EUROPEAN COMMISSION

Directorate-General for Agriculture
and Rural Development

Expert Group for Technical Advice on Organic Production

EGTOP

FINAL REPORT

on

Feed (VI)

and

Pet food (I)

The EGTOP adopted this technical advice at the plenary meeting
of 8 – 10 June 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.

EGTOP reports on organic production | European Commission [2]

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

[2] http://ec.europa.eu/agriculture/organic/home_en

ACKNOWLEDGMENTS

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, GORACCI Jacopo, MARTELLI Giovanna, MOLTENI Roberto; QUINTANA FERNÁNDEZ Paula,

Observers:

DRUKKER Bastiaan and DE-FROIDMONT Denis

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:

- Leonardite should not be included in Annex III.
- Sepiolitic clay should be included in Annex III, part B.
- Peat should not be included in Annex III.

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

- Locust bean gum should be included in Annex III, part B with the following conditions/limits: only for pet food and obtained only from the roasting process and from organic production, if available.
- Acacia-Arabic gum should be included in Annex III, part B with the following conditions/limits: only for pet food and from organic production, if available.
- Carrageenan should be included in Annex III, part B with the following conditions/limits: only for pet food.
- Ammonium chloride should be included in Annex III, part B with the following conditions/limits: only for pet food intended to be used for special nutritional purposes for cats.
- (Ortho-)phosphoric acid should not be included in Annex III.
- Taurine should be included in Annex III, part B with the following conditions/limits: only for cats and dogs, not from GMO origin and if possible not from synthetic origin.
- Methionine should not be included in Annex III.
- Disodium dihydrogen diphosphate (SAPP) should be included in Annex III, part A with the following conditions/limits: only for pet food.
- Pentasodium triphosphate (STPP) should be included in Annex III, part A with the following conditions/limits: only for pet food.

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) 1165/2021[3] and in general, on their compliance with the above mentioned legislation.
With regard to feed, Germany requested the authorisation of leonardite, Spain requested the authorisation of sepiolitic clay and Finland requested the authorisation of peat.
With regard to pet food, France and Italy requested the authorisation of (ortho-)phosphoric acid, locust bean gum and carrageenan, The Netherlands requested the authorisation of acacia-Arabic gum, ammonium chloride, disodium dihydrogen diphosphate (SAPP) and pentasodium triphosphate (STPP), The Netherlands and Italy requested the authorisation of taurine and methionine and Belgium requested the authorisation of algae flour.
Therefore, the Group is requested to prepare a report with technical advice on the matters included in the terms of reference.

[3] EUR-Lex - 32021R1165 - EN - EUR-Lex (europa.eu)

2. TERMS OF REFERENCE

In light of the most recent technical and scientific information available to the experts, the Group is requested to answer if the use of the below listed substances are in line with the objectives, criteria and principles as well as the general rules laid down in 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 Leonardite

Introduction, scope of this chapter

The assessment of leonardite is related to the request for inclusion of it as feed material. The request was submitted before the new organic regulation (EU) 2018/848 started to apply. The relevant place for inclusion is in regulation (EU) 2021/1165, annex III, part A (2) Other feed materials. The dossier was submitted by Germany.

The result of the assessment concerns leonardite as the raw organic sediment rich in humic acids but not extracted humic-like substances obtained from leonardite.

Authorisation in general production and in organic production

Leonardite is listed in the Catalogue of feed materials, Commission Regulation (EU) No 68/2013. It is listed as number 13.10.2 under miscellaneous feed materials.

13.10.2	**Leonardite**	Product that is a naturally occurring mineral complex of phenolic hydrocarbons, also known as humate, which originates from the decomposition of organic matter over the course of millions of years.	Crude Fibre

In organic production, leonardite is authorised as a soil conditioner under Annex II in Regulation (EU) 2021/1165, but only if it is obtained as a by-product of mining activities. Leonardite as a soil conditioner has been discussed in some previous EGTOP reports. First in the 2011 *Report on Fertilisers I,* (2011) when it was assessed as a soil conditioner, the conclusion led to the inclusion as such in the Organic Regulation (EU) No 889/2008. Later in 2018, leonardite was discussed again (*Report on Fertilisers III)* (2018) since it is the raw product to extract humic and fulvic acids; however it was the latter substances the Group assessed. Also, this conclusion led to the inclusion of humic and fulvic acids as soil conditioners in the Organic Regulation.

