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EUROPEAN COMMISSION

Directorate-General for Agriculture
and Rural Development

Expert Group for Technical Advice on Organic Production

EGTOP

FINAL REPORT

on

Plant Protection (X)

and

Fertilisers (VII)

The EGTOP adopted this technical advice at the plenary meeting
of 6 – 8 March 2024

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.

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

ACKNOWLEDGMENTS

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

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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 or fertilising 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.

Recommendations with respect to Annex II to Reg. (EU) 2021/1165:

- The Group recommends adding a specification to the existing entry on 'Stone meal, clays and clay minerals' in Annex II which states 'including heat-treated, e.g. expanded perlite, vermiculite'.
- The Group advises to include calcium acetate in Annex II with the following restrictions: only for foliar treatment of protected vegetable crops and apple trees, to prevent deficit of calcium; obtained from calcium carbonate of natural origin.
- The Group advises to include calcium and magnesium gluconate in Annex II with the restriction 'derived from microbial fermentation with micro-organisms that are not from GMO origin'.
- The Group recommends not to include lignin sulfonates into Annex II at the moment.
- The Group concluded that a broader discussion of fertiliser additives is needed, and considers that a separate mandate and sub-group meeting would be necessary. Meanwhile, the Group advises that fertilizer additives should be allowed in organic farming according to the general legislation of fertilizer products Reg. 2019/1009.
- The Group recommends not to include magnesium chloride into Annex II.
- The Group advises to include calcium phosphate recovered from sewage sludge ash in Annex II with the following restrictions: 'Only from sewage sludge ash origin; The relevant limits for contaminants and organic pollutants set in Reg. 2019/1009 apply'.

Recommendations with respect to Annex VI to Reg. (EU) 2021/1165:

- The Group advises to include the extract of *Swinglea glutinosa* in Annex VI without additional specifications or limits.

1. BACKGROUND

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

- Germany requested the authorization of perlite as an inert material for sprout production.
- The Commission asked the Group for clarification whether calcium acetate, gluconic acid and lignin sulfonates can be used in organic production. The three requests were accompanied by draft dossiers compiled by the Spanish certifier CAAE.
- The Netherlands requested the authorization of magnesium chloride as a fertiliser additive to lower ammonia emissions.
- Sweden requested the authorization of 'calcium phosphate recycled from sewage sludge ash' as a fertiliser.
- Ecocert requested the authorization of Swinglea glutonisa extract as a plant protection product to be used outside the EU.

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 to the current lists in Annexes II and VI to the Regulation (EU) 2021/1165.

3. CONSIDERATIONS, CONCLUSIONS AND RECOMMENDATIONS

3.1 Fertilisers, soil conditioners and nutrients (Annex II of Reg. 2021/1165)

3.1.1 Perlite

Introduction, scope of this chapter

Germany has requested the authorisation of perlite as an inert material for sprout production. Norway has pointed out that perlite is used not only in sprout production, but also as a component of horticultural substrates. Furthermore, Norway pointed out that other inert materials also need to be considered. Denmark has pointed out that until now, Member States are free to decide on the authorisation of inert materials. The authorisation of perlite as an inert material might therefore result in the prohibition of other inert materials in some Member States.

Sprout production takes place on carrier mats, which store liquid and provide support for the roots of the sprouts if necessary. The use of processed mineral substrates (e.g. rock wool) or synthetic substrates (styrofoam) as well as additional enrichment of nutrients has always been avoided in the organic sector in order to meet the goal of the organic principles of a poison-free environment without using mineral fertilizers. In addition, the general principles of "respect for nature's systems and cycles" and "restriction of external means of production to naturally derived substances" must also be taken into account.

Authorization in general production

In non-organic production, perlite is widely used in sprout production, as well as a component of horticultural substrates.

Authorization in organic production

Perlite has been considered as authorised for organic production under the entry ‘clays and clay minerals’ in Annex II. It is used as inert material in organic sprout production for many years. Until the introduction of Reg. (EU) 2018/848 meant that the use of inert material for sprout production required approval in Annex II of Implementing Regulation (EU) 2021/1165.

Agronomic use, technological or physiological functionality for the intended use

Perlite is to be used as an inert material for sprout production and is only used for its water holding capacity and for providing stabilisation to the roots of the sprout. It has no nutritional effect on the sprout. Mineral perlite is inert, chemically neutral and does not influence the soil.

Beyond the proposed use for sprout production (this dossier), perlite is also used as a component of horticultural substrates for organic production in pots. It improves the structure of the substrate without having any nutritional value, helps to increase the surface of the substrate, prevents too compact/tight substrate when using compost and and increase access to air for the roots. Non-agricultural uses include construction (for instances insulation) and water filtration.

Necessity for intended use, known alternatives

Perlite is a durable mineral material, which has long been used for growing sprouts.

Plant fibres might be an alternative which would be more suitable from the biodegradability point of view. However, they are not yet authorised for organic production.

Origin of raw materials, methods of manufacture

Perlite is found in regions with volcanic activity. Most perlite comes from China, Turkey, Greece, USA, Armenia and Hungary. Perlite is heated between 850 and 900 °C in order to evaporate water caught in its structure. This process also causes the material to expand and thus decreasing its bulk density. This means that the final product has roughly 12 times lower density than the mined ore. No chemicals are used in processing perlite.

Environmental issues, use of resources, recycling

Perlite stone is found in regions with volcanic activity. It naturally arises through weathering processes from natural obsidian, which means that its production is secured in the future. Known reserves of perlite will be available for many generations. In the past 60, years less than 1% of the reserve base has been used.

As perlite is chemically inert, no negative environmental impacts are expected from its use.

Animal welfare issues

no concerns

Human health issues

no concerns

Food quality and authenticity

no concerns

Traditional use and precedents in organic production

Perlite has been used as inert material in organic sprout production for many years. Until now, this inert material did not have to be specifically listed in Regulation 889/2008, but since the new Organic Regulation (EU) 2018/848 has come into force, inert materials for sprout production need to be listed in Annex II.

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

Under the US National Organic Program (NOP), perlite is categorized as non-synthetic ('unprocessed mined mineral') and its use in fertilisers and soil amendments is allowed.

In Swiss organic production, 'Prepared clay minerals (e.g. perlite, vermiculite etc.)' are explicitly allowed (EAER Ordinance on Organic Farming, 910.181, Annex 2).

Other relevant issues

Perlite is persistent in the environment, but since it is a natural mineral, the Group has no concerns. When used for sprout production, it will not normally end up in the environment.

