 108
265	fungi	Akanthomyces muscarius Ve6 (formerly Lecanicillium muscarium strain Ve6)
345	fungi	Ampelomyces quisqualis strain AQ10
417	fungi	Aureobasidium pullulans (strains DSM 14940 and DSM 14941)
1336	fungi	Beauveria bassiana 203
1282	fungi	Beauveria bassiana IMI389521
1281	fungi	Beauveria bassiana PPRI 5339
1183	fungi	Beauveria bassiana strain 147
1275	fungi	Beauveria bassiana strain ATCC 74040
1339	fungi	Beauveria bassiana strain GHA
1184	fungi	Beauveria bassiana strain NPP111B005
1215	fungi	Beauveria bassiana strains ATCC 74040 and GHA
501	fungi	Candida oleophila strain O
766	fungi	Clonostachys rosea strain J1446 (Gliocladium catenulatum strain J1446)
569	fungi	Coniothyrium minitans Strain CON/M/91-08 (DSM 9660)
938	fungi	Isaria fumosorosea Apopka strain 97 (formerly Paecilomyces fumosoroseus)

Annex II A: approved under Reg. 1107/2009		
ID	**Group**	**Species and strain**
1319	fungi	Metarhizium brunneum strain Ma 43 (formerly Metarhizium anisopliae var anisopliae)
1306	fungi	Metschnikowia fructicola strain NRRL Y-27328
939	fungi	Paecilomyces fumosoroseus strain Fe 9901
1294	fungi	Phlebiopsis gigantea strain FOC PG 410.3
1295	fungi	Phlebiopsis gigantea strain VRA 1835
1296	fungi	Phlebiopsis gigantea strain VRA 1984
1285	fungi	Purpureocillium lilacinum PL 11
864	fungi	Purpureocillium lilacinum strain 251 (former Paecilomyces lilacinus strain 251)
1102	fungi	Pythium oligandrum M1
1196	fungi	Saccharomyces cerevisiae strain LAS02
1403	fungi	Trichoderma afroharzianum strain T-22 (Formerly Trichoderma harzianum strain T-22)
1396	fungi	Trichoderma asperellum (formerly T. harzianum) strain ICC012
1397	fungi	Trichoderma asperellum (formerly T. harzianum) strain T25
1398	fungi	Trichoderma asperellum (formerly T. harzianum) strain TV1
165	fungi	Trichoderma asperellum (formerly T. harzianum) strains ICC012, T25 and TV1
674	fungi	Trichoderma asperellum strain T34
1402	fungi	Trichoderma atrobrunneum (formerly Trichoderma harzianum) strain ITEM 908
1298	fungi	Trichoderma atroviride (formerly T. harzianum) strain T11
166	fungi	Trichoderma atroviride (formerly T. harzianum) strain T11 and IMI 206040
1231	fungi	Trichoderma atroviride AGR2
1268	fungi	Trichoderma atroviride AT10
167	fungi	Trichoderma atroviride strain I-1237
1205	fungi	Trichoderma atroviride strain SC1
168	fungi	Trichoderma gamsii (formerly T. viride) strain ICC080
169	fungi	Trichoderma harzianum strains T-22 and ITEM 908
192	fungi	Verticillium albo-atrum (formerly Verticillium dahliae) strain WCS850
588	viruses	Cydia pomonella Granulovirus (CpGV)
771	viruses	Helicoverpa armigera nucleopolyhedrovirus (HearNPV)
1287	viruses	Mild Pepino Mosaic Virus isolate VC 1
1288	viruses	Mild Pepino Mosaic Virus isolate VX 1
1334	viruses	Pepino mosaic virus (PepMV) Chilean (CH2) strain, mild isolate Abp2 (PEPMVO)
1335	viruses	Pepino mosaic virus (PepMV) European (EU) strain, mild isolate Abp1 (PEPMVO)
1187	viruses	Pepino mosaic virus strain CH2 isolate 1906
1423	viruses	Spodoptera exigua multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV0004
1173	viruses	Spodoptera littoralis nucleopolyhedrovirus (SpliNPV)

Annex II B: approval under Reg. 1107/2009 pending		
ID	**Group**	**Species and strain**
1476	bacteria	Bacillus amyloliquefaciens AT-332
1448	bacteria	Bacillus amyloliquefaciens FZB42
1262	bacteria	Bacillus licheniformis strain FMCH001
1446	bacteria	Bacillus nakamurai F727
1261	bacteria	Bacillus subtilis strain FMCH002
1264	bacteria	Bacillus subtilis strain RTI477
1502	bacteria	Bacillus thuringiensis strain RTI545
1265	bacteria	Bacillus velezensis strain RTI301
1401	fungi	Aspergillus flavus strain MUCL 54911
1494	fungi	Beauveria bassiana strain BOV1
1511	fungi	Beauveria bassiana strain R444
1283	fungi	Fusarium sp. L13
1479	fungi	Metarhizium brunneum BNL102
1256	fungi	Metarhizium brunneum strain Cb15-III
1464	fungi	Metarhizium pingshaense strain CF62
1465	fungi	Metarhizium pingshaense strain CF69
1466	fungi	Metarhizium pingshaense strain CF78
1468	fungi	Pythium oligandrum strain B301
1484	fungi	Trichoderma afroharzianum Th2RI99
1433	fungi	Trichoderma atroviride 77B
1447	fungi	Trichoderma harzianum B97
1455	fungi	Trichoderma harzianum T78
1483	viruses	Bacteriophage of Potato Soft Rot Enterobacteriaceae (BPSRE)
1510	viruses	Baculoviruses against Adoxophyes orana (virus consortium)
1482	viruses	Cryptophlebia peltastica nucleopolyhedrovirus strain SouthAfrica
1266	viruses	Phthorimaea operculella granulovirus (PhopGV)