Agronomic use, technological or physiological functionality for the intended use

Leonardite is a granular (dark) mineraloid that derives from the decomposition of organic matter, and it is rich in humic substances and minerals. It is generally used in drilling activities and agronomic use as a fertilizer/soil conditioner. It is also authorised since 2013 as feed material. Humic acids, the main component of Leonardite, are also used as veterinarian medicines as they exert a protective action on the mucosa of the intestine and have, among others, anti-inflammatory and antimicrobial properties (EMA, 1999).

In recent years studies have been conducted on different animal species to evaluate the functional properties of leonardite and classify it as a feed additive since it also claims to impact growth and health (e.g., Dell'Anno, M. 2020 or Turan, F. 2020). Humic acids were also assessed by EGTOP (2011) as feed additives. However, the Group concluded that humic acids need first to be authorised under horizontal regulation ((EC) No 1831/2003) to be considered for use in organic regulation.

The intended use is for animal nutrition (raw fibre) for the fibrous effect. It can be used as an ingredient in complementary feed and mineral feed. However, the only need for inclusion, explained in the dossier, is an increasing interest from farmers for the feed material.

Necessity for intended use, known alternatives

As mentioned above, the necessity of the intended use is not totally clear to the Group, although, according to the dossier, farmers apparently request it. As an alternative, it is mentioned that no other humic acid is authorised, but the authorisation of leonardite in the horizontal legislation is as a feed material for crude fibre content. The reference to humic acids in the dossier is more linked to the effects in veterinary medicine or effects that would be reserved for leonardite if it had been a feed additive (for zootechnical properties). However, neither leonardite nor humic acids are listed as feed additives.

Origin of raw materials, methods of manufacture

Leonardite is obtained as a product (or by-product) of the mining of brown coal (lignite). For use as leonardite, it is crushed or milled into a powder. However, leonardite is also often treated with alkaline substances to obtain the humic and fulvic acids it contains.

Environmental issues, use of resources, recycling

A by-product of (coal) mining. On the one hand, can mining, especially brown coal mining, be discussed from an environmental point of view but on the other hand, the use of leonardite in organic production (as soil conditioner) has been restricted to "only if obtained as a by-product of mining activities" as a way to utilising an already existing (by-) product and not to encourage mining for exploiting leonardite.

Animal welfare issues

According to the dossier, it is claimed that positive immune modulation and a healthy gut. It is well known and documented that fibre content in the feed is important for good gut and intestinal health; however, when it comes to studies and evaluation by EMA, the effects are related to humic acids, and it is not clear whether these effects also can be attributed to leonardite as a milled ingredient in feed.

However, a Lithuanian study from 2021 evaluated the influence of feed material based on leonardite for broiler chicken. One of the productivity parameters that were evaluated was the mortality which was shown to decrease. The study concludes that leonardite as a supplement in feed showed positive tendencies on poultry production and meat quality, but more research is needed (Daukšienė, 2021).

Human health issues

EMA evaluated humic acids in 1999 and concluded that there was no need to establish a MRLs for the substance. However, once again, humic acids were evaluated as veterinary medicine and not leonardite.

Food quality and authenticity

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

Traditional use and precedents in organic production

No precedents of use as feed in organic production. There are limited general use precedents in feed production as raw milled leonardite (not humic acids).

Authorised use in organic farming outside the EU / international harmonisation of organic farming

In US organic production, Leonardite is not on the list of the prohibited additives *(§205.604 Non-synthetic substances are prohibited for use in organic livestock production*). So one could conclude that it would be allowed in organic. However, leonardite does not seem to be allowed at all or listed as feed material or additive by horizontal law in the US.