Reflections and conclusions

- Perlite has been safely used as inert material in organic sprout production for many years.
- As technical ingredient in substrate for organic production in pots and in nurseries, perlite has also been used to improve the structure of the substrate without adding nutrients
- In the Group's opinion, vermiculite is already authorised under 'Stone meal, clays and clay minerals'. The Group recommends its continued use. For clarity's sake, perlite and vermiculite can be mentioned as examples in Annex II.
- The Group does not recommend restricting the use only to sprout production.

Recommendations

The Group recommends mentioning perlite in the description for the existing entry on ‘Stone meal, clays and clay minerals’ in Annex II.

Name Compound products or products containing only materials listed hereunder	Description, specific conditions and limits
Stone meal, clays and clay minerals	including heat-treated, e.g. expanded perlite, vermiculite

3.1.2 Calcium acetate

Introduction

The Group was asked to evaluate whether calcium acetate should be included in Annex II with the following specification: “Only obtained by mixing calcium carbonate of natural origin with acetic acid of natural origin (vinegar).”

The compound is classified according to UPAC and EU chemical nomenclature as calcium di(acetate), CAS number 62-54-4, but the common trade name is calcium acetate.

Authorization in general production

According to the dossier, in Spain, the use of calcium acetate as a fertilizer has been allowed by national legislation since 2005, falling under the type ‘Calcium acetate’, with the condition of declaring a minimum content of 12 % CaO soluble in water. The new national legislation of 2013, which repealed the previous one, includes the ‘Calcium acetate solution’ type in addition to the ‘Calcium acetate’ category, requiring a content of 6 % of water-soluble CaO.

Calcium acetate is classified according to Regulation (EU) 2019/1009 under PFC 1(C)(I)(b)(i) as ‘Straight Liquid Inorganic Macronutrient Fertiliser’.

The raw materials used are classified as CMC 1 Substances and Mixtures of Virgin Materials.

Authorization in organic production

The use of calcium acetate as a fertilizer is currently not authorised in EU organic production.

Agronomic use, technological or physiological functionality for the intended use

Calcium (Ca) is an essential element in plants, having a structural role in cell wall and membranes, functioning as counter-cation to organic and inorganic anions in the vacuole and a cell messenger function in cytosol, particularly under abiotic and biotic stresses (Marschner 1995; White and Broadley 2003). Ca-deficiency can have a high-impacting effect on plants, particularly horticultural crops, which appears when Ca is temporarily unavailable to growing tissues due to abiotic conditions (e.g. high transpiration due to high temperatures) or to lack of transport within the plant (White and Broadley 2003). Moreover, it is becoming evident that the main function of calcium lies in its ability to serve as a second messenger in a vast variety of physiological, developmental, and stress-related processes, including immunity signalling (Thor 2019).

Symptoms of calcium deficiency first appear on younger leaves and tissues, but they can differ depending on the species and tissue concerned: tip burn of leafy vegetables, black hearth in celery, blossom end rot in tomato, pepper and watermelon fruits, bitter pit in apple fruits, empty pod in peanut (Shear 1975). Foliar application of calcium compounds can reduce or prevent the occurrence of such deficiencies in the different crops (Olle and Bender 2009). The type of the foliar fertilizers can affect the efficiency and potential of the technology, being dependent on its physical-chemical properties.

Calcium acetate can be used to prevent and correct calcium deficiencies, even though earlier reports concluded that its efficacy is lower compared to calcium chloride or calcium nitrate (references in van der Boon et al. 1968). However, the same authors noted that calcium acetate had the same effect as other compounds in reducing bitter pit and increased significantly more the calcium content in leaves and fruits compared to them. A recent report found a significant reduction of blossom end rot in tomatoes treated with calcium acetate and no differences compared to calcium chloride application (Oliveira de Melo et al. 2022).

In the dossier it is underlined that both solid and liquid forms of Ca acetate are used to provide calcium in an easily assimilated form, particularly in protected horticultural crops, by foliar or drip irrigation. According to the dossier, the following doses are commonly applied, depending to the form used: in vegetable crops, foliar applications are performed with solutions in the range 0.15 – 0.3 % of the product, which equals to about 0.01 – 0.02 % of Ca acetate. For perennial crops (i.e. fruit crops) the foliar application is in the range of 0.2 – 0.4 %. Soil applications are in the range of 5 – 10 l/ha (i.e. 30 – 60 g of the compound per hectare). These doses are in the same order of magnitude of calcium chloride application.

Necessity for intended use, known alternatives

The soil is the primary source of calcium. If this is not sufficient or not available to plants due to abiotic stress, then foliar treatments may be necessary.

Considering the quite wide risk of occurrence of calcium deficiency in different horticultural crops, particularly those grown under protected conditions, it is clear that the availability of alternative compounds to avoid this risk is important. In organic crops, calcium deficiency is usually corrected by soil amendments. Among the products authorized by current EU organic legislation as fertilisers (Annex II), which can provide calcium, are listed soft ground rock phosphate and various materials based on calcium carbonate (e.g. chalk, marl, ground limestone, Breton ameliorant, phosphate chalk). These are all applied to the soil and have a slow effect due to low solubility. Calcium chloride, which is the only substance with greater solubility included in Annex II, is allowed with the condition of use only for foliar treatment of apple trees, to prevent deficit of calcium.

The application of soil amendments can lead to pH and nutrients imbalances in the soil which can affect nutrient uptake by plants. Moreover, the low solubility of these materials does not meet the plant requirements in case of transient needs due to the factors mentioned above, particularly for short-cycle horticultural crops such as vegetable crops.

Origin of raw materials, methods of manufacture

According to the information provided in the dossier, calcium acetate can be manufactured from natural materials which fall within Annex II of Regulation (EU) 2021/1165 as:

- Calcium carbonate, for example: chalk, loam, ground calcareous rock, calcareous sand (maerl), phosphate chalk
- Products and by-products of plant origin: Acetic acid of natural origin (vinegar)

The manufacturing process described in the dossier is the following:

1. Mix calcium carbonate ($CaCO_3$) with water and stir for 12 hours at a temperature between 80 and 90 ºC.
2. Add acetic acid of natural origin (CH_3COOH) to the previous mixture with continuous stirring, maintaining a temperature between 80 and 90 ºC. Add the acetic acid to adjust pH between 4.6 and 4.8.
3. Extract the carbon dioxide (CO_2) formed (it can be reused for other purposes).
4. Decant the mixture obtained. At this stage, the unreacted calcium carbonate will precipitate to the bottom of the reactor and the calcium acetate will remain in the form of a solution.
5. Collect the calcium acetate solution, cool to room temperature and bottle.
6. The decanted calcium carbonate ($CaCO_3$) is reused in order to make the procedure for obtaining the fertilizer more efficient.

This process is described also in the international patent n. WO 2015/190905 A1. Calcium acetate can also be made from calcium carbonate and/or acetic acid which is not from natural origin.

