

Directorate-General for Agriculture and Rural Development

Expert Group for Technical Advice on Organic Production

EGTOP

FINAL

REPORT

On

Plant Protection IV

EGTOP adopted this technical advice at the plenary meeting of 26 to 28 November 2018

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

With the Communication from the Commission to the Council and to the European Parliament on a European action plan for organic food and farming adopted in June 2004, the Commission intended to assess the situation and to lay down the basis for policy development, thereby providing an overall strategic vision for the contribution of organic farming to the common agricultural policy. In particular, the European action plan for organic food and farming recommends, in action 11, establishing an independent expert panel for technical advice. The Commission may need technical advice to decide on the authorisation of the use of products, substances and techniques in organic farming and processing, to develop or improve organic production rules and, more in general, for any other matter relating to the area of organic production. By Commission Decision 2009/427/EC of 3 June 2009, the Commission set up the Expert Group for Technical Advice on Organic Production.

EGTOP

The Group shall provide technical advice on any matter relating to the area of organic production and in particular it must assist the Commission in evaluating products, substances and techniques which can be used in organic production, improving existing rules and developing new production rules and in bringing about an exchange of experience and good practices in the field of organic production.

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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.

<u>https://ec.europa.eu/info/food-farming-fisheries/farming/organic-farming/co-operation-and-expert-advice_en</u>

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TABLE OF CONTENTS

EXECUTIVE SUMMARY5
1. BACKGROUND5
2. TERMS OF REFERENCE5
3. CONSIDERATIONS AND CONCLUSIONS7
3.1 MALTODEXTRIN7
3.2 Hydrogen peroxide9
3.2.1 Use of hydrogen peroxide for seed treatment9
3.2.2 Use of hydrogen peroxide for disinfection of cutting tools 10
3.3 TERPENES (EUGENOL, GERANIOL AND THYMOL)11
3.4 SODIUM CHLORIDE (SEA AND ROCK SALT)12
3.5 CEREVISANE14
3.5.1 Is cerevisane already authorized under the listing of microorganisms? 14
3.5.2 Preliminary evaluation of cerevisane 14
3.6 PYRETHRINS16
3.7 RE-EVALUATION OF CERTAIN SUBSTANCES17
3.7.1 Azadirachtin 17
3.7.2 Pyrethrins 17
3.7.3 Deltamethrin and lambda-cyhalothrin – used in traps 17
3.7.4 Lime sulphur 18
3.7.5 Sulphur 18
3.7.6 Ethylene 19
3.7.7 Carvone 20
3.8 UV RADIATION OF MUSHROOMS 20
3.9 BASIC SUBSTANCES 20
4. MINORITY OPINIONS 23
5. LIST OF ABBREVIATIONS / GLOSSARY 23
6. REFERENCES 23

EXECUTIVE SUMMARY

The Group discussed whether the use of the substances listed in the mandate is in line with the objectives and principles of organic production, and whether they should therefore be included in Annex II of Reg. 889/2008. Moreover, the group discussed the conditions for use and the other questions proposed in the mandate. It concluded the following:

Maltodextrin should be included in Annex II without restrictions.

Hydrogen peroxide should be included in Annex II without restrictions.

Eugenol, geraniol and thymol should be included in Annex II without restrictions.

Sodium chloride should be included in Annex II with the following restrictions: (i) only sea and rock salt; (ii) no use as herbicide. For reasons of consistency, the Group proposes to change the restriction for sodium chloride in Annex I for "only mined salt" to "only sea and rock salt".

Cerevisane may currently not be used in EU organic production. Provided that the non-GM origin can be established, cerevisane should be included in Annex II without restrictions.

Pyrethrins, the current entry should be changed into 'pyrethrins', with the compositional requirement: 'Only from plant origin'.

Azadirachtin, pyrethrins, deltamethrin and lambda-cyhalothrin, lime sulfur, sulphur and carvone, the submission of a dossier, which would allow a full evaluation, is recommended.

UV treatment of mushrooms. The evaluation is moved to the sub-Group on food.

Amendments to the structure of Annex II,

- (i) sub-heading 2 should be renamed into 'Micro-organisms or substances produced by/derived from micro-organisms';
- (ii) (ii) basic substances should be listed in a separate sub-chapter within Annex II;
- (iii) (iii) deltamethrin and lambda-cyhalothrin should be moved from the sub-heading 2 'Substances of plant or animal origin' to the sub-heading 3 'Substances other than those mentioned in Sections 1 and 2'. For clarity, the Group also recommends to re-formulate the entry on basic substances of plant/animal origin which are food.

1. BACKGROUND

Recently, several Member States have submitted dossiers under Article 16(3)(b) of Council Regulation (EC) No 834/20072 concerning the possible inclusion of a number of substances in Annex II to Commission Regulation (EC) No 889/20083 or, more in general, on their compliance with the above mentioned legislation. Therefore, the Group is requested to prepare report with technical advice on the matters included in the terms of reference.

2. TERMS OF REFERENCE

In light of the most recent technical and scientific information available to the experts, the Group is requested to answer if the use of the below listed substances are in line with the objectives, criteria and principles as well as the general rules laid down in Council Regulation (EC) No 834/2007 and, hence, can be authorised to be used in organic production under the EU organic legislation.

Substances:

• Maltodextrin (BE)

- Hydrogen peroxide (BE) For use in plant protection as fungicide and bactericide in seed treatment and for disinfecting cutting tools
- Terpenes (IT)
- NaCl (FR)
- Cerevisiane (BE)
- UV radiation mushroom (BE)
- Pyrethrins from other species of plants (PT)
- Existing uses not evaluated previously by EGTOP: azadirachtin; pyrethrins; deltamethrin and lambdacyhalothrin –attractants in traps; lime sulphur; ethylene, uses to be restricted to where essential
- Any other topics the Group was requested and supplied by sufficient background information.

