Directorate-General for Agriculture
and Rural Development

Expert Group for Technical Advice on Organic Production

EGTOP

FINAL REPORT

on

Feed (VII)

and

Pet food (II)

The EGTOP adopted this technical advice at the plenary meeting
of 12th – 14th December 2022

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

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

EGTOP

The Group's tasks are:

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

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

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

EGTOP Permanent Group

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

Contact

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

The report of the Expert Group presents the views of the independent experts who are members of the Group. They do not necessarily reflect the views of the European Commission. The reports are published by the European Commission in their original language only.

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

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

Permanent Group members:
AUTIO Sari, BESTE Andrea, BLANCO PENEDO María Isabel, BOURIN Marie, GORACCI Jacopo, KOESLING Matthias, MALUSA Eligio, MICHELONI Cristina, OUDSHOORN Frank Willem, QUINTANA FERNÁNDEZ Paula, SPEISER Bernhard, VAN DER BLOM Jan, WÄCKERS Felix

Sub-Group members:
BERNARD Philippe, BLANCO PENEDO María Isabel, BOURIN Marie, BOUXIN Arnaud, GORACCI Jacopo, MARTELLI Giovanna, MOLTENI Roberto, QUINTANA FERNÁNDEZ Paula.

Observers:

DRUKKER Bastiaan, DG AGRI B4 Organics (Secretariat)

All declarations of interest of Permanent Group members are available at the following webpage:
Register of Commission expert groups and other similar entities (europa.eu)

TABLE OF CONTENTS

EXECUTIVE SUMMARY

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

With respect to feed the Group recommends the following:

- Calcium hydroxide **should not** be included in Annex III.
- Calcium pidolate **should not** be included in Annex III.
- Algal oil **should** be included in Annex III, part A.
- The trace elements; Copper (II) chelate of protein hydrolysates, Iron (II) chelate of protein hydrolysates, Manganese chelate of protein hydrolysates and Zinc chelate of protein hydrolysates **should** be included in Annex III, part B.
- The feed for special nutritional purposes; Propylene glycol **should** be included in Annex III, part A.
- The feed for special nutritional purposes; Calcium chloride **should** be included in Annex III, part A.
- The feed for special nutritional purposes; Calcium propionate **should not** be included in Annex III.
- The feed for special nutritional purposes; Iron dextran **should** be included in Annex III, part B.
- The feed for special nutritional purposes; Iron (II) fumarate **should not** be included in Annex III.
- Vegetable charcoal **should not** be included in Annex III.
- Selenised yeast saccharomyces cerevisiae cncm i-3060, inactivated, **should** be included in Annex III, part B.

With respect to pet food, the Group recommends the following:

- Algae flour **should not** be included in Annex III.
- Papain **should** be included in Annex III, part B.

1. BACKGROUND

Several Member States have submitted dossiers under Article 16(3)(b) of Regulation (EU) 2018/848 concerning the possible amendment of Annex IIIA and Annex IIIB to Commission Implementing Regulation (EU) 2021/1165 and, in general, on their compliance with the above-mentioned legislation. With regard to feed, Spain requested the authorisation of calcium hydroxide, France requested the authorisation of calcium pidolate and vegetable charcoal Finland requested the authorisation of several substances for special nutritional purposes (propylene glycol, calcium chloride**,** calcium propionate, iron dextran and iron (II) fumarate) and Ireland requested the authorisation of selenised yeast, algal oil and trace elements (copper (II) chelate of protein hydrolysates, iron (II) chelate of protein hydrolysates, manganese chelate of protein hydrolysates and zinc chelate of protein hydrolysates). With regard to pet food, Belgium requested the authorisation of algae flour. and The Netherlands requested the authorisation of papain. Therefore, the Group is requested to prepare a report with technical advice on the matters included in 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 is in line with the objectives, criteria and principles as well as the general rules laid down in Regulation (EU) 2018/848 of the European Parliament and of the Council and, hence, can be authorised to be used in organic production under the EU organic legislation.

For the preparation of its report, the Group is invited to examine technical dossiers provided to the Commission by the Member States and suggest amendments to the current lists in Annex III to the Regulation (EU) 2021/1165.

3. CONSIDERATIONS, CONCLUSIONS AND RECOMMENDATIONS

FEED

3.1 Calcium Hydroxide

Introduction, scope of this chapter

The assessment of calcium hydroxide (E526) is related to the request for inclusion as processing aid in Reg. (EU) 2021/1165, Annex III. The substance is to be used as processing aid in feed by reducing inbalances associated with increased lipid content in ruminant diets.

(CAS No. 01305-62-0)

Authorization in general production

Calcium hydroxide is listed as a feed material (11.1.7) under Section 11: Minerals and products derived thereof, of Commission Reg. (EU) 2017/1017 of 15 June 2017 amending Reg. (EU) No 68/2013 on the Catalogue of Feed Materials), as amended for the last time by Reg. (EU) 2022/1104.

It is also an authorised technological feed additive (E526) from the functional group "acidity regulator". In 2021, in accordance with the principle that a feed should not hold the double status of feed materials and feed additive, it was decided that calcium hydroxide should be considered as a feed additive only. However, in the absence of a valid application for re-authorisation as feed additive in accordance with article 10 of Reg. (EC) No 1831/2003, the withdrawal of its authorisation as feed additive was ordered by Reg. (EU) 2021/758. In parallel, Reg. (EU) 2022/1104 amending the EU Catalogue of feed materials ordered the withdrawal of calcium hydroxide from the EU Catalogue of feed materials. Considering that these decisions were taken for pure administrative reasons, a transition period was granted until 31 May 2028 to allow the operator to apply for authorisation of calcium hydroxide as feed additive. Until then, calcium hydroxide is permitted for use either as feed material without restriction or a feed additive for the function of acidity regulator and only for cats and dogs.

Calcium hydroxide is authorised by Reg. (EU) No. 1129/2011 of 11 November 2011 amending Annex II to Reg. (EC) No. 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives and can be use as in the following categories:

- processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC (13.1.3) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013) only processed cereal-based foods and baby foods, only for pH adjustment;

- dietary foods for infants for special medical purposes and special formulae for infants (13.1.5.1) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013) only for pH adjustment calcium hydroxide is authorised by Reg. (EU) 2016/691 of 4 May 2016 amending Annex II to Reg. (EU) No 1333/2008 of the European Parliament and of the Council as regards the use of food additives in edible caseinates and can be use as in the following category:

Edible caseinates (1.9) (legislation: (EU) No 2016/0691, applicable as from 25/05/2016).

Authorization in organic production

Calcium hydroxide is authorised by the organic regulation, Reg. (EU) 2021/1165 in:

- Annex I: Plant protection. 1. Basic substances.

- Annex V: Section B - Processing aids and other products, which may be used for processing of ingredients of agricultural origin from organic production in preparation of foodstuffs of plant origin.

- and also for cleaning and disinfection of buildings and installations for livestock, aquaculture animals and seaweed production according to Annex VII to Regulation (EU) No 889/2008.

Agronomic use, technological or physiological functionality for the intended use

The use of calcium hydroxide is related to saponification process: it salifies fatty acids and allows fats to by-pass the rumen by avoiding the phenomenon of biohydrogenation by the ruminal microorganisms. His process allows an increase in the lipid content of the diet, without incurring the reduction in the efficiency of digestion of the fibrous portion (forages-cellulose), the depression of the activity of cellulolytic bacteria, and the imbalance in the composition of the ruminal bacterial flora.

It is also authorised as a phytosanitary active substance (fungicide) in both organic and conventional agriculture.

Necessity for intended use, known alternatives

A calcium salt is obtained by saponification of vegetable oils: the treatment seems not to be possible without the use of calcium hydroxide as adjuvant.

The acidity regulators potassium hydroxide (E525) and sodium hydroxide (E524) have similar functions: E524 is already reported to be included as a surface treatment/acidity regulator in 'Laugengebäck' flavourings, as an authorised substance for use in the production of processed organic food and of yeast used as food or feed in part A "Authorised food additives and processing aids referred to in point (a) of Article 24(2) of Regulation (EU) 2018/848", as reported in the section A1 – Food additives, including carriers, Annex 5 of the Commission Implementing Regulation (EU) 2021/1165.

Origin of raw materials, methods of manufacture

Calcium hydroxide is produced commercially by treating lime with water: $CaO + H_2O \rightarrow Ca(OH)$: it can be prepared by mixing aqueous solutions of calcium chloride and sodium hydroxide.

The limestone from the mine is calcined at high temperature in a furnace to obtain carbon dioxide and "quicklime". This quick lime is mixed with water to produce calcium hydroxide.

Environmental issues, use of resources, recycling

The substance has a high aqueous solubility, but is not volatile and is not considered to be problematic for environmental quality.

Animal welfare issues

These calcium salts are used in the feeding of dairy cattle, sheep and pigs, as well as for other livestock species: that allows the contribution of an energy feed easily assimilated by animals. Because of the simplicity, practicability and lower costs associated with the use of $Ca(OH)_2$ treatment, it was used to detoxify castorseed byproducts on-farm. $Ca(OH)_2$ supplementation resulted in an increased microbial protein synthesis and microbial efficiency in sheep: enhanced intake of digestible nutrients and reduced toxicity to the ruminal microbes (i.e. ricin), as an indicator of the efficiency of use of dietary N and energy substrates by ruminal microbes (Oliveira et al., 2010).

In lambs, results suggest that castor bean meal treated with calcium hydroxide solution can totally replace the soybean meal in the diet of finishing lambs without negative effects on weight gain, intake, digestibility and hepatic function. Castor bean meal treated with calcium hydroxide solution seems to be effectively used for feeding animals after 18 h in room temperature, in wet form, without sun or oven-drying (Ginobelli et al., 2014).

In goat, thanks to the ability of calcium hydroxide to deactivate tannin in-vivo, $Ca(OH)_2$ supplementation increased N digestibility N retention and microbial N supply: that translated into a 35% improvement in growth rate even if calcium hydroxide cannot be recommended as an effective treatment for the amelioration of tannins (Alam et al., 2005).

In cattle, nutritive value of sugarcane bagasse was improved by urea and/or $Ca(OH)_2$ treatment: that increased feed intake, digestibility, and rumen fermentation. This study suggested that sugarcane bagasse treated with 2 % urea + 2 % $Ca(OH)_2$ could be used as an alternative roughage source for ruminant feeding (Gunun et al., 2016).

Human health issues

No significant human health issues have been identified. Food-grade calcium hydroxide is used to make authentic corn tortillas from whole corn, by soaking the corn in calcium hydroxide, in order to significantly increase the bioavailability of niacin in the corn. In addition, this alkaline compound also makes the corn easier to digest.

Unprotected exposure to $Ca(OH)_2$ can cause severe skin irritation, chemical burns, blindness, lung damage or rashes.

Food quality and authenticity

Food quality and authenticity remains unaltered.

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

Calcium hydroxide is listed as an approved synthetic non-agricultural substance allowed as an ingredient in organic processed food in USDA certification.

Reflections and conclusions

The Group considers that the request for inclusion of calcium hydroxide as processing aid in Annex III of Reg. (EU) 2021/1165 should be rejected since, from the information provided in the submitted dossier, calcium hydroxide is not really used as a processing aid. Calcium hydroxide is on the contrary used as a source of calcium, since calcium is remaining present in the final product at the end of the processing.

Even though the dossier claims that calcium hydroxide as such is not a feed material since it is not directly used to feed animals as such, the Group considers it to be a feed material since it constitutes the raw material for the production of calcium salts of fatty acids, which is the product qualifying as feed. Therefore the request for inclusion should have been for calcium hydroxide as a feed material and not as a processing aid.

However the Group points out that the previous EGTOP evaluation of the use of calcium hydroxide as feed material in 2019 was negative, as it was not in line with the objectives, criteria and principles of Organic Reg., because *"calcium salts of fatty acids to dairy diets are predominantly to increase milk yields The principles of organic animal husbandry look at animal welfare, and environmental issues and that's why the EU regulation includes the compulsory high use of roughage and fodder. This use, therefore, has to be considered an unsustainable intensification of dairy production that does not belong to organic production. The group also expressed concern over possible effects on milk quality, increasing yield at the expense of milk protein levels."* Therefore, the Group cannot, at the moment, see probable change in the recommendation even in case calcium salts of fatty acids would be the targets of a future application for inclusion as feed material in Annex III of Reg. (EU) 2021/1165.

Recommendations

The Group does not recommend the inclusion of calcium hydroxide as processing aid in Annex III of Reg. (EU) 2021/1165.

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3.2 Calcium pidolate

Introduction, scope of this chapter

The assessment of calcium pidolate relates to the request for the inclusion of calcium pidolate as a feed material in Reg. (EU) 2021/1165 in annex III, part A (2) Other feed materials. The dossier was submitted by France.

Name of the active substance: calcium oxo-5 pyrrolidonecarboxylate-2 (C10H12CaN2O6)
CAS No.: 31377-05-6 (molecular weight 296.292 g/mol)
IUPAC Name: calcium; (2~{S})-5-oxopyrrolidine-2-carboxylate
E.C Additive Identification No: 250-602-4

Authorization in general production

According to the Reg. (EU) No. 609/2013 of the European Parliament and of the council of 12 June 2013 on food for infants and young children, food for special medical purposes, and total diet replacement for weight control, calcium pidolate is a food product intended for special medical aims. It is a substitute of total daily diet to sustain weight control.

According to Commission Reg. (EU) No. 68/2013 of 16 January 2013 on the Catalogue of feed materials, as amended for the last time by Reg. (EU) 2022/1104, calcium pidolate is a feed material listed in PART C. List of feed materials, point 11. Minerals and products derived thereof number 11.1.16.