Environmental issues, use of resources, recycling

The Group has no concerns. Calcium is common in the environment and calcium acetate can and does occur naturally. Calcium acetate is biodegradable and not hazardous to the environment according to ECHA[2]. It was classified as having no bioaccumulation potential in aquatic organisms, no bioaccumulation potential in terrestrial organisms, no bioaccumulation potential in predators and as not dangerous for the environment, also because being classified as a non-PBT substance (not Persistent, non-Bioaccumulative and non-Toxic) and non-vPvB (not very Persistent and not very Bioaccumulative). These conclusions were also reached by EPA, having 'not identified any toxic endpoints for birds, plants, aquatic, or soil organisms' for the compound.

Animal welfare issues

No concerns.

Human health issues

The Group has no concerns. Calcium acetate is widely used for human health as treatment for calcium deficiency and to treat patients with hyperphosphatemia in end stage renal disease. It has been authorized for human consumption without limitation by the Joint FAO/WHO Expert Committee on Food Additives and it is authorised in the EU as food additive to Regulation (EC) No 1333/2008, belonging to group I additives, with use permitted in several food categories at *quantum satis*.

Food quality and authenticity

The use of calcium acetate can contribute to assure quality of organic foods as it can reduce the risk or prevents the occurrence of Ca deficiencies in different vegetable and fruit crops. In the latter case, apple production could particularly benefit from the treatment since bitter pit is frequently not visible (it affects the inner part -pulp- of the fruit), but can strongly impact on fresh fruits consumption.

Traditional use and precedents in organic production

Use of compounds containing easily soluble calcium to address the prevention of its deficiency is authorized by the current EU legislation in the form of calcium chloride, only for foliar treatments of apple trees.

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

Calcium acetate was requested to be included as a soil amendment, plant micronutrient, soil pH adjuster and as a sunscald protectant in the NOP standard. The Recommendation of the US National Organic Standards Board (NOSB) to NOP of 26.04.2019, concluded that calcium acetate should not be added to the National List. This recommendation was based on the justification that this material is not essential to organic agriculture, since other materials were already available for delivering calcium more readily to plants. Concerning the sunscald protection, NOSB observed that other alternatives also exist (cultural practices and other materials), which were already included in the NOP standard. The NOSB considered the compound as synthetic. However, in the description of the process for obtaining the compound, a reaction of calcium carbonate with acetic acid (and eventually with the addition of other substances such as humic acids) is described. Moreover, the use in that case was only dealing with soil application and also for purposes other than those of the application evaluated here.

It should be underlined that in the NOSB Recommendation it is also acknowledged that synthetic chelating agents like lignin sulfonate or lignosulfonate, which increase the water solubility and bioavailability of cationic nutrients (like calcium), are already approved by the NOP for use in organic agricultural production, which is not the case for the EU legislation.

2 https://echa.europa.eu/it/brief-profile/-/briefprofile/100.000.492

Other relevant issues

The dossier claims that both components (calcium carbonate and vinegar) comply with Annex II. This could be interpreted as a suggestion that calcium acetate is already authorized today, because materials that are mentioned in Annex II can be mixed in a compound fertilizer. The Group clarifies that it does not share this view: although vinegar is a product of plant origin, it is not a fertilizer. Thus, vinegar does not comply with Annex II, and the claim in the dossier is not correct.

Reflections and conclusions

- According to the general principles of organic production, mineral fertilizers should be applied in a form which has low solubility (see Art. 5(g)(iii) of Reg. 2018/848). However, the authorisation of calcium chloride for prevention of calcium deficit in apple trees is a precedent that substances with high solubility can be authorised, if this is essential. The Group considers that authorisations of such fertilisers should be limited to those crops where their use is essential.
- The use of highly soluble calcium should be limited to curative measure in urgent situations, to save part of the crop, particularly in protected vegetable crops.
- It has been documented that with limited climate control in unheated greenhouses, calcium deficiency often occurs. This is caused by difference in soil temperature and air temperature (night below 10, day high), high humidity. Zero heating is ecologically beneficial which is considered as a good argument in favour of treatment.
- Considering that the compound is normally present in nature, the safety of the compound for humans and the environment, that its production process foresees the use of materials already authorised in organic farming and that the reaction is similar to that producing the Bordeaux mixture, the Group concluded that its use in organic farming could be authorised, under conditions that the calcium carbonate is of natural origin.
- For the prevention of calcium deficit in apple trees, calcium chloride is authorised at the moment. In the Group's opinion, apple growers should be given the same opportunities. Therefore, calcium acetate should also be authorised for apple trees.
- If calcium acetate is included in Annex II, the Group suggests to re-consider the listing of calcium chloride after three to five years, when sufficient practical experience with calcium acetate is available. This might permit to limit chloride accumulation in the soil.

Recommendations

The Group advises to include calcium acetate in Annex II with the following restrictions:

Name Compound products or products containing only materials listed hereunder	Description, specific conditions and limits
Calcium acetate	Only for foliar treatment of protected vegetable crops and apple trees, to prevent deficit of calcium Obtained from calcium carbonate of natural origin

3.1.3 Gluconic acid, calcium and magnesium gluconate

Introduction

The Group was asked to evaluate whether gluconic acid should be included in Annex II. The dossier specifically mentions the use of Gluconic acid as complexing agent to provide, in addition to micronutrients, calcium or magnesium in organic crops. It is mentioned that '*deficiency usually is corrected by adding substances included in Annex II of Regulation (EU) 2021/1165 as calcium carbonate or magnesium sulfate in the soil. But, due to the scarce solubility of these compounds themselves, this does not correct this deficiency, until long time has passed*'.

Gluconic acid is known as a complexing agent, but is sometimes also referred to as chelating agent. The use makes it possible to bind metals or salts with the purpose of modifying solubility and plant availability.

Authorization in general production

The dossier refers to the allowance of complexing/chelating substances for micronutrient fertilisers, aligned with the Regulation (EU) 2019/1009; (Product Function Category (PFC) 1 (fertilisers), C (inorganic fertilisers), II (Inorganic micronutrient fertiliser), a (straight) and b (compound), are fertiliser other than an inorganic macronutrient fertiliser aimed at providing plants or mushrooms with one or more of the following micronutrients: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) or zinc (Zn).

Authorization in organic production

For CE-marked fertilizers, chelating or complexing agents are allowed for use in *micro*nutrient fertilisers, but are not allowed in *macro*nutrient fertilisers.