Leonardite is not listed in IFOAM Norms as permitted in Appendix 4 List of approved additives and processing/post-harvest handling aids. However, in chapter 5.5 *Animal nutrition* there is a general requirement (5.5.5) for prohibited substances and leonardite do not belong to any of those. Furthermore, requirement 5.5.6 says that animals may be fed with supplements from natural sources.

Other relevant issues

None

Reflections and conclusions

The Group has some concerns about including leonardite in the list of *feed materials*. There is a conflict in attributing leonardite many positive effects that are not possible according to horizontal law to claim since the substance is not registered as a feed additive. To be assessed as a feed additive, in organic regulation, it needs to be registered as such by the horizontal feed legislation. As a feed material leonardite has limited nutritional effect, as also the dossier concludes in the table for consistency checklist. Therefore, it is challenging to consider leonardite as a crucial feed ingredient necessary to maintain animal health or welfare.

In veterinary medicine, humic acids are used, but it is unclear if the positive effects of these can also be obtained from the feed ingredient of milled leonardite.

Precautionary principles and restrictions of external inputs are ground pillars in organic production. The use of leonardite in feed is relatively new. Its use and whether it is for nutritional purposes or other positive effects (that cannot be claimed commercially) is not fully clear.

The Group is open for a future re-assessment of the substance if above mentioned concerns regarding regulation and also functional effects changes.

The Group considers that the inclusion of leonardite as a feed material in Annex III (2) of Regulation (EU) 2021/1165 is not in line with the objectives, criteria and principles of organic farming as laid down in Regulation (EU) 2018/848 art. 24, because it cannot be considered crucial or necessary to maintain animal health, welfare and vitality.

Recommendations

The Group does not recommend the inclusion of leonardite as a feed material at the moment.

References for the substance

Daukšienė, A., Ružauskas, M., Klupšaitė, D., et al. (2021). Influence of feed material based on leonardite on broiler chicken's productivity and production quality. ISBN: 9783900932725. https://www.lsmu.lt/cris/handle/20.500.12512/109961

EGTOP. (2011). Final Report on Fertilizers and soil conditioners. https://ec.europa.eu/info/sites/default/files/food-farming-fisheries/farming/documents/final_report_egtop_on_fertilisers_en.pdf

EGTOP (2011). Final Report on Feed. https://ec.europa.eu/info/sites/default/files/food-farming-fisheries/farming/documents/final_report_feed_1_en.pdf

EGTOP. (2018). Final report on Fertilisers III. https://ec.europa.eu/info/sites/default/files/food-farming-fisheries/farming/documents/final-report-egtop-fertilizers-iii_en.pdf

EMA (1999). Humic acids and their sodium salts. Summary Report EMEA/MRL/554/99-FINAL. Committee for Veterinary Medicinal Products. Humic acid and salts (europa.eu)

Matteo Dell'Anno, M., Hejnaa, M., Sotiraa, S, et al. (2020).Evaluation of leonardite as a feed additive on lipid metabolism and growth of weaned piglets. Animal Feed Science and Technology. Volume 266. https://doi.org/10.1016/j.anifeedsci.2020.114519.

Turan, F. and Turgut, M. (2020). The Effect of Leonardite as Feed Additive on Growth of Goldfish (Carassius auratus L.). Volume 5, Issue 3, 184 - 191, 27.11.2020. https://doi.org/10.28978/nesciences.832994

3.2 Sepiolitic clay

Introduction, scope of this chapter

The assessment of Sepiolitic clay is related to its inclusion as a feed additive. The relevant place for inclusion is in regulation (EU) 2021/1165, annex III, part B, (1) Technological additives - (d) Binders and anti-caking agents. The dossier was submitted by Spain.

Sepiolitic clay of sedimentary origin is a hydrated magnesium silicate belonging to the group of phyllosilicates containing at least 40% sepiolite (hydrous magnesian silicate) and 25% illite (potassium and iron aluminium silicate).

Authorisation in general production and in organic production

Sepiolitic clay (Category: Technological additives; subclassification: Binders, anti-caking agents, and coagulants; Code: E 563) is authorised in the EU as per Article 10 of Regulation (EC) No 1831/2003 for all animal species or categories at a maximum content of 20,000 mg/kg of complete feeding stuffs.