According to Commission Reg. (EU) 2020/354 of 4 March 2020 (feed intended for particular nutritional purposes) calcium pidolate could be used to reduce the risk of milk fever and subclinical hypocalcemia in dairy cows.

Authorization in organic production

None.

Agronomic use, technological or physiological functionality for the intended use

It is well known that eggshell strength decreases with age. Two combine factors can explain it:
1) Irreversible increase of egg size for a constant eggshell deposit quantity.
2) Change in metabolism linked to age, inducing notably a decrease in calcium intestinal absorption capacity.

Calcium pidolate is claimed to positively impact bone quality (in rearing) and improve egg quality (in laying hens). In fact, to obtain good shell quality, calcium should be added to the hens' diet at an optimum dose, and to enable the birds to utilise it well, vitamin D3 should also be available in the diet at an optimum dose. The production of 1,25 (OH)2D3 (the hormonal form of vitamin D3) is related to the demands for Ca for forming eggshell and bone and growth.

The use of calcium pidolate in drinking water or feed have brought contradictory results such as in maintaining egg quality in longer laying cycles with better performance and profits (Bain et al. 2018; Al-Agblo and Duclos, 2011) but also small effects on egg quality (Zahrani and Roberts; 2015; Joshi at al. 2019).

The frequency of musculoskeletal disorders in commercial broiler has become a real economical and welfare issue. From multifactorial origins (genetic, density, litter quality, nutrition, growth rate, etc.,) those disorders are expressed

by musculoskeletal deformations and inflammations. Associated pain can affect the ability to access resources (feeders, drinkers) for the more seriously hurt animals. Regarding bone quality, Fondevila et al. (2021) observed no effects in supplemented broilers but supplementation with 300 mg/kg of Calcium pidolate improved Feed Conversion Ratio (FCR) and the Total Tract Apparent Retention (TTAR) of P in broilers fed diets with low total Ca and P contents. The reduction of mortality and culling (-21%) and the reduction of FCR (-1.22%) were not significant (Roulleau et al. (2015). However, Roulleau et al. (2015) concluded that calcium pidolate could be a driver for maintaining growth performance until the last day.

Necessity for intended use, known alternatives

Eggshell quality is a major issue in the consumer egg industry. The eggshell must have the sufficient mechanical strength to prevent fractures resulting from impacts throughout the production chain. Broken eggs cause significant economic losses due to the downgrading of eggs and increase the risk of bacterial contamination of eggs. (Bain et al., 2018; Agblo and Duclos, 2011).

Calcium carbonate could be an alternative and is already authorised in the organic regulation. Deroisy et al. (1997) observed no significant changes in serum Ca or Parathyroid Hormone (PTH levels) after oral administration of the vehicle. All calcium salts induced significant increases in serum Ca and decreases in serum PTH compared to baseline values. However, no statistically significant differences were observed between the different calcium salts for serum Ca increments. According to this specific study, all calcium preparations significantly increase serum calcium and decrease serum parathormone, compared to what is observed after oral intake of a vehicle. However, significant differences in suppression of parathormone are observed between the different calcium preparations and might be important for their clinical use with an advantage for calcium carbonate.

Origin of raw materials, methods of manufacture

The manufacturing process begins with fermentation with non-GMO bacteria and using non-GMO sugar sources to produce L-glutamic acid. Then, L-glutamic acid is converted into L-calcium pidolate with a chemical reaction with calcium hydroxide in an aqueous medium. Finally, the L-calcium Pidolate is dried.

The product has an appearance of fine white to cream powder, without odour. Its density is 0,6 to 0,7 g/cm3, and its granulometry is lower than 600 µ. It is hygroscopic, and easily soluble in water at 20°C. Calcium content is 13,5% on the dry product.

Environmental issues, use of resources, recycling

The inclusion of calcium pidolate in the diet for broilers fed low Ca and P levels could be considered an important strategy to reduce the mineral excretion of broilers (Fondevila et al., 2021).

Animal welfare issues

The dossier claims that calcium pidolate contributes to animal welfare thanks to its beneficial effects on animals. In particular, positive effects are seen on osseous structure quality leading to a reduction of and locomotion disorders (Roulleau et al., 2015).

Human health issues

In the opinion of EFSA in 2007, there is no danger recognized for human health, as calcium pidolate is consumed in human nutrition. However, cases in different studies (Domínguez-Ortega et al., 2007 and Núñez et al., 2012) have shown allergic reactions to calcium pidolate but good tolerance to similar tests performed with calcium carbonate.

Food quality and authenticity

According to the dossier, there is no known impact of calcium pidolate affecting food taste, texture, appearance and, more broadly, food quality and authenticity. In its absorption mechanism, the molecule dissolves into calcium and amino acids.

Traditional use and precedents in organic production

None.

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

No

Other relevant issues

Calcium sources used are hard to digest (calcium phosphates and calcium carbonates), depending on size, solubility (release pH) and origin (Kressel et al., 2010). The calcium pidolate contributes to the lower incorporation of these heavy products and reduces their transport. Moreover, it allows mineral phosphorus to decrease in formulations, a not renewable and costly resource. When calcium is incorporated in excessive quantities into the diet, phosphorus digestibility decreases, caused by the formation of calcium-phytates insoluble complexes, which reduce calcium absorption and phytases actions (Tamin et al., 2003). It is important to adapt calcium phosphorus ratio in the diet. An excess of each element interferes with the other element's absorption (Williams et al., 2000). A moderate calcium decrease may improve phosphorus use without deleterious effects. When calcium and phosphorus concentrations are balanced, the calcium pidolate increases the efficiency of calcium utilization by reducing its chelation capacity and calcium-phytates complexes formation.

The absorption of a specific salt of calcium depends on the one hand on its capacity for disassociation, different for the various salts and slightly favouring the citrate and pidolate forms, and on the other, its capacity for dissolution. There are marked differences in the dissolution of the preparations of calcium supplements, in principle supposedly due to differences in pharmaceutical formulation. However, experience shows that not all preparations of the same salt exhibit equivalent absorption.

Reflections and conclusions

The Group was not able to find any peer-reviewed evidence that the product is at least as digestible and effective in terms of contribution to strength of egg shells as other sources of calcium available for use in organic farming. On the contrary, some scientific articles highlight that calcium pidolate supplementation was unable to overcome the effects of reduced levels of calcium in the layer diet during the last phase of the production cycle.

The Group considers that the bibliography provided, although abundant, consists mostly of conference proceedings and internal trials of the company producing the substance, which does not meet the minimum quality standard required to perform a proper assessment.

Calcium carbonate, which could be an alternative, is already authorised in the organic regulation and it is sometimes described as better than calcium pidolate (Deroisy et al., 1997). Furthermore, the articles extolling the merits of calcium pidolate do not compare it to any other combination with calcium, but rather to a control not supplemented with calcium.

The information provided in the dossier is based on only one trade product, meaning that the described manufacturing process using the substance is restricted to only one source and means that the Group only had information on this specific process.

In conclusion, what the Group found is not consistent with the claims of the provided information and therefore the Group is not convinced of the needs for inclusion of the feed material.

Recommendations

The Group does not recommend, at the moment, the inclusion of calcium pidolate as a feed material in Annex III of Reg. (EU) 2021/1165.

References for the substance

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3.3 Algal oil from Schizochytrium sp.

Introduction, scope of this chapter

The request refers to the inclusion of "Algal Oil containing EPA + DHA" as feed material into the lists of authorised products and substances referred to Article 24(7) of Reg. (EU) 2018/848. The relevant place for inclusion is in Reg. (EU) 2021/1165, annex III, part A (2) Other feed materials. The dossier was submitted by Ireland.

Authorization in general production

"Algal Oil containing EPA + DHA" is not specifically listed in Reg. (EC) 68/2013 (Catalogue of feed materials). However, "Algal oil" is listed under the entry number 7.1.4, with the description and compulsory declaration requirement as shown below.

Number	Name	Description	Compulsory declarations
7.1.4	Algal oil	Oil obtained by extraction from algae. May contain up to 0.1 % antifoaming agents.	Moisture if > 1 %

Authorization in organic production

Algae oil containing EPA and DHA is not yet used in feed for organic aquaculture.

Commission Implementing Reg. (EU) 2021/1165, specifically for fertilisers, soil conditioners and nutrients, restricts the use of algae and algae products as far as directly obtained by:
(i) physical processes including dehydration, freezing and grinding;
(ii) extraction with water or aqueous acid and/or alkaline solution;
(iii) fermentation;
only from organic or collected sustainably following point 2.4 of Part III of Annex II to Reg. (EU) 2018/848.

Agronomic use, technological or physiological functionality for the intended use

It is suggested to use the product, as a source of energy and EPA and DHA Omega-3, in aquaculture feed for salmonids, shrimp and marine fish like sea bass and sea bream; agriculture feed for ruminant, swine and poultry; pet food for dogs, cats and horses.

Necessity for intended use, known alternatives

According to the dossier, "Algal Oil Containing EPA + DHA" is required as a critical source of omega-3 EPA and DHA in compound feeds for animals and fish and shrimp. Various studies have described the nutritional requirement for long-chain poly-unsaturated fatty acids in farmed animals such as laying hens, broilers, ruminants, fish and shrimp. The same is true for companion animals. Typically, animals cannot produce enough essential fatty acids to maintain optimum health. Therefore, they rely on exogenous supply, especially the LC-PUFA EPA and DHA, in their feed. Traditionally, this has been supplied by including fish oil in the feed. However, as aquaculture and livestock farming continue to grow, finite sources of fish oil (i.e., wild-capture fisheries) have stagnated, resulting in increasing substitution with alternative oils. Sprague *et al.* (2020) and Nøstbakken *et al.* (2021) have documented how levels of omega-3 EPA and DHA in farmed salmon have declined substantially in recent years, while levels of undesirable dioxin-like contaminants continue to be present.

Froehlich *et al.* (2018) and Cottrell *et al*. (2020) have also shown that with the global supply of forage fish at a plateau, we are reaching the ecological limits of forage fish for fed aquaculture. To realize its growth potential, we must decouple the dependency on wild-caught fish as a source of fishmeal and fish oil used in feeds. Stevens *et al.* (2018) and Hamilton *et al.* (2020) note the opportunity for increased fisheries by-product utilisation to increase the supply of EPA and DHA while also reducing waste. However, significant challenges exist in collecting, processing and ensuring the chain of custody for these waste materials.

Santigosa *et al*. (2020 and 2021) have shown that algae oil is an effective alternative source of omega-3 EPA and DHA in aquaculture feed. Even the complete replacement of fish oil in diets is possible. Algal oil can, therefore, effectively support the sustainable growth of the aquaculture industry without affecting the performance, health, or nutritional value of the product.

The European Union Farm to Fork strategy is a stated objective for a significant increase in organic aquaculture by 2030. EC Action Plan for the development of organic production sets out the measures that will be taken to achieve these objectives. This specifically (Section 2.5) includes updating the standards for organic animal feed, which could include sustainable alternative ingredients like algae. This request is relevant to support the EC Action Plan for significantly increasing organic aquaculture in the European Union by 2030, with the need to reduce reliance on fish oil for the growing organic aquaculture market.

The current alternative solutions are the following:
Fish oil, containing synthetic antioxidant, is by far the primary source of omega-3 EPA and DHA for animal feed. Many studies (i.e., Shepherd and Bacchis, 2014; Tocher *et al.*, 2019) have documented the limitations of fish oil supply.
Alternatives include fishing down the food chain for zooplankton or Antarctic krill, methods in the early stages of development and subject to many questions related to broader ecosystem impacts and economic viability for use in aquaculture feed. And novel technologies unsuitable for organic production, such as genetically modified seed oils, are also becoming available.

Algae oil is widely recognised as having the advantage over alternatives in terms of purity (being completely free of undesirable contaminants), potency (being rich in both essential fatty acids EPA and DHA), and simplicity to use in compound feed formulations.

Origin of raw materials, methods of manufacture

"Algal oil containing EPA + DHA" is a nutritional oil from the marine algae, Schizochytrium sp. (a non-GM strain), which produces a rich source of omega-3 eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).
The algal fermentation process produces the product (Algal oil containing EPA + DHA) under controlled conditions. The strain uses sugar in the form of dextrose as its energy source. Sugar is derived from various sources, including but not limited to wheat, conventional and non-conventional corn, and sugar beet. Sugars are not produced from GMO. After fermentation, the omega-3s are extracted from the algal cells and the oil is separated from the aqueous phase. The algal oil product is free of cell debris and media except for unavoidable fat-soluble residue. Mixed natural tocopherols are added as antioxidants to provide stability.

The proposed analysis method is AOCS method Ce 1b-89 (AOAC, 2017).
Specification of the product:
DHA and EPA content, mg/g oil: min. 500 mg/g
EPA content, mg/g oil: min. 100 mg/g
TOTOX: max. 35 TOTOX = ((2x Peroxide value) + Anisidine value))
Free fatty acid: max. 5 %

Moisture: max. 0.75 %
Dioxins: max. 0.75 ng/kg

Environmental issues, use of resources, recycling

According to the dossier, the application of Algal Oil in aquaculture feed considerably reduces marine impacts of aquaculture by reducing the requirement for fish oil as a source of essential long-chain polyunsaturated fatty acids EPA and DHA. Less than 20% of small pelagic wild capture used to reduce fishmeal and fish oil is Marine Stewardship Council certified. Sources of fish oil for feed used in organic aquaculture may come from trimmings and by-products of wild capture fisheries for direct human consumption. However, these sources may lack traceability and transparency regarding environmental impacts through the supply chain. Algal oil comes from a fully controlled, traceable and transparent manufacturing process where environmental impacts can be fully measured and managed. It is worth noting that algae oil production is an entirely waste-free process where the liquid co-product can be used as a protein source in beef cattle feed.