Agronomic use, technological or physiological functionality for the intended use

In the dossier, an example is stated: 'To prevent and correct a calcium or magnesium deficiency in vegetable crops like tomatoes, it is necessary to have fertilizers that are easily assimilated for plants with medium-fast effect. The fertilizers that provide the items necessary, in a complexing way by the gluconic acid, perform perfectly this function'. [...] 'Sources of calcium and magnesium allowed in organic production and included in Annex II of Regulation (EU) 2019/1009 are all applied to soil and have a slow effect, so the Certified Organic farmers do not have the tools effective and efficient to correct calcium or magnesium deficiencies in a medium-short timeframe.' A typical dose to be applied through foliar treatment is in the same order of magnitude as for calcium chloride or other sources (e.g. calcium acetate).

Gluconic acid appears to have also positive effects in reducing water loss / water stress.

Necessity for intended use, known alternatives

The soil is the primary source of calcium. If this is not sufficient or not available to plants due to abiotic stress, then foliar treatments may be necessary. According to the organic principles, prevention is the normal way to avoid nutritional disorders/deficiencies. Symptomatic treatment should only be allowed in specific and occasional situations, diagnosed by specialists. This is a typical condition when abiotic stresses are affecting vegetable or fruit crops, making a necessity for easily available sources of calcium and magnesium. Crops other than tomatoes are also affected by sudden deficiencies that require a leaf application (see chapter 3.1.2 Calcium acetate).

Calcium chloride would be a theoretical alternative. At the moment, however, it is authorised only for apple trees. In addition, there is a risk of chloride accumulation, with negative impacts on soil fertility. For this reason, the Group does not recommend to solve such problems with calcium chloride.

Origin of raw materials, methods of manufacture

Gluconic acid is traditionally manufactured by glucose fermentation with a strain of *Aspergillus niger* which is not from GMO origin, in a process named 'calcium gluconate process'. This process involves the use of calcium carbonate for neutralization of the fermentation broth. The fermentation is highly efficient. When mixed with calcium and/or magnesium salts, calcium gluconate and/or magnesium gluconate will be formed, which are the substances to be used as foliar application.

Environmental issues, use of resources, recycling

Gluconic acid (2,3,4,5,6-pentahydroxy caproic acid, $C_6H_{12}O_7$) is a noncorrosive, nontoxic, mild organic acid with a brown clear appearance. It is very soluble in water and has a mild and refreshing taste. It is a good chelator at high pH, with better activity than commonly used chelators. According to the dossier, it normally occurs in small quantities in many fruits and in wine. ECHA concluded that it is biodegradable and not bioaccumulative.

The Group has no environmental concerns.

Animal welfare issues

No animal welfare issues.

Human health issues

The Group has no human health concerns, because gluconic acid has various applications in the food industry, in the pharmaceutical and textile industries.

Food quality and authenticity

No negative impacts reported. Product quality (shelf life) can be improved by avoiding calcium deficiencies.

Traditional use and precedents in organic production

Gluconic acid is extensively used in non-organic agriculture, but no traditional use in organic production is known to the Group.

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

Under the US National Organic Program, nonsynthetic chelating agents are allowed (NOP guidance 5034-1). Allowed sources of chelating agents include, but are not limited to, nonsynthetic amino acids, citric acid (to form citrate in solution), humic acids, tartaric acid (made from grape wine), and gluconic acid.

Other relevant issues

When chelating or complexing agents are added to *macro*nutrient fertilisers (Mg, Ca, S), these substances have to be considered as fertiliser additives. Therefore, gluconic acid is considered to be an additive when used for this purpose.

As described in chapter 3.1.5, the Group thinks that a broader discussion of fertiliser additives is needed, before entering the evaluation of a specific substance. Therefore, the Group postponed the evaluation of gluconic acid.

However, calcium gluconate and magnesium gluconate are closely related to gluconic acid and may be used for the same purpose. Because calcium gluconate and magnesium gluconate are plant nutrients, they can be evaluated without waiting for a broader discussion of fertiliser additives. Therefore, the Group decided to evaluate calcium gluconate and magnesium gluconate rather than gluconic acid, as requested in the dossier.

Reflections and conclusions

- The legal status of gluconic acid is subject to the nutrients with which it is combined.
  - When combined with *micro*nutrients, the product may fulfil the requirements for a straight inorganic micronutrient fertiliser, as described under PCF 1(C)(II)(a) of the EU fertiliser regulation 2019/1009. In that case, it also complies with the EU organic production rules, because Annex II allows all Inorganic Micronutrient Fertilisers. Thus, no change in Annex II is required for this use.
  - When combined with *macro*nutrients, it might be considered as a fertiliser additive, but there is no definition in the Fertilizer Regulation 2019/1009. In addition, national legislations may allow the use of gluconic acid in macronutrient fertilisers.
- The Group acknowledges that there might be agronomic situations where it would be useful to make nutrients more plant-available with an additive such as gluconic acid. However, the Group thinks that a broader discussion of fertiliser additives is needed, before entering the evaluation of a specific substance (see chapter 3.1.5).
- Therefore, the Group postponed the evaluation of gluconic acid. Because the microbial-based 'calcium gluconate process' always implies the formation of calcium/magnesium gluconate, the Group decided to evaluate the use of Ca gluconate and Mg gluconate in this report.
- If calcium gluconate is included in Annex II, the Group suggests to re-consider the listing of calcium chloride after three to five years, when sufficient practical experience with calcium gluconate is available. This might permit to limit chloride accumulation in the soil.

Recommendations

The Group advises to include calcium and magnesium gluconate in Annex II as follows:

Name Compound products or products containing only materials listed hereunder	Description, specific conditions and limits
Calcium and magnesium gluconate	derived from microbial fermentation with micro-organisms that are not from GMO origin

3.1.4 Lignin sulfonates

Introduction

The Group was asked to evaluate whether lignin sulfonates should be included in Annex II. The dossier specifically mentions the use of lignin sulfonates as complexing agent to provide, in addition to micronutrients, calcium, magnesium, or sulfur in organic crops, when symptoms of deficiency occur.

Lignin sulfonates are known as complexing agents (see also chapter 3.2.3, gluconic acid).

Authorization in general production.

The dossier refers to the allowance of complexing substances for micronutrient fertilisers, aligned with the Regulation (EU) 2019/1009; (Product Function Category (PFC) 1 (fertilisers), C (inorganic fertilisers), II (Inorganic micronutrient fertiliser), a (straight) and b (compound), are fertiliser other than an inorganic macronutrient fertiliser aimed at providing plants or mushrooms with one or more of the following micronutrients: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) or zinc (Zn).

Authorization in organic production

For CE-marked fertilizers, chelating or complexing agents are allowed for use in *micro*nutrient fertilisers, but are not allowed in *macro*nutrient fertilisers (see also chapter 3.1.3, Gluconic acid).