Agronomic use, technological or physiological functionality for the intended use

Clay minerals are layer-type aluminosilicates formed as products of the chemical weathering of other silicate minerals at the earth's surface. Due to their abundant availability and inexpensiveness, they have been used as raw materials for hundreds of industrial applications. Clays are utilised in agriculture, engineering and construction, environmental remediation, pharmaceuticals, food processing, and many other applications (Ismadi et al., 2015).

For farm animals, clay minerals are primarily used as binding agents in the production of pelleted feeds and as adsorbents for mycotoxins and heavy metals (Slamova et al., 2011).

The fundamental properties for which clay minerals are used in animal nutrition are their high specific surface area, adsorption capacity, cation exchange capacity (CEC), colloidal properties, favourable rheological characteristics, swelling capacity, dispersivity, chemical inertness, low or null toxicity for the animal, and low cost (Nadziakiewicza et al., 2019).

Necessity for intended use, known alternatives

A recent review on clay minerals in animal nutrition (Nadziakiewicza et al., 2019), pointed out that sepiolite addition to the feed of dairy cows and fattening cattle resulted in production benefits, decreased energy consumption during pelleting, enhanced the pellet durability index, and minimized formation of fine particles. Also, bentonite, used for feed for aquaculture, improved pellet physical qualities, growth performance of fish, FCR, specific growth rate, and increased red blood cells and hematocrit. In concentrate mixtures for turkeys, sodium bentonite increased the durability of pellets and reduced the moisture and nitrogen content of broiler litter, while clinoptilolite lowered litter ammonia-nitrogen levels.

The applicant has provided some Spanish studies related to the effectiveness of sepiolitic clay as a binder and anti-caking agent in feeds intended for different monogastric species (chickens, pigs, turkeys, and rabbits).

The additive has very recently been re-assessed by EFSA (2022). In that assessment, EFSA concludes that sepiolitic clay is efficacious as a binder and anticaking agent.

Origin of raw materials, methods of manufacture

Sepiolitic clay is found and exploited in several countries, both in Europe and other parts of the world. According to the information in the dossier, the manufacturing process consists of a series of purely physical drying, shredding, and sieving treatments. It is not necessary to perform any particular purification task. Particle size, mineralogical analysis and routine controls of the production are carried out so that there is no variation in the product.

Environmental issues, use of resources, recycling

Both components of the additive, sepiolite, and illite, are naturally occurring clay minerals, and their use in animal nutrition, therefore, will not increase their concentration in the environment. However, as for many other products extracted from mining process it is always important to have strict surveillance and measures to minimize adverse effects on the environment.

Animal welfare issues

According to the information provided in the dossier, sepiolitic clay is inert and insoluble. Because of its low cation-exchange capacity and its high specific surface, sepiolitic clay does not interfere with other nutrients. Its inclusion at 2% in diets for laying hens, lambs and rabbits, does not result in interactions between the additive and other additives or medicines present in the same diet.

As concerns the safety of the target species, EFSA (2022) concludes that the additive is safe for dairy cows and for weaned piglets with 20,000 mg/kg feed. These conclusions are extrapolated to other dairy ruminants, pigs for

fattening, and other growing *Suidae*. The additive is safe for chickens for fattening at 10,000 mg/kg feed and for salmonids at 17,600 mg/kg feed. The EFSA panel could not conclude on the safety of sepiolitic clay for other animal species/categories.

Human health issues

Clay minerals generally have a high dusting potential.
The applicant provided a series of studies to demonstrate the safety of sepiolitic clay for manufacturers and users.
According to EFSA (2022), sepiolitic clay poses a risk by inhalation; it is not an irritant to the skin or eyes but should be considered a skin and respiratory sensitiser.

Food quality and authenticity

Clay minerals are generally not absorbed by the animals, and, therefore, no effect on the composition and quality of animal-derived foods is expected.

Traditional use and precedents in organic production

None

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

Since the sepiolitic clay under assessment is of natural origin, it can be concluded that its use is allowed in the US, Australia and in Japan.