Animal welfare issues

Due to the complementary and individual health benefits of EPA and DHA, reversing or halting a decline in the content of these n-3 fatty acids found in aquaculture feeds and products is crucial. The skin of fish reared on reduced levels of dietary EPA and DHA loses its functionality as a barrier to pathogens and fillets of such fish often feature melanin spots, suggesting compromised cultured fish's immunological competency. Moreover, the EPA:DHA ratio determines microbiome composition, intestinal health, and feed and protein utilization. Therefore, the dietary availability of both EPA and DHA has implications for fish growth and survival.

Human health issues

In humans, Omega-3 fatty acids, and EPA and DHA specifically, are linked to some developmental and health benefits, including increased cardiovascular integrity and the alleviation of inflammatory syndromes, such as rheumatoid arthritis, ulcerative colitis and atopic dermatitis psoriasis. The replacement of fish meals and oils with plant-based alternatives containing low levels of these essential n-3 acids halved the EPA and DHA content of salmon fillets between 2004 and 2015 and reduced DHA, altering the EPA:DHA ratio in sea bream fillets. This increases the number of fish portions necessary to obtain dietary recommendations of 3.5 g weekly (International Society for the Study of Fatty Acids and Lipids, 2014). A recent study (Sprague, 2020) shows that salmon obtained from UK retailers fulfilled only 26-67% of the 3.5g EPA and DHA recommended weekly, evidencing a very high nutritional variability in fish nutritional value.

Food quality and authenticity

New guidelines from the European Food Safety Authority highlight the risk to animal and human health related to dioxins and dioxin-like PCBs in feed and food, leading to the recommendation for a substantial reduction in the tolerable weekly intake (EFSA, 2018).

A recent study (Nøstbakken *et al*., 2021) documents that while mackerel, herring, and farmed salmon is an excellent dietary source of EPA and DHA and other nutrients, it also contains levels of dioxin-like compounds that can lead to EFSA TWI being exceeded if consumed in accordance to the recommendations.

Using microalgal products reduces contamination of fillets with chemical compounds such as dioxin-like polychlorinated biphenyls (PCBs) or mercury, which typically accumulate in feed made from animals at a higher trophic level, such as fish.

Traditional use and precedents in organic production

Although algae oil containing EPA and DHA is widely used in conventional European aquaculture feed, it is not yet used in feed for organic aquaculture. Several certified organic aquaculture producers, including MOWI, Cooke Aquaculture, and Salmar AS require sustainably sourced EPA and DHA in their feed for organic salmon. They need to have alternatives to wild-caught marine ingredients available for use to support their continued growth, ensure the health and welfare of fish held under their care, and ensure the nutritional and physical quality of the salmon intended for people to eat.

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

Algae oil for food or feed is not yet accepted in organic farming in any part of the world.

However, the IFOAM Norms (2014) mention "Seaweed and seaweed products" specifically for fertilizers and soil conditioners, as far as obtained by:
(i) physical processes, including dehydration, freezing, and grinding;
(ii) extraction with water or potassium hydroxide solutions, provided that the minimum amount of solvent necessary is used for extraction;
(iii) fermentation.

Other relevant issues

According to the dossier, a similar product (containing DHA) is registered as a food additive/formulant in many countries. The product is called Life's DHA. However, there is not a similar food additive authorised in the European Union. In contrast, it is authorised oil from the microalgae *Schizochytrium* sp. as a novel food (Commission Implementing Reg. (EU) 2017/2470).

Reflections and conclusions

EPA and DHA are valuable nutrients in particular in aquaculture and the major traditional source of EPA and DHA is fishmeal. Algal oil rich in EPA and DHA is an interesting alternative. Algal oil is classified as feed material in the EU Catalogue of feed materials and as such permitted for use in conventional farming. The present dossier concerns a specific type of algal oil produced by the microalgae *Schizochytrium* sp. and the request for authorisation in organic farming is linked specifically to this microalga. An extension to algal oil produced by other types of microalgae might be useful to consider, providing that the oil is produced with the same manufacturing process as mentioned in the dossier. In the Group's opinion, the authorization should be extended to oil produced by other microalgae.

The indication "rich in EPA and DHA" is a claim and should not be mentioned in the name of the product as specified in Reg. (EU) 2021/1165, Annex III. Feed business operators placing the product on the market with the claim "rich in EPA and DHA" are reminded that they shall comply with EU legislation on claims (Article 13 of Reg. (EC) No 767/2009).

The growing media for the fermentation are sugars derived from different sources e.g. wheat, corn, sugar beet. All these crops are today widely produced organically, therefore the Groups considers that it would be technically possible to restrict the growing medium to *only* from organic origin. However to be consistent with how other substances are restricted the Group highlights the need for a holistic review of the *Specific conditions and limits* related to organic origin, raw material or production of all the relevant annexes in Reg. (EU) 2021/1165. This would need to be done in separate mandates.

Recommendation

The Group recommends the addition of algal oil to the list of authorised feed materials in Reg. (EU) 2021/1165, Annex III, part A(2), OTHER FEED MATERIALS as follows:

Number in feed catalogue	Name	Specific conditions and limits
ex 7.1.4	Algal oil	Oil obtained by extraction from microalgae: Obtained by fermentation. Growing medium for the fermentation process must not be of GMO origin and should be from organic raw materials, if available.

References for the substance

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3.4 Trace elements

Copper (II) chelate of protein hydrolysates
Iron (II) chelate of protein hydrolysates
Manganese chelate of protein hydrolysates
Zinc chelate of protein hydrolysates

Introduction, scope of this chapter

It is requested add the chelates of protein hydrolysates of the following trace-elements: copper, iron, manganese and zinc to Annex III (Authorized products and substances for use as feed or in feed production) of the Reg. (EU) 2021/1165.

Unlike the already authorised inorganic compounds of copper, iron, manganese and zinc, these chelates deliver these trace elements in an organic form, which is more bioavailable and therefore has the potential to reduce emissions in the environment. The protein hydrolysates are coming from certified organic soya. The application is for use in feed for all animal species.

The dossier was submitted by Ireland.

Authorization in general production and organic production

Copper (II) chelate of protein hydrolysates (3b407), Iron (II) chelate of protein hydrolysates (3b107), Manganese chelates of protein hydrolysates (3b505) and Zinc chelate of protein hydrolysates (3b612) are authorised feed additives for all animal species under the functional group 'compounds of trace elements' of the category 'nutritional additives' (respectively Reg. (EU) 2018/1039, (EU) 2017/2330, (EU) 2017/1490 and (EU) 2016/1095). The product comprises 10% w/w of the trace element and anion of any amino acid from soya proteins. None of the four chelates of protein hydrolysates is permitted for another purpose in organic farming, and no chelates (whether of amino acid hydrates or glycinates hydrates which are the other types of chelates authorised as feed additives in general production) is authorised in organic farming. The chelates are produced with hydrolysed proteins from certified organic soya and sulphates of copper, iron, manganese and zinc, all already listed in Annex III of Reg. (EU) 2021/1165.

Agronomic use, technological or physiological functionality for the intended use

The four chelates are intended to be used in all animal species as organic sources or copper, iron, manganese and zinc, and shall be incorporated in the feed as a premixture. They are meant to compensate for potential deficiencies of the basic diet in essential trace elements. The addition of the compounds of trace elements, is conditioned by an obligation not to exceed the maximum limits set in the authorisation act for the complete diet. These maximum limits may be different depending on the species of destination:

Maximum limits for copper, iron, manganese and zinc in complete feed (mg/kg - 12% moisture)

Copper	Iron	Manganese	Zinc
Bovines: — Bovines before the start of rumination: 15 — Other bovines: 30 Ovine: 15 Caprine: 35 Piglets: — suckling and weaned up to 4 weeks after weaning: 150 — from 5-th week after weaning up to 8 weeks after weaning: 100 Crustaceans: 50 Other animals: 25	Ovine: 500 Bovines and poultry: 450 Piglets up to one week before weaning: 250 Pet animals: 600 Other species: 750	Fish: 100 Other species: 150	Dogs and cats: 200 Salmonids and milk replacers for calves: 180 Piglets, sows, rabbits and all fish other than salmonids: 150 Other species and categories: 120

Maximum limits have been reduced based on a risk assessment by EFSA for copper (EFSA, 2016a) and zinc (EFSA, 2014) at the lowest level to minimise the impact on the environment while avoiding nutritional deficiencies. Chelates of trace elements have been authorised for the first time in the EU in 1998.

Necessity for intended use, known alternatives

According to the EGTOP report Feed II from 9 October 2014, copper is an essential micro-mineral for animals, humans and plants, and the availability of trace elements plays an essential role in optimal health maintenance and performance of livestock. Copper plays an important role in the regulation of enzyme activities but also in iron metabolism (e.g., iron transport), neutralization of free radicals and the maturation of red blood cells, as well as in the bone and cartilage metabolism. Additionally, it has antimicrobial properties and can modulate an immune response in monogastric when fed in excess of nutritional requirements. Maximum limits were revised in 2018 based on an EFSA opinion and adjusted to the nutritional requirements in order to minimise the impact of emissions of copper on the environment and on antimicrobial resistance (EFSA, 2016a). However, the EU legislator ordered that, for piglets the drastic recommended decrease to 25 mg/kg directly after weaning should not be done in one step, in order not to run the risk of not meeting the physiological needs of animals, particularly in that sensitive period, and to avoid any other negative impacts on the health of piglets.
Copper deficiency results, according to its severity, in protean features such as muscle weakness, iron-deficient anaemia, hypopigmentation, bone changes that resemble scurvy, defective connective tissue synthesis, hair abnormalities, impaired myelinisation of nerve tissues and neurological defects, altered lipid metabolism and cardiac malfunction (EFSA, 2016a).

Known alternatives are the presently authorised compounds listed in Annex III of Commission Implementing Reg. (EU) 2021/1165:

3b402	Copper(II) carbonate dihydroxy monohydrate
3b404	Copper (II) oxide
3b405	Copper(II) sulphate pentahydrate
3b409	Dicopper chloride trihydroxide

Iron is the most abundant trace element in mammals. It serves as a constituent in proteins (e.g., haemoproteins: haemoglobin, myoglobin; non-haemoproteins: ferritin, transferrin) and as a cofactor for many important iron-dependent enzymes (e.g., cytochromes A, B, C; peroxidases, catalases). Haemoglobin makes up 70% of the entire iron body pool. The intestinal absorption of iron and its retention is highly regulated via homeostasis. Iron is present in biological systems in one of two oxidation states, and redox interconversions of the ferrous (Fe(II)) and ferric (Fe(III)) forms are central to the biological properties of this trace element. Aerobic metabolism depends on iron. As a constituent of haemoglobin, it is involved in oxygen and carbon dioxide transport. It plays a central role as cofactor for most of the Krebs cycle enzymes and functions as an electron carrier EFSA, 2016b).

Available alternatives are the presently authorised compounds listed in Annex III of Commission Implementing Reg. (EU) 2021/1165:

3b101	Iron(II) carbonate (siderite)
3b103	Iron(II) sulphate monohydrate
3b104	Iron(II) sulphate heptahydrate

Manganese is an essential dietary mineral for mammals; it is a component of metalloenzymes such as superoxide dismutase, arginase and pyruvatecarboxylase, and is involved in amino acid, lipids and carbohydrates. Glycosyltransferases and xylosyltransferases, which are involved in proteoglycan synthesis (e.g., for bone formation), are sensitive to manganese status in animals. Primary manifestations of manganese deficiency in livestock are impaired growth, skeletal abnormalities, depressed reproductive function, ataxia of the newborn and faults in lipid and carbohydrate metabolism (2016c). Environmental exposure to Mn may lead to accumulation in the basal ganglia and the development of Parkinson-like disorders.

Known alternatives are the presently authorised compounds listed in Annex III of Commission Implementing Reg. (EU) 2021/1165:

3b502	Manganese (II) oxide
3b503	Manganous sulfate, monohydrate

The transition metal zinc is essential to all living organisms. It is an integral component of an estimated 10 % of all proteins, in which it contributes to tertiary structure or catalytic activity covering all enzyme classes. It is also a signalling substance as a second messenger and synaptic neuromodulator. The biological functions of zinc are numerous and diverse and include glucose and lipid metabolism, cell proliferation and embryogenesis, and those related to the nervous and immune systems. Dietary zinc is of low toxicity to vertebrates. Some of the most noticeable effects of zinc toxicity are impairment of copper and iron uptake, with knock-on effects on systems that depend on these metals. There are also effects on lipid metabolism and the immune system, as zinc is a natural regulator of functions involved in these processes. Water-breathing organisms are sensitive to waterborne zinc, with acute toxicity concentrations typically being higher than those for metals such as silver, cadmium and copper, but lower than those for manganese and nickel. The relatively high risk of zinc toxicity to aquatic life has led to its inclusion as a 'priority pollutant' by the US Environmental Protection Agency (EFSA, 2015).

Known alternatives are the presently authorised compounds listed in Annex III of Commission Implementing Reg. (EU) 2021/1165:

3b603	Zinc oxide
3b604	Zinc sulphate heptahydrate
3b605	Zinc sulphate monohydrate
3b609	Zinc chloride hydroxide monohydrate

Origin of raw materials, methods of manufacture

Copper (II) chelate of protein hydrolysates is produced by incubation of Copper(II) sulphate pentahydrate with enzymatically hydrolysed organic soy protein to facilitate mineral proteinate chelation. The detailed process is explained hereafter:

- Reaction vessels are cleaned in place (CIP) using a sodium hydroxide solution with a pH of >10.5 at 80°C.
- Soy protein is suspended in water. The pH is adjusted to <8.5 and an alkaline protease enzyme is added (Food grade enzyme from a non-GMO source). The enzyme allows protein hydrolysis to occur. Amino acid production is monitored during the hydrolysis by HPLC.
- Copper (II) sulphate pentahydrate is added at a proprietary ratio of mineral to the reaction vessel allowing maximum chelation of the mineral proteinate. Temperature is maintained during an incubation period at <60°C.
- The mixture is then spray-dried. Freedom from contamination with plant/animal/human pathogens is ensured by pasteurization during the hydrolysis stage of manufacture. Using a high-pressure pump, the slurry is injected into the dryer chamber airflow stream with an inlet temperature of 204°C -222°C. The product is dried to a moisture level of <5.0%.
- The product is cooled and packaged. No anticaking/carrier or other diluents are added.