Agronomic use, technological or physiological functionality for the intended use

The dossier argues with a need to correct calcium or magnesium deficiency in vegetable crops. For details, see chapter 3.1.3, Gluconic acid.

Necessity for intended use, known alternatives

For a discussion of necessity, see chapter 3.1.3, Gluconic acid.

Origin of raw materials, methods of manufacture

Lignosulfonates are by-products from the paper industry. They are derivatives of lignin that are produced during the sulfite wood pulping process. During this process, lignin is extracted from the wood chips and then sulfonated with hydrogen sulfite. The sulfonation process introduces sulfonic acid groups into the lignin structure, resulting in a water-soluble polymer that can be used for various industrial applications.

Environmental issues, use of resources, recycling

According to the dossier, lignosulfonates are biodegradable, non-toxic and from a renewable source. Based on this information, the Group has no environmental concerns.

Animal welfare issues

no issues

Human health issues

no issues

Food quality and authenticity

No negative impacts reported. Product quality can be improved by avoiding calcium deficiencies.

Traditional use and precedents in organic production

Lignin sulfonates have traditionally been used as complexing agents for micronutrients.

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

In the USA (NOP reference 205.601), lignin sulfonate is allowed as synthetic substance for use as chelating agent, or dust suppressant.

In Japan, the use of lignin sulfonate is allowed (JAS Standards: Standards and Individual Procedures for Judging Compliance of Substances Listed in Appendices 1 and 2 of Japanese Agricultural Standards for Organic Plants).

In Mexico, the use of lignin sulfonate as chelant agent is allowed (Mexican National Organic Regulation (LPO): o ACUERDO por el que se modifica el Anexo 1.- Lista nacional de sustancias permitidas para la operación orgánica agropecuaria del diverso por el que se dan a conocer los Lineamientos para la Operación Orgánica de las Actividades Agropecuarias, publicado el 29 de octubre de 2013).

Other relevant issues

When chelating or complexing agents are added to *macro*nutrient fertilisers (Mg, Ca, S), these substances have to be considered as fertiliser additives. Therefore, liognosulfonates are considered to be additives when used for this purpose.

As described in chapter 3.1.5, the Group thinks that a broader discussion of fertiliser additives is needed, before entering the evaluation of a specific substance. Therefore, the Group postponed the evaluation of lignosulfonates.

Reflections and conclusions

- The legal status of lignosulfonates is subject to the nutrients with which they are combined.
  - When combined with *micro*nutrients, the product may fulfil the requirements for a straight inorganic micronutrient fertiliser, as described under PCF 1(C)(II)(a) of the EU fertiliser regulation 2019/1009. In that case, it also complies with the EU organic production rules, because Annex II allows all Inorganic Micronutrient Fertilisers. Thus, no change in Annex II is required for this use.
  - When combined with *macro*nutrients, they might be considered as a fertiliser additive, but there is no definition in the Fertilizer Regulation 2019/1009. In addition, national legislations may allow the use of lignosulfonates in macronutrient fertilisers.
- The Group acknowledges that there might be agronomic situations where it would be useful to make nutrients more plant-available with an additive such as lignosulfonates. However, the Group thinks that a broader discussion of fertiliser additives is needed, before entering the evaluation of a specific substance (see chapter 3.1.5 Short reflection on fertilizer additives).
- Therefore, the Group postponed the evaluation of lignosulfonates.

Recommendations

The Group recommends not to include lignin sulfonates into Annex II at the moment.

3.1.5 Short reflections on fertiliser additives

When discussing the requests for gluconic acid (chapter 3.1.3) and for lignosulfonates (chapter 3.1.4), the Group concluded that a broader discussion of fertiliser additives is needed. This chapter briefly describes why the Group considers such a broader discussion necessary, where the Group sees the main open points for discussion and how the topic could be approached.

Legal situation

- Fertiliser additives are not explicitly mentioned in Annex II of Reg. 2021/1165. This leaves room for different interpretations.
- Apparently, different Member States have different views on whether fertilizer additives are authorized for organic production. The Group has not verified this, but if it should indeed be the case, it would not be desirable.

Necessity

- Fertiliser additives have a number of functions. For example, they may have beneficial effects on handling, use or storage, and they may affect plant availability of nutrients.
- The Group thinks that such functions are also important for organic production.

Open questions regarding authorisation of fertiliser additives

- There is no overview of the necessity for fertiliser additives in organic production. This could be tackled as follows:
  - As a starting point, the organic sector should have an overview of the major functions delivered by fertilizer additives.
  - Then, the organic sector should determine for each function how important it is for organic farming.
- For the important functions, it must then be clarified whether they can be provided by the materials currently in Annex II.
- If the materials currently in Annex II are insufficient, the following questions arise:
  - What other materials / chemical substances are needed?
  - What is their environmental impact?
  - Would their use be in line with organic principles?

Open questions regarding the possibilities for implementation

- To what extent are fertilizer additives declared on product labels?
- In case that not all fertilizer additives are declared: what kind of rules can be observed by organic farmers and enforced by organic inspectors?
- Does it make sense to authorize fertilizer additives substance by substance, or is a generic approach needed (for example as for co-formulants in plant protection products)?

How to approach the topic

- In view of the dimension of this topic, the Group considers a separate mandate and sub-group meeting necessary.
- For this mandate, there would probably not be dossiers for individual substances.
- As background information, the Group would appreciate the following:
  - Information how fertilisers are currently regulated in different member states (inquiry among COP members)
  - Input from of the fertiliser industry regarding different functions of fertiliser additives (invitation of 1 – 2 experts to the sub-group meeting)
- Meanwhile, the Group advises that fertilizer additives should be allowed in organic farming according to the general legislation of fertilizer products Reg. 2019/1009 and national legislations. Under Reg. 2019/1009, there is no definition for technical additives and no certain rules to comply with (except for chelating and complexing agents used in micronutrients fertilisers). However, manufacturers may use any substance or material as a technical additive as long as this complies with the requirements of any of the 15 CMCs of Annex II to Reg. 2019/1009.

3.1.6 Magnesium chloride

Introduction

The Netherlands requested the authorization of magnesium chloride as a fertilizer and manure additive, with the function to reduce ammonia emissions. By adding magnesium chloride to manure, the magnesium reacts with ammonium and phosphate in the manure to form magnesium ammonium phosphate hexahydrate (struvite). Because of this struvite formation, less nitrogen is emitted to the air (ammonium) and less phosphate is leaked from the soil. Magnesium chloride can be added to manure in the barn or in storage, and during application.

The use of magnesium chloride as a fertilizer (source of magnesium) and as a manure additive (to bind ammonia) are different.