3. CONSIDERATIONS AND CONCLUSIONS

3.1 Maltodextrin

Introduction, scope of this chapter

The Group is requested to assess the use of maltodextrin as an insecticide and acaricide according to the information provided in the dossier.

It is a starch derivative also used as a conventional food additive.

Maltodextrin can be produced in two ways and the request concerned only maltodextrin produced by enzymatic lysis of starch.

Authorization in general production

It is authorized as an active substance for plant protection. It is widely authorized as food additive (baby milk, pastries) and cosmetic ingredient according to Annex II of EC Directive No 1169/2011.

Authorization in organic production

No authorisation at present for any purpose (neither as plant protection nor as food additive).

Agronomic use, technological or physiological functionality for the intended use

Control of mites, whiteflies and aphis in greenhouses and fields, as punctual treatment in case of high pest pressure. It is applied at a dose of approximately 1.35 kg/ha. Maltodextrin acts by blocking/entrapping the pests present on the leaves, blocking spiracles and leading to starvation/suffocation. It has no adhesive effect on flying insects after the application of the product. Due to its physical mode of action, it acts non-selectively and mainly on mobile species.

Necessity for intended use, known alternatives

The target species can be controlled by beneficial insects/mites and by several other insecticides listed in Annex II, e.g. pyrethrins, fatty acids. Depending on national registrations, all these alternatives may or may not be available in specific Member States.

In the Group's opinion, the use of natural enemies and agronomic practices should be preferred. If pesticides need to be used, it is advisable to have more than one substance available, e.g. to prevent resistance building in pests. In comparison with fatty acids, maltodextrin has shown, in some trials, a better efficacy against mites. On some crops, maltodextrin also causes less problems of phytotoxicity than fatty acids.

Origin of raw materials, methods of manufacture

Maltodextrin is of plant origin (starch) and is produced by means of enzymes. The starch can originate from various sources, e.g. wheat, corn, rice. At least one product currently on the market is made from corn starch. To be acceptable in organic farming the starch must come from a non-GM plant, and the enzyme must not be a GMO or of GM origin.

Environmental issues, use of resources, recycling

If the product is used according to recommendations, the Group has no concerns. Maltodextrin is a renewable resource and biodegrades fully and rapidly. A potential risk for bees and other non-target insects is not excluded as maltodextrin is a contact insecticide.

Animal welfare issues

No issue, it is used in livestock feed.

A potential risk for bees and other non-target insects is not excluded as maltodextrin is a contact insecticide.

Human health issues

No issue, used widely in food industry. Fast digestibility (as glucose).

Food quality and authenticity

In theory product residues on the crops might be colonized by mould, decreasing crop attractiveness or leading to mycotoxins development. But in practice, the product degrades very quickly. Therefore, the Group has no concerns.

Traditional use and precedents in organic production

No traditional use in organic farming.

Authorised use in organic farming outside the EU / international harmonization of organic farming standards Maltodextrin is not mentioned in the Codex Alimentarius guidelines for the production, processing, labelling and marketing of organically produced food (edition 2013), nor in the IFOAM Norms for Organic Production and Processing (edition 2014). In both cases, it is probably allowed under the entry 'natural plant preparations'. In the USA, maltodextrin, as here evaluated, would probably be classified as 'non synthetic' and be allowed under the National Organic Program (NOP). Maltodextrin will probably be allowed for organic production in Switzerland from 2019 on.

Other relevant issues None.

Reflections of the Group / Balancing of arguments in the light of organic production principles

It is clear that the substance shows a potential risk for short term and mechanical effects on non-target insects, but they are negligible compared to alternatives already allowed in organic plant protection (i.e. spinosad, Azadirachtin and pyrethrins).

The Group has no concerns about the use of maltodextrin providing that the non-GMO origin of the starch and of the enzymes is guaranteed.

Conclusions

The Group concluded that the use of maltodextrin was in line with the objectives, criteria, and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. It should therefore be included in Annex II without restrictions.

3.2 Hydrogen peroxide

The Group was asked to evaluate the use of hydrogen peroxide for seed treatment of lettuce and ornamentals and for disinfection of cutting tools in *Solanaceae* as a prevention against spreading of plant diseases. For clarity sake, the two uses are discussed in two separate sub-chapters.

3.2.1 Use of hydrogen peroxide for seed treatment

Introduction, scope of this chapter

This sub-chapter deals with the use of hydrogen peroxide for seed treatment of lettuce and ornamentals.

Authorization in general production

Aqueous solutions with concentration lower than 5% of hydrogen peroxide is approved as basic substance.

Authorization in organic production

For seed treatment in organic production, hydrogen peroxide is currently not authorized. Hydrogen peroxide is listed in Annex VII (1) "Products for cleaning and disinfection of buildings and installations for animal production" and in Annex VII (2.2) "Products for cleaning and disinfection in Aquaculture in presence or absence of fish" and also listed as processing aid in Annex VIII, section B. *Gelatine production*.

Agronomic use, technological or physiological functionality for the intended use

Hydrogen peroxide is used to disinfect seeds before sowing. It can reduce various pathogens by an oxidizing mode of action. It is currently authorized for use against bacterial and fungal pathogens of lettuce and some ornamentals.