The same process is used to produce iron (II) chelate of protein hydrolysates with iron (II) sulphate heptahydrate, Manganese chelates of protein hydrolysates with Manganous sulphate monohydrate and Zinc chelate of protein hydrolysates from Zinc sulphate heptahydrate.

Environmental issues, use of resources, recycling

Most of the copper consumed by farm animals appears in faeces, particularly when pharmacological 'growth-promoting' levels are applied (EFSA, 2016a). This can result in substantial excretion of copper that is added to the agricultural soil via manure application. Particularly, in livestock-dense areas and regions, this can result in copper accumulation in soil, leading to long-term environmental concerns. With the reduction of the maximum limits for copper in 2018, the environmental risk from using copper-containing feed additives is reduced.

For zinc, there is a potential environmental concern related to drainage and the run-off of zinc to surface water. Most vulnerable to these processes are acidic sandy soils. In order to draw a final conclusion, some further refinement to the assessment of zinc-based feed additives in livestock needs to be considered, for which additional data would be required. With the reduction of the maximum limits for zinc in 2016, the risk to the environment from the use of zinc-containing feed additives is reduced (EFSA, 2014).

For manganese, the use of the manganese chelate of protein hydrolysates in animal nutrition for all animal species is safe for the environment, provided that the current maximum total contents of manganese authorised in the feed are respected (EFSA 2016c).
For iron, the use of iron chelate of protein hydrolysates is not expected to significantly change the concentration of other elements (sulphur, chlorine) which are abundant in the environment (EFSA, 2016b).

Trace elements have been shown to affect microbial populations and actively disrupt the nitrogen cycle in the soil (inhibiting nitrogen mineralisation and nitrification); further exacerbating environmental concerns through actively increasing NO_2 emissions (Liang et al, 1978). It is important, therefore, to control excretion, an easier prospect with chelated mineral forms.

The advantages of chelated minerals over their inorganic forms include a reduced excretion of unabsorbed minerals into the environment. Compared to inorganic minerals, mineral proteinates can facilitate the passage of the mineral ion through the stomach and aid in its absorption in the gut (a process of hydrolysis and direct absorption into the blood at the intestinal brush border (Ma et al, 2014)). In comparison, inorganic mineral forms tend to produce reactive ions during passage through the stomach, binding indiscriminately to other dietary components (non-digestible fibres, for example), passing through the intestine and subsequently excreted into the environment.

A scientific literature review on organic sources of copper, iron, manganese and zinc concludes that organic trace minerals have better bioavailability than inorganic trace minerals, with new data continuously proving better absorption and use in production animals (Byrne et al., 2022). Even when some papers report no differences in relative bioavailability values between the inorganic and organic forms based on selected criteria, on closer inspection, results often show the organic form has advantages when additional parameters are assessed, in the presence of dietary antagonists or under stress conditions. Studies have also unequivocally shown the advantages of incorporating organic forms from an environmental and economic perspective. Organic trace minerals have been perceived as being more

expensive based on direct cost comparisons versus inorganic trace minerals. However, the return on investment in numerous studies has emphatically shown the advantages of incorporating organic forms of minerals.

Animal welfare issues

Copper, iron, manganese and zinc are trace elements that must be contained in optimal concentrations for keeping animal health and welfare.

Human health issues

No concerns for consumer safety are expected from the use of zinc, copper, manganese and iron chelates of protein hydrolysates when used up to the maximum EU-authorised levels in feed. Reducing maximum levels of copper in 2018 has reduced the risk of antimicrobial resistance in animals and the environment.

Food quality and authenticity

The use of zinc, copper, manganese and iron chelates of protein hydrolysates does not have any adverse effects on products of food of animal origin. Food quality and authenticity remain unaltered.

Traditional use and precedents in organic production

Chelates of trace elements have been authorised for the first time in the EU in 1998 and have been used since then in conventional livestock production. No chelate of trace-element has been authorised so far for feeding purposes in organic farming in the absence of application. However, chelates of trace elements are considered to be authorized as fertilisers, and are therefore used in organic fertilisation. They are not explicitly mentioned, but it is the general interpretation of the entry 'Inorganic Micronutrient Fertilizers' in Annex II.

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

Zinc, iron, copper and manganese chelates of amino acids are listed in the OMRI Products list, Web Edition of October 20th, 2022 with restrictions.

Other relevant issues

The Commission's Action plan for organic production in the EU: Action 16: The Commission intends to "support research and innovation under Horizon Europe on alternative sources of organic vitamins and other substances that might turn out to be necessary, and on alternative sources of protein keeping in mind their technical and economic feasibility". Action 21: The Commission "continues working with Member States and civil society to find concrete and operational ways to improve animal welfare in organic production further."

Reflections and conclusions

Supplementation of feed for organic farming with trace element compounds enables to balance the diet and avoids deficiencies. Several inorganic compounds of copper, iron, manganese and zinc are authorised in organic farming but have no organic form. The authorisation granted under Reg. (EC) No 1831/2003 concerns chelates of proteins coming only from soy and the applicant confirms that, for the sake of use in organic farming, the soy proteins are produced from organic soy. The hydrolysation of the organic soy protein into peptides of a smaller size or even individual amino acids is necessary for the chelation to take place. The amino acids used here are not chemically synthetised and they are not meant to balance the amino acid profile of the diet, reasons being the very small quantity of amino acids delivered to the animals via supplementation with chelates of protein hydrolysates, the second being that there is no differentiation in the type of amino acids. Considering the higher bioavailability of these chelates, their authorisation in organic farming has the potential to reduce the environmental impact of organic livestock farming.

Recommendations

The Group recommends adding the following four trace elements to the list of authorised feed additives in Reg. (EU) 2021/1165, Annex III, part B (3) NUTRITIONAL ADDITIVES as follows:

b) Compounds of trace elements

ID number or functional group	Name	Specific conditions and limits
3b407	Copper (II) chelate of protein hydrolysates	only from organic soy production

3b107	Iron (II) chelate of protein hydrolysates	only from organic soy production
3b505	Manganese chelates of protein hydrolysates	only from organic soy production
3b612	Zinc chelate of protein hydrolysates	only from organic soy production

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EFSA. 2015. Opinion on the safety and efficacy of zinc compounds (E6) as feed additives for all animal species (zinc acetate, dihydrate; zinc chloride, anhydrous; zinc oxide; zinc sulphate, heptahydrate; zinc sulphate, monohydrate; zinc chelate of amino acids, hydrate; zinc chelate of glycine, hydrate). EFSA Journal 2015; 13(4):4058. https://doi.org/10.2903/j.efsa.2015.4058.

EFSA. 2016a. Opinion on the revision of the currently authorised maximum copper content in complete feed. EFSA Journal 2016; 14(8):4563. https://doi.org/10.2903/j.efsa.2016.4563.

EFSA. 2016b. Opinion on the safety and efficacy of iron compounds (E1) as feed additives for all animal species: ferrous carbonate; ferric chloride, hexahydrate; ferrous fumarate; ferrous sulphate, heptahydrate; ferrous sulphate, monohydrate; ferrous chelate of aminoacids, hydrate; ferrous chelate of glycine, hydrate. EFSA Journal 2016; 14(2):4396. https://doi.org/10.2903/j.efsa.2016.4396.

EFSA. 2016c. Opinion on the safety and efficacy of manganese compounds (E5) as feed additives for all animal species: manganous carbonate; manganous chloride, tetrahydrate; manganous oxide; manganous sulphate, monohydrate; manganese chelate of amino acids, hydrate; manganese chelate of glycine, hydrate. EFSA Journal 2016; 14(2):4395. https://doi.org/10.2903/j.efsa.2016.4395.

Liang CN, Tabatabai MA. 1978. Effects of trace elements on nitrification in soils. J Eviron Qual.7:291-293.

Ma, X., Liu, S., Lu, L., Li, S., Xie, J., Zhang, L., Zhang, J., Luo, X. 2014. Relative bioavailability of Iron proteinate for broilers fed a casein-dextrose diet. Poultry Science 93:556-563. https://doi.org/10.3382/ps.2013-03296.

3.5 Feed for special nutritional purposes

Feed for special nutritional purposes must also be listed in Reg. (EU) 2020/354. In the case of specific conditions for organic production, they are to be applied in addition to the provisions under Reg. (EU) 2020/354.

Probably some of the feeds listed in this Regulation have also earlier been used in organic production under the advice of veterinarians under very restricted conditions when needed.

The European commission has stated that substances legally defined as feed materials or feed additives have to be authorised according to Annex III of Reg. 2021/1165 in order to be used in organic production, even when the use is restricted to defined special nutritional purposes.

Feeds intended for particular nutritional purposes are specially formulated for animals with impaired metabolism in connection with specific nutritional needs. These feeds are meant to be used at an early stage of disorders and thus prevent the need for veterinary medicines/medical treatment. They are used for a limited time and may include a recommendation to seek a nutritional expert's opinion or advice from a veterinarian. The exact provisions for use are laid down for each nutritional need in Reg. (EU) 2020/354.

3.5.1 Propylene glycol

Introduction, scope of this chapter

The assessment of propylene glycol is related to the request for inclusion of it as feed material and as an essential constituent of feed intended to reduce the risk of ketosis (particular nutritional purpose). The relevant place for inclusion is in Reg. (EU) 2021/1165, annex III, part A(2) other feed materials.

Other names: 1,2-propanediol / propane-1,2-diol / 1,2 dihyhroxy propane / 1,2 –dihydroxypropane
The dossier was submitted by Finland.

Authorization in general production and organic production

Propylene glycol is listed in the EU Catalogue of feed materials (Commission Reg. (EU) No 68/2013, amended for the last time by Reg. (EU) 2022/1104). It is listed as number 13.11.1 Propylene glycol; [1,2-propanediol]; [propane-1,2-diol].

Propylene glycol is listed among the feed constituents intended to reduce the risk of ketosis in (entry number 61 of Annex of Commission Reg. (EU) 2020/354 establishing a list of particular nutritional purposes).

Agronomic use, technological or physiological functionality for the intended use

Propylene glycol is widely and routinely used in diets to reduce the risk of ketosis in conventional European dairy husbandry. It is commercially readily available on the market globally. In organic production, propylene glycol has been restricted for use only in specific cases when needed.

Necessity for intended use, known alternatives

Active prevention of ketosis. The alternative is a veterinary medicinal treatment of intravenous dextrose or glucose.

Origin of raw materials, methods of manufacture

Propylene glycol used for sensitive like food purposes is generally produced through the hydrolysis of high-purity propylene oxide.

Environmental issues, use of resources, recycling

The animal consumes propylene glycol as energy, thus not present in manure. When correctly used, it is unlikely to cause a harmful environmental impact on farms. The breakdown products are carbon dioxide and water.

Animal welfare issues

The dossier claimed that propylene glycol positively affects animal health and welfare by reducing the risk of subclinical or clinical ketosis.

Human health issues

Propylene glycol (E1520) is authorized as a food additive in the EU (Reg. (EC) No 1333/2008 on food additives), and specific purity criteria have been defined by the mission Reg. (EU) No 231/2012. It has an acceptable daily intake of 25 mg/kg body weight.

Food quality and authenticity

According to the dossier, the use of propylene glycol in feeding does not have any adverse effects on products of food of animal origin. Food quality and authenticity remain unaltered.

Other relevant issues

None.

Reflections and conclusions

Negative energy balance is a physiological process in which animals use adipose tissue as an energy source. Feed and cow management practices should primarily focus on preventing ketosis, but timely identification of ketosis in individual cows is critical for quick interventions. Also, using propylene glycol or some feed additives may be useful in preventing ketosis in some high-risk herds. The best strategy for preventing ketosis is not over conditioning cows before calving and developing diets to minimize the drop in intake before calving and optimizing ruminal conditions

after calving. Secondary ketosis occurs after the onset of another disease that causes a reduction in appetite in early lactation.

The Group is concerned about the risk of systematic treatments (using propylene glycol) related to production disease and an intensive productive environment, which is improper for organic production; therefore, the recommendation should be accompanied by the restriction of not being used systematically but when specifically needed for individual animals and a limited period.

Recommendations
The Group recommends the addition of propylene glycol to the list of authorised feed materials in Reg. (EU) 2021/1165, Annex III, part A(2), OTHER FEED MATERIALS as follows:

Number in feed catalogue	Name	Specific conditions and limits
13.11.1	Propylene glycol; [1,2-propanediol]; [propane-1,2-diol]	Restricted to use according to Commission Reg. (EU) 2020/354 as feed intended for particular nutritional purposes: Reduction of the risk of ketosis. On dairy cows, ewes and goats. The use should be restricted as selective therapy (only to individual animals and for a limited period)

References for the substance

Zhang F, Na X, Wang H, Zhao Y, Guo Y, Xiong B. 2020. Effects of Propylene Glycol on Negative Energy Balance of Postpartum Dairy Cows. Animals, 10(9), 1526; https://doi.org/10.3390/ani10091526

3.5.2 Calcium chloride

Introduction, scope of this chapter

The assessment of calcium chloride is related to the request for the inclusion of it as a feed material and essential constituent of feed intended for the reduction of the risk of milk fever and subclinical hypocalcaemia (particular nutritional purpose). The relevant place for inclusion is in Reg. (EU) 2021/1165, III A(1), FEED MATERIALS OF MINERAL ORIGIN.