Authorization in general production

Magnesium chloride can be used as additive in manure in conventional agriculture to enrich the manure with magnesium and to increase fertilizing efficiency of the nitrogen in the manure also to (partially) replace synthetic fertilizers. Magnesium chloride containing products may be covered the fertilising products Regulation (Reg. 2019/1009).

Authorization in organic production

The use of magnesium chloride as a magnesium fertilizer is currently not authorized for EU organic production.

Manure additives in general are currently not listed in Annex II. As manure additives are a special case of fertilizer additives, the general considerations outlined in chapter 3.1.5 apply also for this use.

Agronomic use, technological or physiological functionality for the intended use

The product can be bought as flakes or liquid, suitable for addition to stable floors, storage or field injectors. According to the dossier, a dose of 5 – 10 liter/ per m^3 manure is recommended, dependent on the ammonium content of the manure, and the application mode.

The Group has some doubts regarding the practical feasibility of this application, because the required dose is quite high and the product is expensive. From a practical point of view, the Group considers use in liquid slurry more realistic than use on solid manure. The dossier was supplemented with the results of a pot experiment, where reduction of ammonium up to 40 % was noted. A more recent report from research done at Wageningen university concluded that these effects were doubtful, and noted substantial uncertainties on dosage, frequency of application, and possible structure damage on the soil, as also problems with chloride surplus in the soil (Boxmeer et al., 2023).

Slurry is a known Ca rich flow and some authors have found some limitations when precipitating struvite at high Ca concentration and high Ca/Mg ratios as phosphorus can tend to be precipitated as $CaPO_4$ rather than as struvite (Enyemadze et al., 2021). pH has been recognised to significantly affect the struvite formation and literature reports the need of continuous stirring of the mixtures to improve the mass transference (Astals et al., 2021). More clarification on the practical feasibility of the process described at real scale would be needed.

Necessity for intended use, known alternatives

It is a common problem that ammonium can evaporate from manure on floors, storage or in the field, when applied. Ammonium contents varies very much, from 1 – 3 kg NH_4/ ton, of which up to 0,25 (12 %) kg NH_4 can evaporate in barn and storage together, field evaporation with injection is calculated to be between 8 % for cattle slurry injected, and 6 % for pig manure when injected, for online application the emission rates are higher, especially in the spring and summer.

There are two problems associated with ammonia losses: (i) As organic agriculture is in need of nitrogen for the production of field crops, losses should be avoided as much as possible. (ii) Ammonia is considered to contribute to the formation of nitrous oxide, a very potent greenhouse gas (GHG).

The dossier claims that magnesium chloride addition can reduce ammonia losses by 25 %.

As a possible alternative, ion-exchange-based additives such as natural zeolites, activated zeolites or clay minerals (Lamkaddam et al., 2021) can be used to adsorb ammonia from the liquid phase of manure. Experiments demonstrated a reduction of 40 % of ammonia. Sulfuric acid is commonly used for this purpose in conventional agriculture. However, this is currently not allowed in organic production, and the Group would not recommend authorizing it.

Origin of raw materials, methods of manufacture

The product is a pure mineral, regularly consisting of 32 % magnesium chloride, water and trace elements. Relevant trace elements are sulfate, sodium, calcium, bromide (all < 1%) and iron. The origin of the raw material is often from natural brines containing bischofite. Bischofite is a hydrous magnesium chloride mineral with formula $MgCl_2$ x $6H_2O$. There are few bischofite rich deposits, one in the Volgograd region in Russia, and one in the Poltova region in Ukraine, but also in the Netherlands. Bischofite is extracted via solution mining.

Magnesium chloride can also be extracted from seawater. The dossier mentions locations such as the Qarhan Salt Lake, the Dead sea and the Great Salt Lake. In Chile, bischofite can be obtained in dry state. In addition, magnesium chloride is also a by-product of potassium production from brines.

Environmental issues, use of resources, recycling

The dossier contains no information of possible negative impacts on the environment from solution mining or recovery from seawater.

The binding of ammonia has a positive environmental impact. However, the accumulation of magnesium and chloride may have negative impacts on the soil, and possible ground or surface water (Boxmeer et al., 2023).

Animal welfare issues

When used in barns, the reduction of ammonia in the air would be beneficial for animal health/welfare.

Human health issues

Magnesium chloride can be taken orally, and is non-toxic for humans and animals. The dust is hygroscopic (attracts moisture) and therefore sometimes used as dust control. When used in stables, the reduction of ammonia in the air is beneficial for human health.

Food quality and authenticity

No issues

Traditional use and precedents in organic production

In case of magnesium deficiency, small doses of seawater salts, with traces of magnesium chloride, have traditionally been used in agriculture.

Magnesium chloride is used as feed material of mineral origin and listed as such in Annex III (11.2.1), Magnesium chloride (also called Nigari) is used as processing aid and listed as such in Annex V of regulation 2021/1165, section A2. This in addition to the conditions of the authorisations under Regulation (EC) No 1333/2008.

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

In the USA (NOP reference 205.105), magnesium chloride is allowed as non-synthetic substance for crop production and soil amendment. It is also allowed in Canada (COR), with the specification 'derived from natural brines and not chemically treated'.

Other relevant issues

In countries with great ammonium evaporation problems, the use of magnesium chloride might be a solution, and maybe even subsidised. The use of magnesium chloride results in the formation of struvite, which is itself allowed in organic production (see Annex II).

Reflections and conclusions

- Ammonia adsorption is important for several reasons: (i) it can contribute to climate protection, and thus helps to address a major environmental concern; (ii) it is beneficial for the health of humans and livestock; (iii) it may reduce water pollution (eutrophication); (iv) it converts phosphate from an easily soluble to a slow-release form, which is line with organic production principles.
- Maintenance of nitrogen in the manure is important, because nitrogen is a highly valuable plant nutrient in organic farming.
- Amounts of Magnesium Chloride used are high (up to 30 kg per cubic meter of slurry), leading to risks of chloride accumulation in soil and excess of magnesium, which might affect soil structure and fertility and nutrient balance (Boxmeer et al., 2023). This needs to be further investigated, considering also long term use.
- In addition, the Group has doubts about practical feasibility of ammonium binding with magnesium chloride. Magnesium chloride is expensive and has, when used in barns, to be applied very often (six times a day) to have the desired effect. However, practicability may depend on the stage of development of the technology, and may be influenced by subsidies, if there should be any.
- There are several alternative methods for conserving nitrogen in manure, for example covering the manure storage, frequent emptying of the manure tank, temperature control in the barn, injection of liquid manure into the soil, etc.
- Magnesium chloride is available from natural sources, and it is a by-product of the salt industry. These origins are in line with the objectives and principles of organic production.

Recommendations

The Group recommends not to include magnesium chloride into Annex II.