Necessity for intended use, known alternatives

Healthy seed is very important for organic production. The supply of organically propagated seeds is still very limited and should be boosted. Conventional seeds, as they can be used in organic farming only if they have not been treated with synthetic pesticides, can be vectors of plant diseases (as well as untreated organic seeds). Seed health should be managed in first priority through agronomic measures (of mother plants) and secondly with thermal methods, such as hot water or hot air treatment and that is what currently the seed companies apply. Vinegar, mustards seed powder, micro-organisms (e.g. *Bacillus subtilis*, mild strains of Pepino mosaic virus) and copper (only for industrial treatment) may also be used for seed treatment (depending on national registration).

Origin of raw materials, methods of manufacture

Hydrogen peroxide is naturally produced in trace quantities by organisms, most notably by a respiratory burst as part of the immune response. The substance used for disinfection is manufactured synthetically, most frequently by the anthraquinone process (see EGTOP report on Aquaculture, part B).

Environmental issues, use of resources, recycling No concerns for this use.

Animal welfare issues No concerns for this use, see also human health.

Human health issues No concerns, as it is used as a hand disinfectant in hospitals and in the food industry.

Food quality and authenticity No concerns.

Traditional use and precedents in organic production

Not authorized for seed treatment, but authorized for disinfection of livestock buildings and installations, aquaculture (in presence or absence of fish) (Annex VII of 889/2008) and also listed as processing aid in Annex VIII, section B. *Gelatine production*.

Authorised use in organic farming outside the EU/international harmonization of organic farming standards The Codex Alimentarius guidelines for the production, processing, labelling and marketing of organically produced food (edition 2013) do not cover disinfectants and therefore do not mention hydrogen peroxide. The IFOAM Norms for Organic Production and Processing (edition 2014) mention hydrogen peroxide as an 'equipment disinfectant'. In the USA, hydrogen peroxide is allowed as an 'algicide, disinfectant and sanitizer'

under the National Organic Program (NOP). Under this rule, disinfection of cutting tools is clearly allowed. Whether it allows seed disinfection would require a more in-depth legal analysis. Hydrogen peroxide acceptability as disinfectant will probably be assessed in a next EGTOP Mandate specific for disinfectant and cleaning agents.

Other relevant issues None.

Reflections of the Group / Balancing of arguments in the light of organic production principles

Basic substances are generically authorized in Annex II of Commission Regulation (EC) 889/2008 if they are foodstuff and of plant or animal origin. This is not the case for hydrogen peroxide. Therefore, a separate listing is needed.

The Group's main question is to what extent this substance is necessary. However, it may open additional opportunities for seed treatment.

Considering the low environmental impact, the natural occurrence in small ephemeral amounts and the low doses required, the Group comes to the conclusion that it should be authorized.

The Group assumes that hydrogen peroxide would also be effective for seed treatment of other crops where it is not currently authorized. In case that further uses are authorized in the future, the Group has no concerns over such uses.

Conclusions

The Group concludes that the use of hydrogen peroxide for seed treatment is in line with the objectives, criteria, and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. It should therefore be included in Annex II without restrictions.

3.2.2 Use of hydrogen peroxide for disinfection of cutting tools

Introduction, scope of this chapter

This sub-chapter deals with the use of hydrogen peroxide for disinfection of agricultural cutting tools used in *Solanaceae*.

Authorization in general production and in organic production

A distinction has to be made between disinfection of tools in general (for reasons of hygiene) and agricultural cutting tools (to prevent the spread of plant diseases). The former use falls under biocide legislation and is currently not regulated for organic production. The latter use falls under pesticide legislation, and only products listed in Annex II are authorized for organic production.

The Group assumes that many organic farmers and also certifiers are not familiar with such subtle legal distinctions. Therefore, the Group assumes that disinfection of cutting tools is considered as authorized by many stakeholders if done by products listed in Annex II or in Annex VII.

Agronomic use, technological or physiological functionality for the intended use

Hydrogen peroxide is used to disinfect cutting tools and equipment. This prevents the spread of plant pathogens (soil bacteria, *Ralstonia solanacerum*, *Botrytis cinerea*). It is also used by some wine-growers as cutting tool disinfectant as it is thought to limit the spread of 'Esca' disease.

Necessity for intended use, known alternatives

The spreading of plant diseases should be avoided and disinfection of cutting tools and other equipment is part of preventive measures. Disinfection can also be done with hot water or vinegar but hot water is impractical while working in the field.

Origin of raw materials, methods of manufacture See 3.2.1.

Environmental issues, use of resources, recycling See 3.2.1.

Animal welfare issues See 3.2.1.

Human health issues

See 3.2.1.

Food quality and authenticity See 3.2.1.

Traditional use and precedents in organic production See 3.2.1.

Authorised use in organic farming outside the EU / international harmonization of organic farming standards See 3.2.1.

Other relevant issues None.

Reflections of the Group / Balancing of arguments in the light of organic production principles

Considering the low environmental impact, the natural occurrence in small ephemeral amounts and the low doses required, the Group comes to the conclusion that it should be authorized. Hydrogen peroxide could be considered when a list of substances authorized for disinfection in plant production is established.

The Group assumes that hydrogen peroxide would also be effective on tools and equipment on crops other than Solanaceae where it is not currently authorized. In case that further uses are authorized in the future, the Group has no concerns over such uses.

Conclusions

The Group concluded that the use of hydrogen peroxide for disinfection of cutting tools and equipment is in line with the objectives, criteria, and principles of organic farming as laid down in Council Regulation (EC) No 834/2007.

In the previous sub-chapter, the Group recommends including hydrogen peroxide in Annex II without restrictions. This covers the use for seed treatment as well as for tools and equipment.