Other names: calcium dichloride, calcium chloride anhydrous
The dossier was submitted by Finland.

Authorization in general production and in organic production

Calcium chloride is listed in the Catalogue of feed materials, Commission Reg. (EU) No 68/2013, as amended for the last time by Reg. (EU) 2022/1104. It is listed as number 11.1.6.
Calcium chloride is listed among the constituents of feed intended for the reduction of the risk of milk fever and subclinical hypocalcaemia (entry number 60 of Annex of Commission Reg. (EU) 2020/354 establishing a list of particular nutritional purposes).

In organic production, calcium chloride is authorised in Milk-based products only as a coagulation agent in Reg. (EU) 2021/1165, SECTION A1 – FOOD ADDITIVES, INCLUDING CARRIERS. Calcium chloride is authorised in products of plant-origin sausages based on meat only as a coagulation agent in Reg. (EU) 2021/1165, SECTION A2 – PROCESSING AIDS AND OTHER PRODUCTS, WHICH MAY BE USED FOR PROCESSING OF INGREDIENTS OF AGRICULTURAL ORIGIN FROM ORGANIC PRODUCTION. Calcium chloride is authorized in processing aids and other products to produce yeast and yeast products referred to in point (c) of Article 24(2) of

Reg. (EU) 2018/848 part 3 with no specific conditions.
Calcium chloride solutions are authorized as a fertiliser, soil conditioners and nutrients referred to in point (b) of Article 24(1) of Reg. (EU) 2018/848 only for foliar treatment of apple trees to prevent deficit of calcium.

Agronomic use, technological or physiological functionality for the intended use

Calcium chloride is an inorganic, non-toxic salt of natural origin. It is a nutritional source of calcium.
Oral Ca supplementation around parturition is a common and effective practice in the prevention of hypocalcaemia in ruminants. Oral Ca supplementation is also used in the treatment of subclinical cases of hypocalcaemia, as well as for follow-up treatment after intravenous Ca by the veterinarian. This oral supplementation is made via complementary feed in the form of gels, liquids, pastes or boluses.

Necessity for intended use, known alternatives

Calcium chloride is very soluble and rapidly absorbed per osmosis. It effectively increases calcium concentration in the blood. However, Calcium chloride is more caustic than other calcium compounds, thus, other calcium sources, such as calcium propionate, are commonly used in the same products with calcium chloride

Origin of raw materials, methods of manufacture

Inorganic salt of natural origin. Several production methods: derived directly from the limestone reaction with hydrochloric acid, as a by-product of the Solvay process or by reacting hydrochloric and calcium carbonate solution acid.

Environmental issues, use of resources, recycling

There are not environmental concerns on Calcium chloride production methods when it is derived directly from the limestone reaction with hydrochloric acid.

Animal welfare issues

According to the dossier, it is claimed that the authorisation of calcium chloride in calcium products is used in feeding for the reduction of the risk of milk fever and subclinical hypocalcaemia.

Human health issues

None. Moreover, the substance is allowed as food additive by horizontal law and organic regulation.

Food quality and authenticity

The use of calcium chloride in feeding does not have any adverse effects on products of food of animal origin. Food quality and authenticity remain unaltered.

Traditional use and precedents in organic production

No precedents as feed material.

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

$CaCl_2$ is on the NOP list of Non-agricultural (nonorganic) substances allowed as ingredients in or on processed products.

It also appears in the Japanese organic standard (JAS) (Japanese Agricultural Standard for Organic Plants, 2017). The listing does not have criteria to limit source or use.

In IFOAM standards it is listed in Appendix 2, *Fertilizers and Soil Conditioners*, (IFOAM, 2014).

In the Canadian General Standards Board (CGSB) it is listed as permitted substance with the following note: “Calcium chloride derived from naturally occurring brines and not chemically treated” (CAN/CGSB, 2020).

Other relevant issues

The Commission’s Action plan for organic production in the EU:

Action 16: The Commission intends to "support research and innovation under Horizon Europe on alternative sources of organic vitamins and other substances that might turn out to be necessary and on alternative sources of protein keeping in mind their technical and economic feasibility"
Action 21: The Commission "continues working with Member States and civil society to find concrete and operational ways to improve animal welfare in organic production further"

Reflections and conclusions

Calcium chloride as feed for nutritional purposes should be specially formulated for animals with impaired metabolism to reduce the risk of milk fever and subclinical hypocalcaemia. These feeds are meant to be used at an early stage of disorders and thus prevent the need for veterinary medicines/medical treatment. In organic farming, calcium chloride would be the most effective product for these disorders. There are some concerns regarding the production method of calcium chloride, whereas only the calcium chloride produced from natural purification from brine, via evaporation, is non-synthetically, therefore, the Group recommends a limitation of origin of the substance.

Recommendations

The Group recommends the addition of calcium chloride to the list of authorised feed materials in Reg. (EU) 2021/1165, Annex III, part A(1), FEED MATERIALS OF MINERAL ORIGIN as follows:

Number in feed catalogue	Name	Specific conditions and limits
11.1.6	Calcium chloride	Restricted to use according to Commission Reg. (EU) 2020/354 as feed intended for particular nutritional purposes: Reduction of the risk of milk fever and subclinical hypocalcaemia. On dairy cows. The use should be restricted; as selective therapy, only for individual animals in need for it and for a limited period. Restricted to calcium chloride when purified from naturally occurring brine.

References for the substance

Technical Evaluation Report Page 1 of 23 Compiled by Nexight Group for the USDA National Organic Program. (2021).

3.5.3 Calcium propionate

Introduction, scope of this chapter

The assessment of calcium propionate (E282) relates to the inclusion of the substance as feed additives in Reg. (EU) 2021/1165, Annex III, part B (1) Technological additives, (a) Preservatives and as essential constituent of feed intended for the reduction of the risk of milk fever and subclinical hypocalcaemia (particular nutritional purpose). The request is limited to dairy ruminants. Calcium propionate was assessed as a preservative by EGTOP (2018) and EGTOP decided not to include it in Annex VI.

Other names: calcium propanoate, calcium dipropionate.

The dossier was submitted by Finland.

Authorization in general production and in organic production

Reg. (EU) 2022/415 of 11 March 2022 concerning the authorisation of malic acid, citric acid produced by Aspergillus niger DSM 25794 or CGMCC 4513/CGMCC 5751 or CICC 40347/CGMCC 5343, sorbic acid and potassium sorbate, acetic acid, sodium diacetate and calcium acetate, propionic acid, sodium propionate, calcium propionate and ammonium propionate, formic acid, sodium formate, calcium formate and ammonium formate, and lactic acid produced by Bacillus coagulans (LMG S-26145 or DSM 23965), or Bacillus smithii (LMG S-27890) or Bacillus subtilis (LMG S-27889) and calcium lactate as feed additives for all animal species.

Calcium propionate is listed among the constituents of feed intended for the reduction of the risk of milk fever and subclinical hypocalcaemia and for the reduction of the risk of ketosis (resp. entries number 60 and 61 of Annex of Reg. (EU) 2020/354 establishing a list of particular nutritional purposes). In organic production, there are no precedents in the regulation.

Agronomic use, technological or physiological functionality for the intended use

Calcium compounds are common feed materials. Oral Ca supplementation is used in the treatment of subclinical cases as well as for follow-up treatment after intravenous Ca by the veterinarian. Calcium propionate is also glucogenic. The risk of milk fever and subclinical hypocalcaemia in ruminants might get reduced.

Supplementation of oral calcium and Vitamin D metabolites reduces the incidence of transient postoperative hypocalcaemia and the severity of hypocalcemic symptoms. This oral supplementation is made via complementary feed in the form of gels, liquids, pastes and boluses. Calcium propionate is a calcium salt of propanoic acid and, thus a highly available form per oral calcium source.

Necessity for intended use, known alternatives

It might be considered relevant in dairy farming since it is common in older cows and has negative energy balance during parturition in herds worldwide. Timely administration of oral calcium formulations for dairy cows with normal swallowing reflexes may prevent the need for intravenous calcium infusion (veterinary medicine treatment). Per oral calcium salts effectively maintain adequate calcium concentrations in plasma. Thus, the development of clinical milk fever can be prevented in most cases. Oral Ca supplementations are also used as a follow-up treatment after intravenous Ca by the veterinarian, as Ca in the blood tends to decrease to hypercalcaemic levels five hours after intravenous treatment. If hypocalcaemia is not effectively prevented, treatment of milk fever increases the risk of secondary diseases, such as ketosis.

Alternative solutions are an intravenous infusion of calcium (veterinary medicine treatment) for hypocalcemia.

Origin of raw materials, methods of manufacture

Calcium propionate is an organic salt of natural origin. Formed by a reaction between calcium oxide, propionic acid and water, followed by drying of the salt.
For the quantification of calcium propionate as total propionic acid in feed: Ion Chromatography with Conductivity Detection, IC-CD (EN 17294).
Inorganic, non-toxic salt of natural origin. Formed by a reaction between calcium oxide, propionic acid and water, followed by drying of the salt.

Environmental issues, use of resources, recycling

No information was provided in the dossier, but the Group is not aware of any environmental concerns with the substance.

Animal welfare issues

Propionic acid and Ca^{2+} are basic components in the rumen fluid (Zhang, 2018) which means that calcium propionate is safe to add to the feed of dairy cows.

Human health issues

Authorised as a food additive (E282) by Reg. (EC) No 1129/2011amending Annex II to Reg. (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives.

Food quality and authenticity

According to the dossier, the use of the additive in feeding does not have any adverse effects on products of food of animal origin. Food quality and authenticity remain unaltered.

Traditional use and precedents in organic production

Calcium propionate is widely used as a highly available calcium source for the reduction of the risk of milk fever and subclinical hypocalcaemia as well as ketosis in conventional dairy farming in Europe. It is commercially available on the market.

Specification in the use: Reg. (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC.
Entry No. 60 Reduction of the risk of milk fever and subclinical hypocalcaemia
Entry No. 61 Reduction of the risk of ketosis

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

Calcium propionate authorised in NOP and listed in section 205.603 as a synthetic substance, allowed for use in organic livestock production – for treatment of milk fever only (CAS # 4075-81-4).

Other relevant issues

Action 16: The Commission intends to "support research and innovation under Horizon Europe on alternative sources of organic vitamins and other substances that might turn out to be necessary, and on alternative sources of protein keeping in mind their technical and economic feasibility".
Action 21: The Commission "continues working with Member States and civil society to find concrete and operational ways to further improve animal welfare in organic production"

Reflections and conclusions

Even though it is practically impossible to eliminate hypocalcemia from a dairy herd, adopting strategies that prevent this health disorder is key to any successful transition cow program. Negative energy balance (NEB) or milk fever are closely related to dairy health and performance.

In the Group's opinion calcium chloride and Propylene glycol addresses the same needs as Calcium propionate. There is a contradiction due to the inconsistency in the horizontal legislation where calcium propionate is listed as a feed additive and as a preservative. The Group wants to emphasize that the substance was not recommended as a *Preservative* (in accordance with the previous EGTOP report in 2019). The Group foresee a huge risk of misuse, with the alternative decision.

Recommendations

The Group does not recommend the inclusion of calcium propionate to the list of authorised feed additives in Reg. (EU) 2021/1165, Annex III.

References for the substance

Goff JP: Treatment of calcium, phosphorus, and magnesium balance disorders. Vet Clin North Am: Food Anim Prac 15(3):619-639, 1999.

Goff JP, Horst RL. 1993. Oral administration of calcium salts for treatment of hypocalcemia in cattle. J Dairy Sci76:101–8.

Goff JP, Horst RL, Jardon PW, et al. 1996. Field trials of an oral calcium propionate paste as an aid to prevent milk fever in periparturient dairy cows. J Dairy Sci79:378–83.

Green M. 2012. Dairy Herd Health, Oxfordshire UK CAB International 2012. ISBN 9781845939977. Control of major nutrition related disease p. 268-270.

Lean IJ, Saun RV, DeGaris PJ. 2013. Energy and Protein Nutrition Management of Transition Dairy Cows, Veterinary Clinics of North America: Food Animal Practice, 29(2) 337-366, https://doi.org/10.1016/j.cvfa.2013.03.005.

Lean IJ, Saun RV, Degaris PJ. 2013. Mineral and antioxidant management of transition dairy cows. Vet Clin North Am Food Anim Pract. 29(2):367-86. https://doi.org/10.1016/j.cvfa.2013.03.004

Oetzel GR, 2013. Oral Calcium Supplementation in Peripartum Dairy Cows, Veterinary Clinics of North America: Food Animal Practice, 29(2), 447-455, https://doi.org/10.1016/j.cvfa.2013.03.006.

Peek SF, Divers TJ. 2017. Rebhun's Diseases of Dairy Cattle, 3rd Ed.St.Louis, Missouri Elsevier 2018. ISBN 978-0-323-39055-2. Metabolic diseases p. 722-728

Rodríguez EM, Arís A, Bach A, 2017. Associations between subclinical hypocalcemia and postparturient diseases in dairy cows, Journal of Dairy Science 100(9), 7427-7434. https://doi.org/10.3168/jds.2016-12210.

Venjakob, P, Pieper, L., Heuwieser, W., Borchardt, S. 2018. Association of postpartum hypocalcemia with early-lactation milk yield, reproductive performance, and culling in dairy cows. Journal of Dairy Science 101. https://doi.org/10.3168/jds.2017-14202.