3.1.7 Calcium phosphate

Introduction

Sweden requested the inclusion of ‘Calcium phosphate recycled from sewage sludge ash’ into Annex II.

Under the denomination ‘renewable calcined phosphate’, the Group has previously evaluated a similar material (see chapter 4.3 of the EGTOP report on Fertilizers and Soil Conditioners II). The Group was positive about this material, but did not recommend its inclusion into the organic regulation, because it was not authorised by the EU fertiliser regulation at that time (2016).

Authorization in general production

Calcium phosphate derived from sewage sludge ash may comply with requirements of component material category (CMC) 13 ‘Thermal oxidation materials or derivatives’, as specified by the fertilising products Regulation (Reg. 2019/1009). It may also comply with national legislations, but this was not further investigated by the Group.

Authorization in organic production

Calcium phosphate derived from sewage sludge ash is currently not authorised for organic production.

Agronomic use, technological or physiological functionality for the intended use

Calcium phosphate derived from sewage sludge ash is a solid product. According to the dossier, it has low solubility in water, but high solubility in citric acid. Thus, it can be classified as a ‘low solubility mineral fertiliser’, but the P is plant available.

Calcium phosphate may be used alone (as a P fertiliser), or mixed with other component materials to form a multi-nutrient fertiliser. It is applied in the same way as other fertilisers with similar nutrient contents (e.g. based on rock phosphate) and acts as slow-release P fertiliser.

Necessity for intended use, known alternatives

Phosphorus (P) is an essential element for all living organisms. In animal husbandry, P is imported via feed, and ends up in the manure. Farms with many animals may be able to cover the total crop need for P with manure, while farms with fewer or no animals have to import P fertilisers. In organic farming, the main sources of P are manure, animal by-products, digestate, compost and rock phosphate. Recovered struvite has recently been authorised, but is quantitatively not yet important.

Considering that global reserves of rock phosphate are limited and that P is a vital plant nutrient, organic farming needs to have access to P from recycled sources.

Origin of raw materials, methods of manufacture

In the last years, a number of processes for sewage sludge recycling have been developed. Here, the process 'Ash2Phos' is briefly described as a case study, based on the description given by Theuring and Kabbe (2023). As a first step, sewage sludge is burnt, resulting in sewage sludge ash. This process eliminates organic contaminants such as per- and polyfluoroalkyl substances (PFAS), microplastic and pathogens. The sewage sludge ash is then transported to the plant where phosphorus is recovered with the Ash2Phos process.

As a second step, the sewage sludge ash is treated with hydrochloric acid, solubilizing most of the phosphorus and calcium. The solid fraction is removed and forms the so-called 'sand fraction', which may be utilized in the construction sector as a concrete additive.

As a third step, the liquid fraction is treated with calcium hydroxide. As the pH increases gradually, calcium phosphate is first formed and precipitates as solid particles. These particles are filtered out, and the remaining liquid is further treated with calcium hydroxide to sequentially recover iron and aluminium, and in some cases also the heavy metals. The calcium phosphate is the material discussed in this chapter.

The calcium phosphate may be used directly as a low solubility P fertiliser, which is the use discussed in this chapter, but it can also be used as a raw material for the manufacture of other substances including more soluble P fertilisers, industrial chemicals and feed materials.

A wide range of organic materials contain P which could potentially be recovered by similar processes (see description for CMC 13 in the fertilising products Regulation Reg. 2019/1009). However, the dossier is explicitly limited to calcium phosphate derived *from sewage sludge ash*, and the Group agrees with this limitation (see section considerations and conclusions).

The website of the European Sustainable Phosphorus Platform (ESPP)[3] provides an overview of several processes. The information for seven processes is summarized in table 1 (below). In this chapter, only the phosphorus generated by the processes no 1 and 2 is discussed.

Table 1: Overview of several processes for recycling of sewage sludge ash (information compiled from ESPP website). In this chapter, only the phosphorus generated by the processes no 1 and 2 is discussed.

No	Process	Substance used for dissolving the sewage sludge ash	Phosphorus output material
1	Ash2Phos	Hydrochloric acid	Calcium phosphate (RevoCaP)
2	Metawater	Sodium hydroxide	Calcium phosphate (hydroxyapatite)
3	Prayon	Sulphuric, hydrochloric or phosphoric acid	Dicalcium phosphate or phosphoric acid

3 https://www.phosphorusplatform.eu (accessed on 26 January 2024)

No	Process	Substance used for dissolving the sewage sludge ash	Phosphorus output material
4	Susphos	Sulphuric acid	Monoammonium phosphate, diammonium phosphate or phosphoric acid
5	Parforce	Hydrochloric or nitric acid	Phosphoric acid
6	Phos4Life	Sulphuric acid	Phosphoric acid
7	Tetraphos	phosphoric acid	phosphoric acid

Environmental issues, use of resources, recycling

- When used correctly, recovered calcium phosphate will not lead to phosphorus pollution of the environment, because it has low solubility in water.
- Sewage sludge is a renewable source of P, while the deposits of rock phosphate are limited.
- Sewage sludge is available all over the world, while most of the deposits of rock phosphate are limited to a few countries. Thus, the use of sewage sludge results is shorter transportation distances.
- Calcium phosphate derived from sewage sludge ash has a much lower cadmium content than rock phosphate.
- The extent of energy consumption for incineration varies greatly between installations, mainly due to the presency or absence of heat recovery systems.

Animal welfare issues

No issues.

Human health issues

Calcium phosphate derived from sewage sludge ash has no negative impact on human health. In comparison to rock phosphate, the use of calcium phosphate derived from sewage sludge ash results in lower cadmium contamination of crops, which is beneficial for public health.

Food quality and authenticity

No issues.

Traditional use and precedents in organic production

Calcium phosphate derived from sewage sludge ash is a new product and therefore has no traditional use in organic production.

Recovered struvite and precipitated phosphate salts have recently been authorized for organic production. This is a precedent for the use of sewage sludge for the purpose of P recycling.

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

The Group assumes that calcium phosphate produced in this way would be classified as 'synthetic' under the US National Organic Program (NOP), and synthetic calcium phosphate is prohibited (NOP 7 CFR 205.105(a)).

Other relevant issues

none

Reflections and conclusions

- The Group considers the recovery of P from sewage sludge as a valuable contribution to the closing of nutrient cycles and to the reduction of the use of non-renewable sources of P (see also chapter 4.3 of the EGTOP report on Fertilizers II and chapter 3.2.2 of the report on Fertilisers V).
- The Group has no concerns over organic contaminants and pathogens.
- The Group considers that organic materials such as meat and bone meal, animal manure, plant residues and anaerobically digested agricultural waste residues should be used directly as fertilizers, and not processed to calcined phosphate, because this is a more efficient way of re-using organic matter and nutrients (see chapter 4.3 of the EGTOP report on Fertilizers II). Therefore, the Group proposes that recovered calcium phosphate should be limited to material derived from sewage sludge.