3.3 Terpenes (eugenol, geraniol and thymol)

Introduction, scope of this chapter

The Group was asked to evaluate the use of 'terpenes'. The request refers to a plant protection product which combines eugenol, geraniol and thymol and the Group restricts its evaluation to those three substances.

Eugenol, geraniol and thymol are present in a wide range of plants. They are volatile substances with a characteristic smell and have therefore traditionally been used for various purposes such as scents, as feed additives for poultry and as flavouring agents for food.

Eugenol is also known under the names 4-allyl-2-methoxyphenol or 2-methoxy-4-(2-propenyl)-phenol and has the CAS number 97-53-0. Geraniol is also known under the name (E) 3,7-dimethyl-2,6-octadien-1-ol and has the CAS number 106-24-1. Thymol is also known under the name 5-methyl-2-propan-2-yl-phenol and has the CAS number 89-83-8.

Authorization in general production

Eugenol, geraniol and thymol are all approved as active substances for plant protection.

Authorization in organic production

Eugenol, geraniol and thymol are currently not allowed for plant protection in organic farming. In beekeeping, thymol is authorized and traditionally used for controlling the varroa mite.

Agronomic use, technological or physiological functionality for the intended use

The representative uses of eugenol, geraniol and thymol were *Botrytis cinerea* (grey mould) in table and wine grapes in all three cases. The group cannot exclude that it might be effective also for other uses and later approved for those uses, e.g. powdery mildew on grapevine.

The terpenes are applied as foliar sprays. For the combined product mentioned in the introduction, the doses per treatment are 0.05 - 0.25 kg/ha for each of the three compounds. Eugenol, geraniol and thymol are contact action fungicides which prevent the development of fungal mycelium from spores or destroy existing mycelium by a direct action on the cell membranes. The three terpenes are lipophilic and disrupt fungal cell membranes, thus destroying the cells. Due to this mode of action, no problems with resistance or cross-resistance are expected.

Necessity for intended use, known alternatives

Botrytis, grey mould, is an important disease of grapes which can cause great economic losses depending on weather conditions. Alternatives:

- Pruning and training systems (to improve ventilation within the canopy)
- clay minerals
- Micro-organisms (e.g. Ampelomyces quisqualis) are sometimes also effective

Botrytis also affects other crops (e.g. strawberries, vegetables), where it has a similar impact. The short interval between treatment and harvest could be an advantage.

Origin of raw materials, methods of manufacture

Eugenol, geraniol and thymol are naturally present in a wide range of plants, particularly in herbs and spices. For plant protection purposes, however, geraniol and thymol are chemically manufactured but are identical to the natural substances. Eugenol can be manufactured enzymatically, but the Group could not verify whether the material used for plant protection is extracted from plants or manufactured.

Environmental issues, use of resources, recycling

EFSA identified a high hazard for aquatic organisms. Presuming good agricultural practice and considering the amounts used per hectare, the Group is not concerned.

Animal welfare issues No concerns.

Human health issues No MRLs were set for these three substances. For the authorized use, the Group has no concerns.

Food quality and authenticity

All three terpenes are volatile. A few days after application, no residues can be detected anymore.

Traditional use and precedents in organic production

In organic farming, these terpenes have no traditional use in plant protection. In beekeeping thymol is used for the control of varroa mite.

Authorised use in organic farming outside the EU / international harmonization of organic farming standards Eugenol, geraniol and thymol are not mentioned in the Codex Alimentarius guidelines for the production, processing, labelling and marketing of organically produced food (edition 2013), nor in the IFOAM Norms for Organic Production and Processing (edition 2014). Considering their synthetic mode of production, it is doubtful whether they can be considered as 'natural plant preparations'. In the USA, the substances here evaluated would be classified as 'synthetic' and would be prohibited under the National Organic Program (NOP).

Other relevant issues None

Reflections of the Group / Balancing of arguments in the light of organic production principles

In the Group's opinion, substances of natural origin should be used as a first priority. However, substances which are chemically produced but are identical to natural material are allowed according to Art. 16 of Council Regulation (EC) 834/2007. The short interval between treatment and harvest could be an advantage together with the absence of MRL.

Conclusions

The Group concluded that although the natural origin is to be preferred, the use of these terpenes eugenol, geraniol and thymol is in line with the objectives, criteria, and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. They should therefore be included in Annex II, preferably from natural origin.

3.4 Sodium chloride (sea and rock salt)

Introduction, scope of this chapter

The original request was limited to sea salt. By analogy with Annex I, the Group decided to evaluate «Sodium chloride – Only mined salt», which covers rock salt and sea salt, but not sodium chloride obtained from chemical processes.

Authorization in general production

Sodium chloride is approved as a basic substance.

Authorization in organic production

Sodium chloride is currently not authorized for plant protection. However, it is authorized as a fertilizer (Annex I) as a feed material (Annex V) and as a food additive (Annex VIII). Also as biological control of ectoparasites in fish (889/2008 Article 25s.6)

Agronomic use, technological or physiological functionality for the intended use

Sodium chloride acts as a fungicide. The mode of action is by desiccation. It can be used on grapevines against powdery mildew. It can also be used as a spot treatment in mushrooms, to prevent the spread of diseases. In addition, it also has an insecticidal effect on the grapevine moth.

Sodium chloride would also have an herbicidal effect, but:

- this use was not actually requested and
- is explicitly prohibited (see Commission Regulation (EC) 889/2008),
- phytotoxicity is observed at doses lower that the ones needed to obtain a herbicide effect (in general, the dose used is 1 kg/ha, under phytotoxic concentrations of 20 g/l (2 kg/ha) and largely appear with herbicide concentrations.