Mostert, P. 2018. The impact of diseases in dairy cows on greenhouse gas emissions and economic performance, PhD thesis, Wageningen University, Wageningen, the Netherlands pages 152 https://edepot.wur.nl/445487

Zhang, X.Z.; Chen, W.B.; Wu, X.; Zhang, Y.W.; Jiang, Y.M.; Meng, Q.X.; Zhou, Z.M. Calcium propionate supplementation improves development of rumen epithelium in calves via stimulating G protein-coupled receptors. Animal 2018, 12, 2284–2291.

3.5.4 Iron dextran

Introduction, scope of this chapter

The assessment of iron dextran 10% relates to the request for inclusion of the substance as feed additives in Reg. (EU) 2021/1165, Annex III, part B (3) Nutritional additives (b) Compounds of trace elements.

The authorization of iron dextran is only sought to be used in feeds for particular nutritional purposes (entry 64 compensation for insufficient iron availability after birth up to 3 weeks) according to the conditions laid down in COMMISSION REG. (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC.

Other names: Iron dextran solution, Ferric hydroxide dextran complex; Dextran iron complex, Ferric dextran
The dossier was submitted by Finland.

Authorization in general production and organic production

Iron dextran 10% is authorised as a feed additive, category ‘nutritional additives’.
1) Commission Implementing Reg. (EU) 2017/2330 of 14 December 2017 concerning the authorisation of Iron(II) carbonate, Iron(III) chloride hexahydrate, Iron(II) sulphate monohydrate, Iron(II) sulphate heptahydrate, Iron(II) fumarate, Iron(II) chelate of amino acids hydrate, Iron(II) chelate of protein hydrolysates and Iron(II) chelate of glycine hydrate as feed additives for all animal species and of iron dextran as a feed additive for piglets and amending Reg.(EC) No 1334/2003 and (EC) No 479/2006
2) Particular nutritional purpose (Reg. (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC; entry number 64 Compensation for insufficient iron availability after birth).

Agronomic use, technological or physiological functionality for the intended use

The practice of administering oral iron in the form of a paste directly into the mouth of piglets is often used (Svoboda and Píšťková, 2018).

Necessity for intended use, known alternatives

Only piglets that grow outdoors (on outdoor farms) with access to soil can find enough iron in their natural environment, probably by foraging and ingesting soil. Outdoor farming of piglets is not possible in harsh climates, thus, iron supplementation via per oral route is needed.

Iron sulphate and carbonate are currently authorised for use in feeds for animals in organic production. However, iron sources with better bioavailability for newborn piglets are essential; thus, iron forms like dextran are used in conventional pig farming. Ferrous carbonate is efficacious for adult animals only.

Alternative solutions are iron injections (veterinary medicine) and currently authorized iron sulfate-based products. Non-invasive alternative methods, such as oral administration of iron to piglets, are considered. Research indicates that this single dose is nearly as effective as an iron injection if dosage occurs within the first six hours of life (Ullrey, 2007).

Even if not systematic, iron preparations administered to piglets are considered to be a drug treatment by some inspectors of certifying bodies in France. In this case, the meat of a pig will be downgraded if it receives another treatment to treat a disease. This leads some farmers not to perform neonatal iron injections (Prunier et al., 2022).

Environmental issues, use of resources, recycling

The safety for the environment of iron compounds used as feed additives has been previously assessed by the FEEDAP Panel, concluding that the supplementation of feed with the evaluated compounds was not expected to pose an environmental risk (EFSA FEEDAP Panel, 2013; EFSA, FEEDAP Panel, 2014a,b; EFSA FEEDAP Panel, 2015, 2016a). Considering the maximum amount of iron that could be supplied to a suckling piglet, respecting the legal provisions and the proposed levels considered safe for the target animals and the amount of iron that will be fed during the fattening period of one pig, the additional quantity for one piglet (500 mg) would amount to 2.5% of that consumed and calculated as excreted by a fattening pig. The additive also contains 15% dextran. It has been demonstrated that both rats and humans are able to digest the orally administered dextran; it is assumed that the polysaccharide is hydrolysed by an intestinal enzyme as well as by bacterial action (Fischer and Stein, 1960); no dextran has been detected in faeces after feeding experiments with dextran containing diets (Dahlqvist, 1961; Dahlqvist, 1963; Jeanes, 1975). EFSA (2017) concluded that iron dextran 10% as an additive for suckling piglets at the proposed level does not pose a safety concern to the environment.

Animal welfare issues

Iron deficiency has negative adverse effects on defence mechanisms of piglets and iron deficiency predisposes piglets to different kinds of secondary bacterial infections that can cause mortality without antibiotic treatments. Disorders may occur when a piglet does not receive enough iron, its body does not produce enough haemoglobin. This leads to slowed growth, inadequate weight gain and anaemia, that which can be fatal in severe cases. As a result of iron deficiency anaemia small piglets may become unthrifty, pale and they can suffer from laboured breathing due to oedema in the lungs as one of the lesions. Piglets can die after showing typical clinical signs of severe iron deficiency anaemia. Sudden deaths due to an insufficient supply of iron can also occur at the age of about three to four weeks. Unthrifty piglets suffering from iron deficiency anaemia are also more susceptible to chilling than normal piglets (Zimmerman et al., 2019).

Human health issues

According to the Dossier, the oral use of iron dextran for piglets does not pose safety concerns to consumers under the conditions of use.
No maximum residue level (MRL) is required for veterinary medicinal products in foodstuffs of animal origin (Reg. (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin).

Food quality and authenticity

According to the dossier, the use of the additive in the feeding of piglets does not have any adverse effects on products of food of animal origin. Food quality and authenticity remain unaltered.

Traditional use and precedents in organic production

None.

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

Iron sulphate (oral administration) and carbonate are currently authorised for use in feeds for animals in organic production. However, iron dextran is not authorised in organic standards.

Other relevant issues

The Commission's Action plan for organic production in the EU:
Action 16: The Commission intends to "support research and innovation under Horizon Europe on alternative sources of organic vitamins and other substances that might turn out to be necessary and on alternative sources of protein keeping in mind their technical and economic feasibility"
Action 21: The Commission "continues working with Member States and civil society to find concrete and operational ways to improve animal welfare in organic production further"

Reflections and conclusions

The two key principles of organic animal husbandry are prevention of the diseases and promoting high animal welfare standards. Every method where traditional, invasive veterinary practices can be safely avoided promote animal welfare. The use of iron dextran from natural origin is in line with the objectives and principles of organic production. The growing medium used in the fermentation process must be non- GMO origin and must avoid phenols for iron dextran preparation.

This study within the CORE Organic Cofund project POWER aimed to describe the practices in French organic pig farms regarding iron supplementation of piglets at birth and determine the iron status of the piglets at weaning. It shows that iron supplementation is necessary indoors but not outdoors (Prunier et al., 2022). Except for soils where the content of bioavailable iron is very low, piglets from outdoor farms do not require iron supplementation, unlike those raised indoors (Prunier et al. 2022).

Recommended only for piglets up to three weeks raised indoors. Intended to be administered via water for drinking at a dose of 1 mL/kg body weight (100 mg Fe/kg bw) on the second and ninth days of age. The additive should not be given to piglets with diarrhoea, or to vitamin E-deficient animals; it should not be administered in combination with tetracyclines (EFSA, 2017).

Recommendations

The Group recommends adding iron dextran to the list of authorised feed additives in Reg. (EU) 2021/1165, Annex III, part B (3) NUTRITIONAL ADDITIVES as follows:

a) Compounds of trace elements

ID number or functional group	Name	Specific conditions and limits
3b110	Iron dextran 10%	Restricted to use according to Commission Reg. (EU) 2020/354 as feed intended for particular nutritional purposes: Compensation for insufficient iron availability after birth. Only for piglets. Growing medium for the fermentation process should be of non-GMO origin, non-phenols included. The use should be restricted; as selective therapy, only for piglets in need for it and for a limited period.

References for the substance

EFSA 2017. Safety and efficacy of iron dextran as a feed additive for piglets. https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4701

EU project (2018-2021): Do piglets on organic farms need iron supplementation?

https://projects.au.dk/coreorganiccofund/news-and-events/show/artikel/do-piglets-in-organic-farms-need-iron-supplementation/

Iowa State University, College of Veterinary Medicine. Iron Deficiency Anemia. https://vetmed.iastate.edu/vdpam/FSVD/swine/index-diseases/iron-deficiency-anemia

Knight L.C., Dilger RN. 2018. Longitudinal Effects of Iron Deficiency Anemia and Subsequent Repletion on Blood Parameters and the Rate and Composition of Growth in Pigs. Nutrients, 10, 632; https://doi.org/10.3390/nu10050632

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Svoboda M, Píšťková K. 2018. Oral iron administration in suckling piglets – a review. ACTA VET. BRNO, 87: 7783; https://doi.org/10.2754/avb201887010077

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Zimmerman J.J., A. Ramirez, L.A. Karriker, A.R. K.J. Schwartz, G.W. Stevenson, J. Zhang (Eds), (2019), Diseases of Swine 11th edition Wiley Blackwell, NJ, US.

3.5.5 Iron (II) fumarate

Introduction, scope of this chapter

The assessment of iron (II) fumarate relates to the request for inclusion of the substance as feed additives in Reg. (EU) 2021/1165, Annex III, part B (3) Nutritional additives (b) Compounds of trace elements.

Request to include iron (Fe) source to compensate for insufficient iron availability in piglets after birth up to 3 weeks. The authorization of iron fumarate is only sought to be used in feeds for particular nutritional purposes (entry 64 compensation for insufficient iron availability after birth up to 3 weeks) according to the conditions laid down in Reg. (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC.

Other names: iron fumarate / ferrous fumarate / ferrofumarate / fumaric acid/ iron(2+) salt.
The dossier was submitted by Finland.

Authorization in general production and organic production

Feed additive (3b105) iron (II) fumarate. Functional group 'compounds of trace elements' of the category 'nutritional additives'. Iron (II) fumarate is permitted under Reg. (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (Consolidated 20210327).

According to the specifications of Reg. (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC; entry 64 (compensation for insufficient iron availability after birth up to 3 weeks)

Agronomic use, technological or physiological functionality for the intended use

Iron (II) fumarate is widely used in feed products to complement for insufficient iron for piglets in conventional swine farming in Europe. It is commercially available on the market. Orally in the form of powder or paste complementary feeds.

Necessity for intended use, known alternatives

Iron (II) fumarate form has higher peroral bioavailability for newborn animals than the currently authorised forms (carbonate and sulphate) in organic production.

Alternatives are iron injections or iron sulphate-based products. Iron injections are veterinary medicines.

Origin of raw materials, methods of manufacture

Iron (II) fumarate, as a powder with a minimum content of 30 % iron. Formed by dissolving sodium carbonate in water and adding fumaric acid. The resulting solution of sodium fumarate is mixed with the solution of ferrous sulfate.

Environmental issues, use of resources, recycling

The dossier claim that the oral use of iron (II) fumarate in complementary feed (for particular nutritional purposes) does not pose a safety concern to the environment. The Group is not aware of any contradictions to this statement.

Animal welfare issues

Iron deficiency in the early life of piglets impairs their body weight gain. In addition, iron deficiency in piglets during the first few weeks of their lives can also negatively affect the growth rate later in the growing period.

Human health issues

The use of iron (II) fumarate in the feeding of piglets does not pose safety concerns to consumers under the conditions of use.

No maximum residue level (MRL) is required for veterinary medicinal products in foodstuffs of animal origin (Reg. (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin).

Food quality and authenticity

The use of the additive in piglets feeding does not have any adverse effects on products of food of animal origin. Food quality and authenticity remain unaltered.

Traditional use and precedents in organic production

None.

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

Iron (II) fumarate is allowed under the NOP regulation section 205.603(d) (1-2). (Appendix A: Livestock Vitamins and Minerals).

Other relevant issues

The Commission's Action plan for organic production in the EU: Action 16: The Commission intends to "support research and innovation under Horizon Europe on alternative sources of organic vitamins and other substances that might turn out to be necessary, and on alternative sources of protein keeping in mind their technical and economic feasibility". Action 21: The Commission "continues working with Member States and civil society to find concrete and operational ways to improve animal welfare in organic production further"

Further to the publication of EGTOP Report Feed VI and Pet Food I (July 2022), the Finish authorities requested a re-assessment of peat thru a letter with argumentation and a new dossier for peat. This time to stress the use of peat limited as a carrier of iron (II) fumarate. After careful consideration of the arguments provided by Finish authorities, the EGTOP did not consider that there was any new element that would require a modification of the previous opinion and; therefore, the Group reiterates it. Furthermore, as the Group do not recommend the inclusion for iron (II) fumarate, it does not see either the need to recommend inclusion of peat as a carrier for the substance.

Reflections and conclusions

Feed for nutritional purpose should be specially formulated for animals with impaired metabolism in connection with specific nutritional needs. These feeds are meant to be used at an early stage of disorders and thus prevent the need for veterinary medicines/medical treatment. It should be taken into account possible alternatives to iron (II) fumarate. The necessity of use could be replaced by alternative sources with an even better production method than iron (II)

fumarate such as iron dextran. In organic farming, iron dextran would be the most effective product for iron deficiency. Therefore, the Group recommends that iron dextran is authorised, but not iron (II) fumarate.

Recommendations

The Group does not recommend the inclusion of iron (II) fumarate as feed additive to Annex III in Reg. (EU) 2021/1165.

References for the substance

Brown JME, Edwards SA, Smith WJ, et al.: Welfare and production implications of teeth clipping and iron injection of piglets in outdoor systems in Scotland. Prev Vet Med. 1996; 27(3–4): 95–105.