- The limits for contaminants and organic pollutants given in the fertilising products Regulation (Reg.2019/1009, product function category (PFC) 1(C)(I)(a): SOLID INORGANIC MACRONUTRIENT FERTILISER and for component material category (CMC) 13: THERMAL OXIDATION MATERIALS OR DERIVATES must be respected.

Recommendations

The Group advises to include calcium phosphate recovered from sewage sludge ash in Annex II as follows (to be inserted immediately after the entry for recovered struvite):

Name Compound products or products containing only materials listed hereunder	Description, specific conditions and limits
Calcium phosphate recovered from ash	Only from sewage sludge ash origin The relevant limits for contaminants and organic pollutants set in Reg. 2019/1009 apply

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

3.2.1 *Swinglea glutinosa* extract

Introduction

Extract of *Swinglea glutinosa* is used as a fungicide, against important fungal diseases in food and non-food crops in North and Latin America. According to local legislation, this is authorised also for organic production. The present request aims to authorise this plant extract for the use in organic crops destined for the EU market, i.e. inclusion in Annex VI of Reg. 2021/1165. The dossier was submitted by Ecocert SAS, with technical assistance from Gowan Crop Protection Ltd. and with recommendation from the International Biocontrol Manufacturers' Association (IBMA).

In the Final Report on Plant Protection (IX), the Group stated that inclusion in Annex VI should be requested separately for each plant extract, and a dossier should be provided in each case. The Group sees the present dossier as a 'test case' for this new procedure.

Authorization in general production

Swinglea glutinosa extract is currently not authorised as plant protection product in the EU. Approval of *Swinglea glutinosa* extract as an active substance in plant protection products under EU Regulation 1107/2009 is currently pending (date of admissibility 14 January 2020). However, the resolution concerning this product is not expected in 2024.

Authorization in organic production

The use of *Swinglea glutinosa* extract is currently not allowed in organic production in the EU.

Agronomic use, technological or physiological functionality for the intended use

Extract of *Swinglea glutinosa* is used as an organic fungicide, acting as plant elicitor and having preventive and contact action in many diseases such as powdery mildew, apple scab, botrytis, various leafspots and blights, among others. These fungal diseases are responsible for major crop losses all over the world. Combinations of crops and diseases against which this product is used are;

- Grape / Botrytis and Powdery mildew
- Berries (including strawberry) / Botrytis
- Cucurbits and Solanaceous crops / Powdery mildew
- Avocado and Mango / Anthracnosis (Colletotrichum) with pre and post-harvest application
- Banana / Black sigatoka (Mycosphaerella fijiensis)
- Pome fruits / Apple scab and Powdery mildew
- Stone fruits and almonds / Brown rot blossom blight, Shot hole, Alternaria

The product is applied preventatively, by means of foliar spray, soil treatment or post-harvest treatment, before the disease pressure is very high. It is not use as a curative control if the disease is already well established. Post harvest treatments with this product are frequently carried out on products that are sensitive to saprophytic fungal diseases. It seems to have both direct and indirect mode of action, but there is not much information publicly available.

Necessity for intended use, known alternatives

In organic production, only few fungicides are available, often with a limited efficacy. This refers to products based on sulphur, copper, bicarbonate or certain oils. Furthermore, there are microbiological products, e.g. based on antagonist fungi, like *Trichoderma* spp. and antagonist bacteria like *Bacillus subtilis*, and plant extracts with fungicidal properties, like *Allium sativum*. Most of the microbiological fungicides, as well as the plant extracts do not have a curative effect but must be applied preventively. In some cases (e.g. apple scab), the use of *Swinglea glutinosa* extract might contribute to a reduction of copper fungicides, which is a declared goal of organic production.

The targeted fungal diseases cause major yield losses, in many crops, world-wide, so control measures are fundamental.

Origin of raw materials, methods of manufacture

Swinglea glutinosa (Rutacea) is a wild citrus plant not normally cultivated for consumption, original from SE Asia, currently widely used in hedging of pastureland in most Latin-American countries and other parts of the world. Usually, these hedges are pruned, and the wastes are burned. For the extract, the leaves are dried, fragmented and drenched in ethanol/water. The final extract is soluble in water, ethanol, methanol, acetone, isopropyl alcohol.

The active substance is a UVCB-substance (i.e., a substance of unknown or variable composition, complex reaction products or biological materials).

Environmental issues, use of resources, recycling

As *Swinglea glutinosa* is widespread in most Latin-American countries, the Group has no concerns over the harvesting of its leaves. According to the dosseri, the ecotoxicological studies show no adverse effect against bees, aquatic organisms, and worms.

Animal welfare issues

No issues

Human health issues

Extract of *Swinglea glutinosa* has a very favourable toxicological profile and is therefore exempt from MRL in countries where it is registered.

Food quality and authenticity

No issues

Traditional use and precedents in organic production

Swinglea glutinosa extract has no traditional use in the EU. In terms of precedents, other plant extracts (e.g. garlic extracts) have traditionally been used in EU organic farming. Orange oil is authorised for plant protection.

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

According to the dossier, it is approved for organic production under NOP (USA), JAS (Japan) and for organic production in Chile.

Other relevant issues

The present request is for inclusion of *Swinglea glutinosa* extract in Annex VI. When it has been approved as active substance in the EU, authorisation for EU organic production (=inclusion in Annex I) should be considered. In case that it is categorised as a low-risk active substance, it will be automatically authorised for organic production.

Reflections and conclusions

- In the Final Report on Plant Protection (IX), The Group stated that 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. In this case, the Group thinks that the dossier is sufficient to allow an adequate evaluation of its use outside the EU.
- The Group has previously recommended to add an introduction to Annex VI, requiring that when plant protection products are used outside the EU, they shall be applied in compliance with the authorisations granted by the country where they are used (see EGTOP Report on Plant Protection IX). If this recommendation is adopted, the Group has no concern over environmental or human health impacts of its use outside the EU.
- Based on the available data, as well as on the different certifications the product complies with, the Group has no objections against the authorisation of the use of the extract of Swinglea glutinosa on organic crops with harvests for the EU market in the countries where this product is registered.

Recommendations

The Group advises to include the extract of *Swinglea glutinosa* in Annex VI of Reg. 2021/1165 without additional specifications or limits.

Number and part of Annex	CAS	Name	Specific conditions and limits
-	-	Swinglea glutinosa, ext.	(none)

4. MINORITY OPINIONS

None.

5. LIST OF ABBREVIATIONS / GLOSSARY

None.

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