Necessity for intended use, known alternatives

Annex II contains no substances for controlling mushroom diseases.

Powdery mildew is an important disease of grapes which can cause great economic losses depending on weather conditions. Main alternatives are:

- canopy management (to improve ventilation within the canopy)
- sulphur
- oils (plant and mineral)
- microbial products
- lecithin
- other mineral compounds.

The grapevine moth is usually managed with mating disruption or *Bacillus thuringiensis*. Theoretically, spinosad would also be an alternative method.

Origin of raw materials, methods of manufacture

Sodium chloride is a natural substance of mineral origin which is ubiquitous in nature. It is either harvested from the sea or mined from fossil deposits. There is also sodium chloride from synthetic origin, but this is excluded from this evaluation.

Environmental issues, use of resources, recycling

In the case of grapevine, the Group is concerned about the potential contribution to soil salinity. However, the Group assumes that the risk of phytotoxicity will limit its use.

Animal welfare issues No concerns.

Human health issues No concerns.

Food quality and authenticity No concerns. No MRL is required.

Traditional use and precedents in organic production

Sodium chloride is allowed as a fertilizer / soil conditioner, as a feed material and in food production. It is traditionally used in biodynamic strategies.

Authorised use in organic farming outside the EU / international harmonization of organic farming standards 'Sea salt' is mentioned as a plant protection agent and 'sodium chloride' as a fertilizer in the Codex Alimentarius guidelines for the production, processing, labelling and marketing of organically produced food (edition 2013). In the IFOAM Norms for Organic Production and Processing (edition 2014), 'sodium chloride' is only mentioned as a fertilizer. In the USA, sea and rock salt are classified as 'non-synthetic' and are allowed under the National Organic Program (NOP).

Other relevant issues

Sodium chloride may not be used as an herbicide, and this should be stated explicitly in Annex II. However, with the quantities approved for fungicide and insecticide use, there is no risk of diversion for herbicide use.

Reflections of the Group / Balancing of arguments in the light of organic production principles

For mushroom production, the Group believe that sodium chloride is useful.

Regarding the use in grapevine, the subgroup has doubts about its usefulness and the efficacy is questionable against its side-effects (phytotoxicity and soil salinization).

Conclusions

The Group concludes that the use of sodium chloride is in line with the objectives, criteria, and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. It should therefore be included in Annex II with the following restrictions:

- only sea and rock salt
- no use as herbicide

Comment

For reasons of consistency, the Group proposes to change the restriction for sodium chloride in Annex I for "only mined salt" to "only sea and rock salt".

3.5 Cerevisane

The Group was asked the following clarifications:

- can the active substance 'cerevisane' (cell walls of *Sacharomyces cerevisiae* strain) be used in organic production as a plant protection product under Annex II?
- annex II mentions 'micro-organisms'. Does 'cerevisane' fall under the category 'micro-organisms'?
- if micro-organisms are strictly interpreted as the 'whole' micro-organism, can Annex II be amended by adding the words 'or parts of micro-organisms'.

No dossier was provided, nevertheless the group decided to analyse the questions and provide possible clarifications.

3.5.1 Is cerevisane already authorized under the listing of microorganisms?

In 2008, an ad-hoc expert group discussed whether spinosad should be authorized in organic production (Forst*er et a*l., 2008) and the experts wrote: «The expert group recommends to clarify in the Regulation that microorganisms are generally allowed, while specific microbial products are only allowed on a case-by-case basis and need to be listed individually». In this occasion, the group confirms the previous group opinion that only entire micro-organisms are covered by the listing in Annex II of Commission Regulation 889/2008. This means that cerevisane may currently not be used in EU organic production.

The Group is sceptical about the proposal of adding the term 'parts of micro-organisms' as such term is unclear and might be interpreted in different ways. The Group prefers that cerevisane is evaluated individually and possibly separately listed in Annex II. The next sub-chapter deals with this possibility.

3.5.2 Preliminary evaluation of cerevisane

Introduction, scope of this chapter

As no dossier was submitted the Group provides only a preliminary evaluation of 'Cerevisane', which denominates dried cell walls of the yeast *Saccharomyces cerevisiae* strain LAS117.

Authorization in general production

Cerevisane is authorized in the EU as an active substance for plant protection. It is classified as a 'low-risk active substance'.

Authorization in organic production

Cerevisane is currently not authorized in EU organic production (see section 3.5.1) but By-products from *Saccaromices* Cs *erevisiae*, whose cells have been inactivated or killed are allowed as feed additive (Annex V)

Agronomic use, technological or physiological functionality for the intended use

Cerevisane is an inducer of systemic resistance. It can potentially be used in a number of crops against plant diseases. For example, the Group found registered uses (in France) on cucumber, lettuce, tomato, melon, strawberry and grapevine. In these crops, 8 - 10 applications per season are allowed and the pre-harvest interval is set to 1 day. The recommended dose is very low (below 100 g/ha).

The agronomic use is similar to the other inducers of systemic resistance, previously evaluated: laminarin and COS-OGA.

Necessity for intended use, known alternatives

Cerevisane has a limited efficacy, particularly under conditions of high disease pressure. The use of cerevisane allows for reducing the number of fungicide or bactericide treatments on a crop, but it cannot replace all of them. Depending on the crop and pest to be controlled, there are several alternatives (e.g. copper, sulphur and some PPP based on micro-organisms), besides the preventive agronomic measures.