Delsart M, Pol F, Dufour B, et al.: Pig Farming in Alternative Systems: Strengths and Challenges in Terms of Animal Welfare, Biosecurity, Animal Health and Pork Safety. Agriculture. 2020; 10(7): 261.

EFSA (2017). Safety and efficacy of iron compounds (E1) as feed additives for all animal species: ferrous carbonate; ferric chloride, hexahydrate; ferrous fumarate; ferrous sulphate, heptahydrate; ferrous sulphate, monohydrate; ferrous chelate of aminoacids, hydrate; ferrous chelate of glycine, hydrate, based on a dossier submitted by FEFANA asbl.

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4396

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Radostits Otto M., Gay Clive C., Hinchcliff Kenneth W., Constable Peter D. Iron Deficiency. In Veterinary Medicine A textbook of the diseases and disorders of cattle, horses, sheep, pigs and goats 10th edition. Saunders Elsevier 2007; 1725-1729.

Svoboda, M., Drábek, J. Effect of Oral Administration of Fe2+-Fumarate on Erythrocyte Profile and Growth Rate of Suckling Piglets. ACTA VET. BRNO 2002, 71: 217–222.

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Valli, V.E.O. Hematopoietic system. In Jubb, Kennedy, Palmers's Pathology of Domestic Animals. Edited by M. Grant Maxie. Elsevier Saunders; 2007 (Vol. 3); 222-223.

Prunier, A.; Pauwels, M.; Jaillardon, L.; Leblanc-Maridor, M.; Belloc, C. Merlot, E. (2022) Evaluation of the potential benefits of iron supplementation in organic pig farming. *Open Research Europe*, 2, p. 11.

3.6 Vegetable charcoal

Introduction, scope of this chapter

The assessment of vegetable charcoal relates to the request for inclusion of vegetable charcoal as a feed material in annex III A (2) OTHER FEED MATERIALS of Reg. (EU) 2021/1165.

CAS2 No. 16291-96-6
E.C Additive Identification No 240-383-3
The dossier was submitted by France.

Authorization in general production

Vegetable carbon (Charcoal). is authorized by Reg. (EU) 2017/1017 of 15 June 2017 amending Reg. (EU) No 68/2013 on the Catalogue of feed materials in PART C: List of feed materials, point 7. Other plants, algae and products derived thereof as a product obtained by carbonisation of organic vegetal material.

Authorization in organic production

Charcoal is authorised by the Reg. (EU) 2021/1165 for use in the production of processed organic food and of yeast used as food or feed section a2 – processing aids and other products, which may be used for processing of ingredients of agricultural origin from organic production; part d, authorised products and substances for the production and conservation of organic grapevine products of the wine sector referred to in point 2.2 of part VI of annex II to Reg. (EU) 2018/848 for oenological use.

Also in Annex II of Reg. 2021/1165 the substance biochar is allowed as soil conditioner.

Agronomic use, technological or physiological functionality for the intended use

Activated charcoal, long known to the ancients as a substance of therapeutic value in a variety of maladies, has been relatively recently rediscovered to be of great general use as an oral antidote for drug overdoses and poisonings. Over the past several decades, orally administered activated charcoal has been proven to be highly effective in reducing the systemic absorption of analgesics and antipyretics, sedatives and hypnotics, alkaloids, tricyclic antidepressants, cardiac glycosides, and a wide variety of other kinds of drugs and chemicals. The efficacy of activated charcoal in binding drugs and poisons, especially non-polar or lipophilic ones, has been demonstrated emphatically by a host of in vitro studies and in vivo tests with humans, dogs, rabbits, pigs, cattle, sheep, rats, and mice (Conney et al., 1995).

Anecdotally, it is also reported as an organic medicinal charcoal could be used as a feed additive in pig diets because it improves the digestibility of feed, lowers faecal odour, and has positive effects on the population of microorganism in faeces (Kim et al. (2017).

Necessity for intended use, known alternatives

Used for digestion and methane production from animals; generally, wood charcoal has the best potential to provide a way to prevent negative effects of gases. It also offers an economical way to eliminate noxious substances (Kim et al., 2017). In broiler chicks and laying hens, the wood charcoal in the diet considerably improves feed intake and body weight gain.

Origin of raw materials, methods of manufacture

In the dossier, the applicant claims that the vegetal charcoal is produced from oak trees but this could also derive from other plant material or wood.

Environmental issues, use of resources, recycling

None.

Animal welfare issues

Vegetable charcoal acts by binding toxins that may be present in the animals' feed: Adsorption process (the toxins stick to the surface). This adsorption is due to Van der Waals Forces (dispersion forces).

Human health issues

None

Food quality and authenticity

None

Traditional use and precedents in organic production

Traditionally used and allowed as feeding material for animals. In organic also allowed as food additive for ash-coated goat cheese and "Morbier", traditional use. Biochar is used as soil conditioner.

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

Authorised in IFOAM norm in APPENDIX 2: FERTILIZERS AND SOIL CONDITIONERS, point I. PLANT AND ANIMAL ORIGIN as Wood, bark, sawdust, wood shavings, wood ash, wood charcoal, only if not chemically treated. Authorised in USDA, Title 7, Subtitle B, Chapter I, Subchapter M, Part 205, Subpart G, The National List of Allowed and Prohibited Substances § 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labelled as "organic" or "made with organic (specified ingredients or food group(s))."", (b) Synthetics allowed: Activated charcoal (CAS #s 7440-44-0; 64365-11-3) - only from vegetative sources; for use only as a filtering aid.

In the Permitted Substances Lists of Canada for Organic production systems as:
5. Permitted substances lists for livestock production, Table 5.3 ─ Health care products and production aids: Activated charcoal, shall be of plant origin.
6.Permitted substances lists for preparation, 6.2.3 Other commercial availability requirements specified in the substance listing annotations of Tables 6.3, 6.4 or 6.5 apply to substances used in organic products composed of 70% or more organic content. Table 6.3 ─ Ingredients classified as food additives: Activated charcoal Shall be of plant origin. Prohibited for use in the production of maple syrup.
6. Permitted substances lists for preparation, Table 6.5 ─ Processing aids: Activated charcoal, shall be of plant origin. Prohibited for use in the production of maple syrup.

Other relevant issues

None

Reflections and conclusions

In the dossier, no information was provided about the production process so the group assumes that vegetable charcoal is produced in the same way as other charcoal and the group is therefore concerned about pyrolysis and its consequences in terms of residual PAH products.

Recommendations
The Group does not recommend the inclusion of vegetable carbon [charcoal] to the list of authorised feed materials in Annex III of Reg. (EU) 2021/1165.

References for the substance

Cooney, D., 1995. Activated Charcoal in Medical Applications, 2nd ed. CRC Press, Boca Raton. https://doi.org/10.1201/9780367803964

Kim, K.S., Kim, Y.-H., Park, J.-C., Yun, W., Jang, K.-I., Yoo, D.-I., Lee, D.-H., Kim, B.-G., Cho, J.-H., 2017. Effect of organic medicinal charcoal supplementation in finishing pig diets. KJOAS 44, 50–59. https://doi.org/10.7744/KJOAS.20170006

Olson, K.R., 2010. Activated Charcoal for Acute Poisoning: One Toxicologist's Journey. J Med Toxicol 6, 190–198. https://doi.org/10.1007/s13181-010-0046-1

3.7 Selenised yeast Saccharomyces cerevisiae CNCM I-3060, inactivated

Introduction, scope of this chapter

The request is to extend the list of selenised yeasts Saccharomyces cerevisiae already authorised in organic farming to Selenised yeast Saccharomyces cerevisiae CNCM I-3060. This product differs from the already authorised Selenised yeast Saccharomyces cerevisiae CNCM I-3060 (3b810i) by its new formulation consisting of an increased

concentration of selenium. The request aims to ensure a level playing field with suppliers of other strains. The application is for use in feed for all animal species.

Other name: selenium enriched yeast.

The dossier was submitted by Ireland.

Authorization in general production and organic production

Feed additive (3b810i) Selenised yeast Saccharomyces cerevisiae CNCM I-3060, inactivated, is authorised as a feed additive for the functional group 'compounds of trace elements' of the category 'nutritional additives' by Reg. (EU) 2022/1459. This additive is a more concentrated form of the feed additive (3b810) Selenised yeast Saccharomyces cerevisiae CNCM I-3060 (3b810), which is authorised for use as feed or in feed production in Annex III (Authorized products and substances for use as feed or in feed production) of the Reg. (EU) 2021/1165 authorizing certain products and substances for use in organic production and establishing their lists. The product contains 3,000 to 3,500 mg Se/kg with 97 to 99% of total Se in the form of organic selenium and 63% of total Se in the form of selenomethionine.

Agronomic use, technological or physiological functionality for the intended use

Additive 3b810i is authorised by Reg. (EU) 2022/1459 from 2 September 2022. It is intended to be used in all animal species as organic selenium sources and shall be incorporated into the feed as a premixture. The maximum level of selenium in animal feed is 0.5 mg/kg. The level of selenium via additives currently authorised for use in animal nutrition and with regards to all animal species is 0.2 mg Se/kg of complete feed (measured at moisture content 12%). Selenised yeast has been administered to animals through feed since 1974.

Necessity for intended use, known alternatives

As indicated in the EGTOP report Feed II of 9 October 2014, selenium is a naturally occurring element essential to human and animal health in trace amounts but is harmful in excess. The major biological functions of selenium are: antioxidant (to prevent oxidative stress), proper thyroid function, maintenance of cellular redox status, and development and maintenance of immuno-competence. The concentration of selenium in plant material is highly correlated with those of the soil in which the plants are grown. However, an important factor that may determine selenium-related health problems is the wide-ranging ability of different plant species to accumulate selenium. Plants contain many different Se compounds and the main form in non-accumulator species is selenomethionine, but other forms, such as selenocysteine and selenonium have also been described. In most European countries, Se content in grain and forages is low and the regular use of such feeds can lead to deficiency symptoms like myodistrophy, exudative diathesis and depression of productive and reproductive performances (EFSA, 2006a). Subclinical deficiencies of Se may alter the immune response raising animal susceptibility to infectious diseases (EFSA, 2009). As concerns excess, acute selenosis occurs when plants high in Se are consumed in large quantities over a short period or as a consequence of errors in the formulation of the feed. Chronic selenosis ("alkali disease") is related to the ingestion of plants containing 5 – 40 mg/kg feed for weeks or months. The usual clinical signs of chronic selenosis in horses, cattle and swine are loss of hair, emaciation, hoof lesions and lameness. Consumption of 2 mg/kg of Se has also been shown to cause hoof deformation, hair loss, hypochromic anaemia, increased alkali and acid phosphatase activities in sheep (Levander, 1986 and WHO, 1987 cited by Fordyce, 2005). The form of selenium in selenium enriched yeast is more bioavailable and less toxic than the inorganic form and may therefore be incorporated in smaller amounts.

Origin of raw materials, methods of manufacture

Selenised yeast is produced when Saccharomyces cerevisiae transforms the inorganic salt of selenium (a non-metal element), in a culture medium used for its growth through assimilation and metabolism. This gives rise to a selenium rich yeast. The strain is not genetically modified and is inactivated.

Environmental issues, use of resources, recycling

As indicated in the EGTOP report Feed II, the use of selenised yeast, in the form naturally available, does not add to the current environmental load of selenium as stated in EFSA's Opinion, as selenised yeast would replace other selenium sources, 'its use will not alter the concentration and distribution of Se in the environment'. In fact, literature-based evidence indicates that organic Se is retained at a higher degree than inorganic Se. If smaller quantities of Se are needed to meet the animals' nutritional requirements using selenised yeast instead of inorganic Se as a feed

additive, this would reduce the use of Se resources and pollution of the environment in regions where there is no lack of Se in the fields.

Animal welfare issues

As indicated in the EGTOP report Feed II, selenium is an essential element both for humans and animals and it is used in conventional and organic animal feeding to maintain several basic physiological functions (e.g., thyroid function, immune response, oxidative status) thus contributing to the attainment of a good level of animal health and welfare. In most European countries, Se content in grain and forages is low due to the low content of Se in the soil. Regular use of such feeds can lead to deficiency symptoms if supplemental Se is not added to the animal diets at appropriate levels as described by EFSA.

Human health issues

Selenium is vital for human (and animal) functions. It is a component of anti-oxidative enzymes (such as glutathione peroxidise) that reduce specific oxidised molecules in humans. It is also a vital component of an enzyme(s) implicated in the conversions of thyroid hormones.
Some parts of the world have reported selenium deficiency in certain susceptible individuals and the latest reports suggest that not enough selenium is consumed in certain parts of the world, including in Europe, thus giving way to wider strategic policies to achieve an optimum intake of selenium. For example, in the EU and the US, selenium in the form of selenium enriched yeast are authorised as nutritional supplement. The EFSA's Panel on Dietetic Products, Nutrition and Allergies (NDA) published a report in 2008 concerning selenium enriched yeast and its use as a food supplement (EFSA, 2008). The Regulatory limits set on the total amount of selenium in complete feed and the maximum amount for organic selenium were established to secure that the contribution of animal products to the daily intake of selenium does not impair the health of EU consumers of all categories.

Food quality and authenticity

The use of the additive does not have any adverse effects on products of food of animal origin. Food quality and authenticity remain unaltered.

Traditional use and precedents in organic production

Selenised yeast Saccharomyces cerevisiae is widely used as an organic selenium source feed for conventionally kept mammalians.

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

As indicated in the EGTOP report Feed II, according to Codex Alimentarius – Organically Produced Foods (2013), Table 3: Ingredients of non-agricultural origin referred to in section 3 of the guidelines, section 3.5: Minerals (including trace minerals), vitamins, essential fatty and amino acids and other nitrogen compounds, such products are only approved in so far as their use is legally required in the food products in which they are incorporated. Codex Alimentarius does not mention any ingredients of non-agricultural origin which are allowed in feed products.