Sepiolitic clay is not listed among the prohibited substances by the USDA rules for Organic Production. According to OMRI US NOP standards (2022) sepiolite pure can be used as binder, anticaking and coagulating agent in feeding stuffs in Mexico.

The Australian National Standard for Organic and Bio-Dynamic Produce (2016) reports that binders, anti-caking agents can be used only if from natural sources.

The Japanese Agricultural Standard for Organic Feeds (2005) allows the use of feed additives which are natural substances or derived from natural substances without chemically treated.

Other relevant issues

None

Reflections and conclusions

In the Group's opinion, the inclusion of sepiolitic clay as a feed additive is in line with the organic regulation. The Group highlights the following:

Regulation 2021/1165 lists among the additives with properties of binders and anti-caking agents some compounds, including sepiolite, with characteristics very similar to those of sepiolitic clay (i.e., bentonite, clinoptilolite).

Clay minerals have well-documented properties as anticaking and binding agents.

From the evaluation of the dossier, no elements emerge that could determine the exclusion of sepiolitic clay from the category of technological additives that can be authorised in animal feeding according to the principles of organic production.

The feed industry needs anticaking and binders also for organic feed production. Considering that two binders and anti-caking agents already authorised in organic feeding, namely vermiculite, and perlite, have been moved to Annex II of the EU Feed Additives Register (Annex II: additives to be withdrawn shortly), it is desirable for organic feed producers to have access to viable alternatives.

The Group considers that the additive can be allowed in feed for organic livestock as a binder and anti-caking agent. Sepiolitic clay is an additive of natural origin that can improve feed's technological properties. Its use in feed does not cause health problems or issues due to sepiolitic clay emission into the environment through the animal excreta.

In the Group´s opinion sepiolitic clay is in line with the objectives, criteria and principles of organic farming as laid down in Regulation (EU) 2018/848 art. 24, and should be authorised.

Recommendations

The Group recommends to add sepiolitic clay to the list of authorised feed additives in Regulation (EU) 2021/1165, Annex III, part B (1) TECHNOLOGICAL ADDITIVES as follows:

d) Binders and anti-caking agents

ID number or functional group	Name	Specific conditions and limits
E 563	Sepiolitic clay	

References for the substance

Australian National Standard for Organic and Bio-Dynamic Produce (2016) https://www.awe.gov.au/biosecurity-trade/export/controlled-goods/organic-bio-dynamic/national-standard Accessed on 30 April 2022

EFSA. 2022. Safety and efficacy of a feed additive consisting of Sepiolitic clay for all animal species (Mineria y Tecnologia de Arcillas SA - MYTA).EFSA Journal 2022;20(6):7344. https://doi.org/10.2903/j.efsa.2022.7344

Japanese Agricultural Standard for Organic Feeds (2005) https://www.maff.go.jp/e/policies/standard/specific/organic_JAS.html#Organic%20Standards Accessed on 30 April 2022

Ismadji S., Soetaredjo F.E., Ayucitra A. (2015) Natural Clay Minerals as Environmental Cleaning Agents. In: Clay Materials for Environmental Remediation. Springer Briefs, Springer. ISBN 978-3-319-16711-4

Nadziakiewicza M., Kehoe S., Micek P. (2019) Physico-Chemical Properties of Clay Minerals and Their Use as a Health Promoting Feed Additive. Animals, 9: 714. https://doi.org/10.3390/ani9100714

OMRI Products List (2022) https://www.omri.org/omri-search?page=1&query=&exactMatch=false&types=category Accessed on 30 April 2022

Slamova R., Trckova, M., Vondruskova H., Zraly Z., Pavlik I. (2011) Clay minerals in animal nutrition. Applied Clay Science, 51: 395-398. https://doi.org/10.1016/j.clay.2011.01.005

3.3 Peat

Introduction, scope of this chapter

The request refers to the possible authorisation of peat as feed material in organic production. The relevant place for inclusion is in regulation (EU) 2021/1165, annex III, part A (2) Other feed materials. Finland submitted the dossier.