Origin of raw materials, methods of manufacture

Cerevisane consists of dried cell walls of the yeast *Saccharomyces cerevisiae* strain LAS117. Information collected in internet indicates that the strain LAS117 is not a GMO and the EFSA report does not mention the strain as GMO. However, the Group would like this aspect to be verified, before cerevisane is included in Annex II.

Environmental issues, use of resources, recycling

The Commission's review report identified no unacceptable effects on the environment.

Animal welfare issues No issues.

Human health issues The Commission's review report notes an absence of any hazardous potential for consumers.

Food quality and authenticity No issues.

Traditional use and precedents in organic production

Yeasts are traditionally used in baking, wine-making and brewing, also in organic production.

The micro-organism *Aureobasidium pullulans* is a yeast-like fungus. It is authorized as a microbial biocontrol agent against fire blight and may be used also in organic production. Products made from dried cell walls are approved for organic wine-making.

Authorised use in organic farming outside the EU / international harmonization of organic farming standards Cerevisane is not mentioned in the Codex Alimentarius guidelines for the production, processing, labelling and marketing of organically produced food (edition 2013), nor in the IFOAM Norms for Organic Production and Processing (edition 2014). However, both standards allow 'microorganisms'. In the USA, cerevisane, as here evaluated, would probably be classified as 'non-synthetic' and would be allowed under the National Organic Program (NOP).

Other relevant issues

The Group emphasizes that this evaluation is preliminary, because no dossier was provided to the Group.

Reflections of the Group / Balancing of arguments in the light of organic production principles

From an environmental point of view, the Group prefers the use of systemic resistance inducers such as laminarin, COS-OGA and cerevisane over the use of fungicides. From the information available at present, the Group has no concerns over the use of cerevisane.

Conclusions

The Group clarifies that at the current regulatory state, cerevisane is not allowed in Organic Production. Nevertheless, the Group preliminary concludes that the use of cerevisane is in line with the objectives, criteria, and principles of organic farming as laid down in Council Regulation (EC) No 834/2007 and recommends including cerevisane in Annex II without restrictions providing that the non-GM origin can be established,.

Comment on the structure of Annex II

The Group recommends that the sub-heading should be renamed to 'Micro-organisms or substances produced by/derived from micro-organisms'.

3.6 Pyrethrins

Introduction, scope of this chapter

Currently, Annex II lists 'Pyrethrins extracted from *Chrysanthemum cinerariaefolium*'. The Group was asked whether pyrethrins extracted from other plant species could also be allowed.

Origin of pyrethrins

Pyrethrins are extracted from flowers of plants of the genus *Chrysanthemum*. When dried flowers are traded, a distinction is sometimes made between 'dalmatian' (aka 'montenegrian') and 'persian' (aka 'armenian' or 'caucasian') powder. The former is made from *Tanacetum cinerarifolium* (also known as *Chrysanthemum cinerarifolium*), while the latter is made from *Tanacetum coccineum* (also known as *Chrysanthemum coccineum*, *Pyrethrum roseum* or *Pyrethrum carneum*)¹.

Authorization in general agriculture

Currently, only pyrethrins from *Chrysanthemum cinerariaefolium* are approved under pesticide legislation (see Appendix I of the review report, SANCO/2627/08 – final from 16 July 2013).

Origin of the restriction of plant species

The restriction to the plant species *Chrysanthemum cinerariaefolium* was already present in the first version of first organic regulation, Reg. 2092/91, when it was published in 1991. The Group did not trace the restriction further back in time, and does not know why it was written into the organic regulation. However, pyrethrins from *Chrysanthemum cinerariaefolium* are the only form currently allowed for plant protection by the horizontal legislation.

Reflections of the Group / Balancing of arguments in the light of organic production principles

In the Group's opinion, the use of pyrethrins from plant origin is equally acceptable regardless of the species from which they are produced. However, they must be authorized as active substances under pesticide legislation. For pyrethrins from other *Chrysanthemum (Tanacetum)* species, this is currently not the case.

Nevertheless, the current listing could be amended. There is no need to specify the plant species, because this is already specified by the pesticide approval.

Conclusions

The Group recommends to amend the current listing of pyrethrins as follows:

- Listing: 'pyrethrins'
- Compositional requirement: 'Only from plant origin'.

¹ Information taken from the website of the Julius-Kühne institute, <u>https://oekologischerlandbau.julius-kuehn.de/index.php?menuid=50</u>, accessed on 15. 10. 2018.

3.7 Re-evaluation of certain substances

A number of substances have never been evaluated by EGTOP or by an ad-hoc expert group. The Group can only assess these substances, if it receives a dossier. In the following, the Group summarizes the most important aspects for a number of substances.

3.7.1 Azadirachtin

Preliminary considerations:

EU approval under general pesticide regulation expires in 2024. A new EFSA report was published on 14th September 2018, which evaluates a representative use on potatoes. EFSA considered the risks to non-target organisms to be acceptable, provided that risk mitigation measures are used to protect aquatic organisms and non-target arthropods. No major human health hazards were identified, but a potential for skin sensitisation was observed.

The Group would welcome a dossier. This should in particular focus on:

- environmental impact (non-target organisms),
- human health impact from residues.

3.7.2 Pyrethrins

Preliminary considerations:

EU approval under general pesticide regulation expires in 2022. There is no new EFSA report, nor other recent publications. See also chapter 3.6.

The Group would welcome a dossier. This should in particular focus on:

• environmental impact (non-target organisms).

3.7.3 Deltamethrin and lambda-cyhalothrin – used in traps

Preliminary considerations:

EU approval of deltamethrin under general pesticide regulation expires in 2019. A new EFSA report is on the way.