Selenium yeast is listed in the US and Canadian OMRI Products list, Web Edition of October 20th, 2022 with restrictions "Shall not be provided in amounts above those required for adequate nutrition and health maintenance for the species at its specific stage of life. It may only be used if organic sources are not commercially available. May only be used if unprocessed rock dust; ground animal or plant material (other than blood or bone meal); and seawater sources are not commercially available. Shall not be used to stimulate growth or production."

Other relevant issues

The Commission's Action plan for organic production in the EU: Action 16: The Commission intends to "support research and innovation under Horizon Europe on alternative sources of organic vitamins and other substances that might turn out to be necessary, and on alternative sources of protein keeping in mind their technical and economic feasibility". Action 21: The Commission "continues working with Member States and civil society to find concrete and operational ways to improve animal welfare in organic production further"

Reflections and conclusions

The feed additive is produced in the same conditions as other selenised yeast Saccharomyces cerevisiae authorised presently for use in organic farming. This feed additive 3b810i is produced by the same manufacturing process as 3b810, the only difference being the concentration of the active substance in the final product. The benefit for the environment is clear, due to the higher bioavailability, limiting the emissions in the environment.

Recommendations

The Group recommends adding the following selenised yeast to the list of authorised feed additives in Reg. (EU) 2021/1165, Annex III, part B (3) NUTRITIONAL ADDITIVES as follows:

b) Compounds of trace elements

ID number or functional group	Name	Specific conditions and limits
3b810i	Selenised yeast Saccharomyces cerevisiae CNCM I-3060, inactivated	

References for the substance

EFSA. 2008. Selenium-enriched yeast as source for selenium added for nutritional purposes in foods for particular nutritional uses and foods (including food supplements) for the general population. The EFSA Journal (2008) 766, 1-43. https://doi.org/10.2903/j.efsa.2008.766

PET FOOD

3.21 Algae flour

Introduction, scope of this chapter

The request refers to the inclusion of "Algae flour" from Eucheuma algae (red algae) as feed material into the lists of authorised products and substances referred to Article 24(7) of Reg. (EU) 2018/848. The relevant place for inclusion is in Reg. (EU) 2021/1165, annex III, part A (2) Other feed materials. Belgium submitted the dossier.

Authorization in general production

Seaweed meal derived by macro-algae is listed in Reg. (EC) 68/2013 (the Community Catalogue of feed materials) under the entry number 7.1.6, with the description and compulsory declaration requirement as shown below.

Number	Name	Description	Compulsory declarations
7.1.6	Seaweed meal	Product obtained by drying and crushing macro-algae, in particular brown algae. This product may have been washed to reduce the iodine content. May contain up to 0,1 % antifoaming agents.	Crude ash

The Catalogue of feed materials includes other Algae products but not Algae flour. Based on a few information provided (Algae flour is produced by grinding dried algae), the entry number 7.1.6 fits better, although the physical state should be different.

Authorization in organic production

According to the EU Organic Regulation, Algae flour was still approved for the production of organic food.
Furthermore, the IFOAM Norms (2014) mention "Seaweed and seaweed products" as possible fertilizer and soil conditioners, as long as they are obtained by:
(i) physical processes, including dehydration, freezing, and grinding;
(ii) extraction with water or potassium hydroxide solutions, provided that the minimum amount of solvent necessary is used for extraction;
(iii) fermentation.

Furthermore, Reg. (EU) 2021/1165, specifically for fertilisers, soil conditioners and nutrients, restricts the use of Algae and algae products as far as directly obtained by:
(i) physical processes, including dehydration, freezing and grinding
(ii) extraction with water or aqueous acid and/or alkaline solution
(iii) fermentation
only from organic or collected sustainably following point 2.4 of Part III of Annex II to Reg. (EU) 2018/848.

Agronomic use, technological or physiological functionality for the intended use

Algae flour is considered a stabiliser, thickener, and emulsifier in feeding stuff for all animal species under the proposed conditions of use and brings many vital nutrients and trace elements.
According to the dossier, the proposed condition of use has no minimum or maximum value specified regarding feed law.

It will be used in organic premixes and organic wet pet food.

The application method requires pouring in cold or hot water and stirring / homogenizing until there are no more lumps.

Necessity for intended use, known alternatives

Algae flour is an efficacious stabiliser, emulsifier and thickener in wet organic dog- and cat food and necessary as a stabilizer during production.

It is stated that there are not alternatives to that kind of usage. However, in the European Union Register of Feed Additives, several feed additives (Emulsifying and stabilizing agents, thickeners and gelling agents) are specific for pets and other non-food producing animals (non-food fur animals).

Origin of raw materials, methods of manufacture

Algae flour is produced by grinding dried algae and the product comes from Indonesia, China or the Philippines.

Environmental issues, use of resources, recycling

In the dossier, the question about environmental impact is only answered with a “No”. This short answer is not satisfactory to determine whether there is an environmental impact or not in the production or use of algae flour.

Animal welfare issues

In the dossier, the question about the impact on animal welfare is only answered with a “No”. This short answer is not satisfactory in determining whether there is an impact on animal welfare.

Human health issues

In the dossier, the question about the impact on human health is only answered with a “No”. This short answer is not satisfactory in determining whether there is an impact on human health.

Food quality and authenticity

According to the dossier, algae flour has a positive impact on pet food.

Traditional use and precedents in organic production

According to the dossier, Algae flour is used for production since there are producers of wet pet food. It is also used for organic wet pet food.

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

No information was provided in the dossier.

Other relevant issues

Several novel foods based on seaweed are authorised (Reg. (EU) 2017/2470), but there is no seaweed authorised for the genus Eucheuma.

On the other hand the food additive E 407a, Processed Eucheuma seaweed, is authorised.

Reflections and conclusions

There is not sufficient information in the dossier to assess the environmental impact. According to the dossier, Algae flour is not available in organic quality, but they should declare if seaweed is collected sustainably in accordance with point 2.4 of Part III of Annex II to Reg. (EU) 2018/848, providing also a flowchart of the production process.

In the Community Catalogue of feed materials, the entry number 7.1.6 refers to "Seaweed meal". In contrast, the dossier refers to Algae flour.

Moreover, the functions claimed are the same as those of the food additive "E 407a processed eucheuma seaweed", although in the feed additive register is listed only E 407 Carrageenan.

The Group considers that the product is more in line with the characteristics of an additive. It is not clear for the Group what the need for the feed material is since the explained needs are more related to functions of feed additives hat are already allowed in organic production (consider also EGTOPs recommendation for inclusion of Carrageenan (E407) in the previous Feed and Pet food report).

Recommendations

The Group does not recommend the inclusion of "Algae flour" as it was not able to do a proper assessment due to missing information and inconsistencies in the provided information and need for the substance.

References for the substance

IFOAM Norms (2014): The IFOAM Norms for organic production and processing. Version 2014.

3.15 Papain

Introduction, scope of this chapter

The assessment of papain relates to the request for the inclusion of the substance as a processing aid in annex III B of Reg. (EU) 2021/1165. The dossier was submitted by the Netherlands.

Other names: Papaya peptidase
CAS No.: 9001-73-4
Other code(s): Enzyme EC 3.4.22.2

Authorization in general production

Processing aids are permitted in feed, and they are defined in the Reg. (EC) No 1831/2003 on feed additives.

Authorization in organic production

No

Agronomic use, technological or physiological functionality for the intended use

Enzymes, as papain is, are processing aids commonly used in pet food manufacturing processes, especially for the production of palatability enhancers which are essential components of pet food, in particular dry pet food, in order to ensure the proper consumption of complete and nutritionally balanced food by the pets. Papain is used to hydrolyse the proteins in the raw material into small peptides.

In the food industry papain stands out for its activity as meat tenderizer, acting in the muscle fibers and connective tissue components; in the drink industry it is used to hydrolyze high molecular weight proteins in clarification of beer, to prevent its turbidity during storage and prolonged cooling (Andrade-Mahecha et al., 2011).

Necessity for intended use, known alternatives

Palatability enhancers are an asset in the formulation. Using papain is essential for the manufacture of high-quality palatability enhancers for pet food. Formulating pet food and reaching a satisfactory organoleptic profile can be challenging. The absence of papain approved as a processing aid for the manufacture of organic feed would create inequity between organic and non-organic manufacturers.

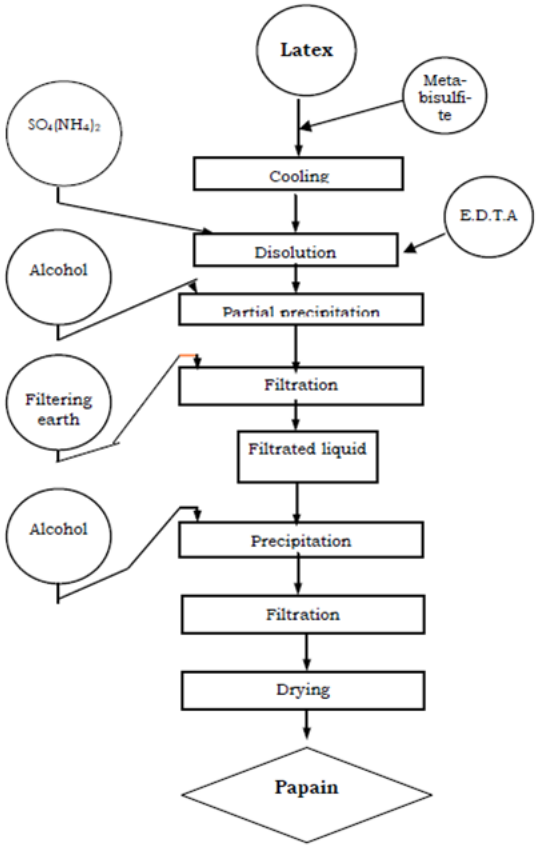
Papain authorization as processing aid for the manufacture of palatability enhancers is key for formulating complete pet food and developing the organic pet food sector. The absence of palatability enhancers on pet food will negatively impact the intake of the pet food. A lack of authorization at EU level will damage the current growing market of organic pet food in Europe.

Origin of raw materials, methods of manufacture

In the dossier, it is attested that the concentration of active substance is between 3 and 30 % of the product, and glycerin or sodium metabisulphite could be present when there is a preparation. The substance is in liquid form and comes from *Carica papaya L.*

In the literature, the process is described as follow: Papain (EC 3.4.22.2) is an endolytic plant cysteine protease enzyme that is isolated from papaya (Carica papaya L.) latex. Papain is obtained by cutting the skin of the unripe papaya and then collecting and drying the latex, which flows from the cut. The greener the fruit, the more active the papain (Mamboya and Amri, 2012).

Andrade-Mahecha et al. (2011) proposed the flow chart below to explain how is produces papain, explaining that the most important stages are extraction process conditions in the precipitation phase and drying method.



Environmental issues, use of resources, recycling

Papain enzyme is extracted from Carica papaya, a tropical and herbaceous succulent plant with self-supporting stems that grows in all tropical countries and many sub-tropical regions of the world. Moreover, there is no limitation due to seasonality as the papaya is available almost round the year (Mamboya and Amri, 2012).

Animal welfare issues

None

Human health issues

None

Pet food quality and authenticity

Papain is a processing aid that allows a better palatability of the feed and therefore improves the quality by increasing the propensity for pets to consume it.

Traditional use and precedents in organic production

It has been used in organic pet food production under the former regulation that allowed national rules for organic pet food. Papain was not listed as itself but used since enzymes were broadly allowed to be used. Allowed, for example, according to the French Cahier des charges " pet food made from organically produced raw materials " (2004).

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

Normally enzymes are listed as allowed feed additives. However, it is not specified if and how enzymes can be used as feed processing aids. In NOP, for instance, the following text is found:

"The following nonagricultural substances may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section: …Enzymes - must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria."

If the word "on" could be interpreted as relevant for processing aids, substances as papain should be understood as allowed then.

Other relevant issues

None

Reflections and conclusions

According to the dossier, other components could be present as glycerine and sodium metabisulphite. To avoid these components (especially sodium metabisulphite), the solution is dried papain (and, if possible, from organic raw material).

Papain would be the first processing aid in the list of animal feed additives. This section is, at the moment of writing this report, not present in Annex III, even though the section B of Annex III mentions processing aids in the title of the section.

Recommendations

The Group recommends the inclusion of papain, as a processing aid, to the Reg. (EU) 2021/1165, Annex III, part B and suggest the following presentation in the current annex:

5) PROCESSING AIDS

Description	Name	Specific conditions and limits
Enzyme	Papain	Processing aid for pet food. Only from organic production, if available or derived from organic raw material, if available.

References for the substance

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4. MINORITY OPINIONS

None

5. REFERENCES

Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (Consolidated 20220101).

Commission Implementing Regulation (EU) 2021/1165 of 15 July 2021 authorising certain products and substances for use in organic production and establishing their lists.

Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (Consolidated 20210327)

Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (Consolidated 20200701).

Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (Consolidated 20220803).

Commission Regulation (EU) 2020/354 of 4 March 2020 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC.

Commission Implementing Regulation (EU) 2017/2330 of 14 December 2017 concerning the authorisation of Iron(II) carbonate, Iron(III) chloride hexahydrate, Iron(II) sulphate monohydrate, Iron(II) sulphate heptahydrate, Iron(II) fumarate, Iron(II) chelate of amino acids hydrate, Iron(II) chelate of protein hydrolysates and Iron(II) chelate of glycine hydrate as feed additives for all animal species and of Iron dextran as feed additive for piglets and amending Regulations (EC) No 1334/2003 and (EC) No 479/2006. (Consolidated 20220925)