Authorisation in general production

Peat is listed in Reg. (EC) 68/2013 (the Catalogue of feed materials) under the entry number 13.10.1, with the description and compulsory declaration requirement as shown below.

Number	Name	Description	Compulsory declarations
13.10.1	Peat	Product from the natural decomposition of plant (mainly sphagnum) in anaerobic and oligotrophic environment.	Crude fibre

Authorisation in organic production

The IFOAM Norms (2014) mentions peat as possible substrate for mushroom production, permitted in horticulture (floriculture, nursery plants, potting mixes) but prohibited for general soil conditioning. Furthermore, Regulation (EU) 2021/1165 also restricts the use of the peat to horticulture (market gardening, floriculture, arboriculture, and nursery). Peat is also authorised as substrate for organic mushroom production according to (EU) 2018/848, ANNEX II, Part I, 2.1 (c).

Agronomic use, technological or physiological functionality for the intended use

The application dossier describes the feed material peat as a product of the natural decomposition of a plant (mainly sphagnum). Heat–treated sphagnum peat is used as a feed material (carrier) for organic iron compounds to compensate for the insufficient iron intake in piglets after birth for up to 3 weeks.

Furthermore, peat has a low pH, which benefits gastro-intestinal health. Peat can stimulate the development of digestive capacity and enhance feed intake after weaning. Peat also has a positive effect on piglets' wellbeing since it supports the natural rooting behaviour in swine. The beneficial effects of various peat preparations on digestion, growth and the immune systems of animals and the absorbent and detoxifying capabilities are associated with the high content of favourable humic substances.

However, an EFSA scientific assessment of human use of humic acids as a food supplement (EFSA, 2009) concluded that the bioavailability of iron, chromium, selenium, or other minerals from their humic acid/fulvic acid chelates might be limited or even absent. In contrast, the possibility that the source may reduce the bioavailability of the metals and nutrients from other sources in the diet cannot be excluded.

According to the dossier but without specific references, peat and various products resulting from its processing, particularly humic preparations, are widely used in animal husbandry and veterinary medicine. The application of humic substances from peat effectively increases the productivity and resistance of pigs of different ages. Peat preparations also protect the highly sensitive mucosa of the digestive tract, stomach, and intestines, particularly in young farm animals.

EMA (1999) states that humic acids are used in horses, ruminants, swine and poultry at an oral dose level of 500 to 2000 mg/kg body weight to treat diarrhoea, dyspepsia and acute intoxications. They exert a protective action on the mucosa of the intestine and have antiphlogistic, adsorptive, antitoxic and antimicrobial properties. Although many advantages have been claimed for humic substances from peat, the evidence provided was insufficient to support these claims.

Necessity for intended use, known alternatives

Peat as a feed material is a natural carrier for iron, supports the natural rooting behaviour of piglets and gastro-intestinal health.

According to the dossier, alternative solutions are organic feed materials with high insoluble fibre content.

Origin of raw materials, methods of manufacture

Peat is a natural feed material, and sphagnum moss (peat moss) one of the most common components in peat. Peat is abundant in the Nordic countries and is a natural feed material for swine.
Humidity and saturated soil water content in sphagnum peat are the highest compared to other origins of peat. According to the dossier, the manufacturing includes also a heat–treatment and the visual inspection is used as method of analysis.
However, there is no production flow chart with a detailed description of the extraction and, in particular, of the heating phase, including an energy balance to assess the sustainability of the process.

Environmental issues, use of resources, recycling

Peat extraction from bog wetlands is leading to environmental concerns (loss of biodiversity, carbon emissions). Peat use for agriculture scope is a minor percentage of the global use, where heat production is, by far, the scope using the majority of the extracted peat. But even if the use in farming is limited, the organic sector is striving to further decrease its use and find viable alternatives. The effort resulted in the proposal to phase it out (OWC, 2020), that was not approved due to lack of alternative so far.