EU approval of lambda-cyhalothrin under general pesticide regulation expires 2023. It is a candidate for substitution. The last EFSA report dates from 2014.

In the Group's opinion, the synthetic pyrethroids deltamethrin and lambda-cyhalothrin are the last choice of products to be used, and must only be used in traps and their use has been accepted (based on Art. 16 of Reg 834/2007) only because their use is limited to traps. Theoretically, there are alternatives available, but their use might be limited by costs and/or labour intensity and/or reduced effectiveness. The practical applicability of such alternatives should be pursued and it should be discussed to what extent they can replace these pyrethroids, with the long-term objective of phasing out these substances. Some alternative already exists. In some Member States (i.e. IT, FR...) an insecticide bait based on spinosad and specific attractive substances are developed for the control of diptera thieves (fruit flies). It is applied not in traps but in spots and is more labour intensive as after rain the renewal of spots treatment is needed.

The Group recommends asking the member states whether both of these substances are in use in their country, and whether there are any alternative methods in use to control the target flies. In case that an essential need for such insecticides is declared, the Group recommends to reconsider which substance should be authorized. Considering that lambda-cyhalothrin is a candidate for substitution, the Group considers that it should be phased out even faster than deltamethrin. If no country asks for maintenance of lambda-cyhalothrin and provides a dossier it should be eliminated from Annex II in 2021. However, in case deltamethrin is not re-approved in 2019, this decision might need to be revised.

Comment on the listing

Deltamethrin and lambda-cyhalothrin are currently listed in Annex II under the sub-heading 2 'Substances of plant or animal origin'. The Group recommends to move them to section 3 'Substances other than those mentioned in Sections 1 and 2'.

3.7.4 Lime sulphur

EU approval of lime sulphur under general pesticide regulation expires in 2025. The latest EFSA report dates from 2010, there is no MRL and it was briefly discussed in EGTOP Plant Protection III. Lime sulphur is an important copper alternative, particularly in apple production. Therefore, the Group recommends reconsidering it in the context of copper and copper alternatives. In case a Member State considers it important, it should submit a dossier that should in particular focus on environmental impact (non-target organisms).

3.7.5 Sulphur

EU approval of sulphur expires 2020 under general pesticide regulation expires in 2020. The latest EFSA report dates from 2009, there is no MRL and sulphur is an essential fungicide in the organic production of many crops. In case a Member State considers it important, a dossier should be submitted and should in particular focus on environmental impact (non-target organisms).

3.7.6 Ethylene

The restrictions for ethylene have changed several times in the past with or without use-restriction. The last change dates from 23^{rd} October 2018.

Situation between 2014 and 2016

From 2014 to 2016, ethylene was authorised in organic production with the following use indications and restrictions:

- indoor, meaning post-harvest, use for degreening (maturation) of bananas, kiwis and kakis;
- indoor use for degreening of citrus fruit only as part of a strategy for the prevention of fruit fly damage in citrus;
- indoor use for sprouting inhibition in potatoes and onions;
- field use for flower induction of pineapple.

In addition, the entry stated: 'Only indoor uses as plant growth regulator may be authorised. Authorisations shall be limited to professional users'. This entry reflected the range of crops where the organic sector had agreed to use ethylene.

However, it was contradictory as flower induction of pineapple is not an indoor use. In addition, there was no registration in the EU for some of the crops mentioned.

Situation between 2016 and 2018

Between 2016 and 2018, there were no restrictions. As a consequence, other uses might have been possible, for example the acceleration of maturation of greenhouse crops like tomatoes and peppers.

Actual situation from October 2018 on

Since 23 October 2018, the restriction reads: «Only indoor uses as plant growth regulator may be authorised. Authorisations shall be limited to professional users». This sentence reflects the restrictions of ethylene approval as an active substance. However, national registrations also allow the use in greenhouses. The group highlights that 'indoor use' (=warehouses / post-harvest) is not the same thing as 'greenhouse use'.

The consequences of this wording are:

- the greenhouse use for acceleration of maturation of greenhouse crops like tomatoes and peppers is not allowed, because 'greenhouse use' is not included in 'indoor use';
- the indoor use for degreening is allowed in all fruit for which there is a national registration (not only citrus), also when this is not done to prevent fruit fly attack;
- the indoor use for sprouting inhibition is allowed in all tubers for which there is a national registration;
- the field use for flower induction in **pineapple** is not allowed, because it is not an 'indoor use'.

Pineapple

As stated in the Report on Plant Protection III, ethylene is applied in pineapple to synchronize the onset of flowering (field use). This is necessary if the fruits are to be transported to Europe, as, for economic reasons, large quantities of pineapples have to be shipped together. By contrast, if the pineapples are sold on the local market, synchronization of flowering is not necessary.

Comment: According to plant protection legislation, field uses of ethylene is not authorised in the EU at the moment. However, one should be aware that such uses might be legal in third countries.

Degreening of citrus and other fruit

With respect to the degreening of fruit, the Group recommends to restore the restriction which was in place until 2016 (see above). For citrus fruit, degreening should only be allowed as part of a strategy for the prevention of fruit fly damage. For other fruit, degreening should not be allowed at all. Proposed restriction in Annex II: 'degreening of citrus fruit only as part of a strategy for the prevention of fruit fly damage; degreening of other fruit not allowed'.

3.7.7 Carvone

Carvone (extracted from caraway seeds) inhibits sprouting in potatoes and has been used by the organic sector for this purpose for many years.

At the moment, carvone is accepted in organic plant protection as it is regarded as a plant oil. However, the Group considers that carvone is a fraction of a plant oil and not a plant oil by itself. Therefore, it would be more appropriate to list carvone separately in Annex II.

Considering the importance of carvone for the organic potato sector, the Group recommends that a dossier is submitted in order to enable a proper evaluation. The Group recommends that carvone should remain in use until the re-evaluation has been completed.

3.8 UV radiation of mushrooms

Introduction, scope of this chapter

The Group was asked whether UV radiation may be used in organic production of mushrooms.

Agronomic use, technological or physiological functionality for the intended use

In conventional mushroom production, UV B-radiation is sometimes used at the end of the production cycle (at harvested mushrooms), in order to stimulate the production of Vitamin D in the mushrooms. Such mushrooms are categorized as 'novel food'.

Reflections of the Group / Balancing of arguments in the light of organic production principles

The purpose of the UV treatment is to stimulate the production of Vitamin D, and not to protect the mushrooms against a pest or disease. The sub-Group on plant protection is not qualified to evaluate such a use, and suggests that it is submitted to a Food sub-group.

The Group strongly recommends that the request is supported by a full dossier.

Uses of UV for disinfection should be considered in the context of a mandate on disinfection.

Conclusions

The Group proposes to move the assessment on the UV treatment of mushrooms to a Food sub-Group.

3.9 Basic substances

In 2016, the Group prepared an overview of all basic substances authorized in organic production at that date (see EGTOP report on Plant Protection III). Meanwhile, a number of other substances have been approved. Therefore, the Group updates its overview.

Basic substances of plant/animal origin which are food

Basic substances of plant/animal origin which are food are authorized for organic production according to the entry in Annex II. Since 2016, the following substances have been authorized in this way:

- beer (used in traps to control pest slugs and snails)
- mustard seeds powder (seed treatment in cereals against common blunt, *Tilletia* spp.)
- onion oil (used in traps to protect Umbelliferous crops -carrots, celeriac, parsnip, parsley root- against the Carrot root fly, *Psila rosae*)
- sunflower oil (applied to tomato foliage for the control of powdery mildew)
- *Urtica* spp. (applied to fruit trees, grapevines, vegetables, potatoes, ornamentals against various aphids, certain moths and beetles and spider mites, as well as various diseases).

The Group has no objections against any allowed use and confirms that all uses are in line with the objectives, criteria, and principles of organic farming as laid down in Council Regulation (EC) No 834/2007.

Clayed charcoal

Clayed charcoal is approved as a basic substance. It is a mixture of charcoal, meeting the criteria of the food additive E 153 (vegetable carbon), and bentonite, meeting the criteria of feed additive E 558, in the form of granules. Both components are food/feed grade. Charcoal is of plant origin, while bentonite is of mineral origin. Clayed charcoal is sometimes applied as a soil treatment in vineyards against ESCA, a disease caused by a complex of fungi.

Clayed charcoal is not authorized for organic production by default, and would need to be evaluated and authorized individually. Considering the impact of ESCA in viticulture, the Group recommends that a dossier for clayed charcoal is submitted, enabling the evaluation and possible authorization of this product.

Talc

Talc is approved as a basic substance. It is a food additive (E553b) and it is of mineral origin. Talc is applied to the foliage of Fruit trees (e.g. apple, pear, olive) as a physical barrier against insect and mite pests such as *Cacopsylla pyri*, *Cacopsylla fulguralis*, *Drosophila suzukii*, *Panonychus ulmi* and *Bactrocera oleae*.

Talc is not authorized for organic production by default, and would need to be evaluated and authorized individually. Considering the impact of some of these pests, the Group recommends that a dossier for talc is submitted, enabling the evaluation and possible authorization of this product.

Listing of basic substances in Annex II

Considering the growing number of basic substances authorized for organic production, the Group suggest to list them in a separate sub-chapter within Annex II. For clarity sake, the Group also recommends to re-formulate the entry on basic substances of plant/animal origin which are food. At the moment (i.e. after 23 October 2018), this sub-chapter would contain the following substances according to Regulation (EU) 2018/1584:

- calcium hydroxide,
- chitosan hydrochloride,
- di ammonium phosphate (DAP),
- Equisetum arvense,
- fructose,
- lecithins,
- *Salix* spp. Cortex (aka willow bark extract),
- sodium hydrogen carbonate,
- sucrose,
- sunflower oil,
- vinegar,
- whey.

4. Basic substances

Only those basic substances as defined by Article 23 of Regulation (EC) No 1107/2009. Basic Substances not to be used as herbicides

Basic substances of plant or animal origin which are food	All substances must meet the criteria of 'foodstuff' defined in Article 2 of Regulation (EC) No 178/2002 and must have plant or animal origin. Examples include beer, chitosan hydrochloride that must be obtained from sustainable fisheries or organic aquaculture, fructose, lecithins, mustard seed powder, onion oil, sucrose, sunflower oil, vinegar, whey, and <i>Equisetum arvense</i> Substances not to be used as herbicides
<i>Salix</i> spp. Cortex (aka willow bark extract)	
Calcium hydroxide	When used as Fungicide, only in fruit trees, including nurseries, to control <i>Nectria galligena</i>
Diammonium phosphate	Only as attractant in traps
Sodium hydrogen carbonate (aka sodium bicarbonate)	

4. MINORITY OPINIONS

None

5. LIST OF ABBREVIATIONS / GLOSSARY

None.

6. REFERENCES

Forster, R., Micheloni, C., Regouin, E., Speiser, B., Viñuela, E., 2008. Report of the ad-hoc expert group on pesticides in organic food production. Meeting on 22-23 January 2008. European Commission, Directorate F.5. Organic Farming, Brussels.