There are many policy efforts currently focusing on the protection and restoration of peatlands within the GAP, with ongoing discussion on nature restoration targets for peatlands under the new Nature Restoration Law, LULUCF, nature directives, etc. Also many projects are working with phasing out peat as a growing medium in horticulture (e.g. MITODE, Organic-Plus etc.) as well as projects focusing on Peatland conservation and restoration (e.g. INTERREG CARE-PEAT, LIFE RESTORE, etc.).

Animal welfare issues

Improves animals' gut health and provides natural rooting material.

Human health issues

According to the dossier: N/A.
However, one potential risk is the possibility of contamination with "atypical or potentially pathogenic mycobacteria" that can contaminate sterile underground peat after extraction (Trckova *et al*., 2005).

Food quality and authenticity

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

Traditional use and precedents in organic production

No specified uses and precedents in organic production as feed material.

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

Not specified in the dossier.
Furthermore, the IFOAM Norms (2014) does not mention Peat as feedstuff.

Other relevant issues

According to the dossier, peat is widely used as bedding and feed material (including as a carrier) in conventional farming due to its beneficial properties.

While burning peat as a heat source is declining, peat is used for other purposes like feed, specifically for swine.

Reflections and conclusions

The Group is missing important information in the dossier, and has major doubts regarding the possible inclusion of peat as feed material into the lists of authorised products and substances.

- There is no information regarding the "essential" need for use of peat according to the requirements of the Regulation (EU) 2018/848. There is not sufficient information regarding the nutritional value of peat.
- The sustainability of the peat production is not documented, and the Group has doubts whether it is sustainable.

Recommendations

The Group does not recommend the inclusion of peat as a feed material.

References for the substance

EFSA (2009). Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on chromium(III)-, iron(II)- and selenium- humic acid/fulvic acid chelate and supplemented humifulvate added for nutritional purposes to food supplements following a request from the European Commission. The EFSA Journal (2009) 1147, 1-36.

EMA (1999). Humic acids and their sodium salts. Summary Report EMEA/MRL/554/99-FINAL. Committee for Veterinary Medicinal Products.

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

OWC (2020). Organic World Congress. Peat, Plastic and Fertilisers in Organic Growing across Europe – Current use and Future.

Trckova M., Matlova, L., Hudcova, H., Faldyna, M., Zraly, Z., Dvorska, L., Beran, V., Pavlik, I. 2005. Peat as a feed supplement for animals: a review. Vet. Med. – Czech, 50, 2005 (8): 361-377.

PET FOOD

According to the *Organic Pet Food Market*[4] report the prediction is that the global organic pet food market will grow. Consumers are more aware of the ingredients in the food for their pets and expect it to cover the same request than their own organic food. The importance of driving even the pet food industry towards more organic goals should be taken care of in this trend.

The manufacturing processes for pet food products are very similar to those for food- and feedstuffs (canning, cooking-extrusion, etc.). Numerous pet food products cannot be manufactured without technological additives such as emulsifiers, stabilizers, or thickeners.

Impacted by limited supply and technical constraints, organic pet food is still a tiny share of the overall pet food market. In addition, the lack of harmonised European regulations created barriers to these products' market access. The Group expects that the inclusion of pet food in Regulation (EU) 2018/848 will harmonise the implementation.

The Group emphasizes that the nutrition of pets should not compete with human nutrition and take in full consideration the organic principles. Pet foods made with by-products (not edible for humans or not chosen by the food industry) are to be preferred to pet foods made from products designated for human consumption. Pet food production should prevent from adding extra pressure to a global food system that will have to feed an estimated 9 billion people by 2050.

Beyond the human-to-pet bond, ingredients used in dog and cats pet food should balance nutrients to preserve animal health and welfare.

Note that 'pet' or 'pet animal' means any non-food producing animal belonging to species fed, bred or kept, but not normally used for human consumption in the Community; (definition of pet is in Regulation (EC) No 767/2009, Art. 3(2)(f))

3.4 Locust bean gum

Introduction, scope of this chapter

The assessment of Locust bean gum, also known as Carob gum, Carob bean gum, and Algaroba gum (*Ceratonia silique)* is related to its inclusion as a feed additive. Locust gum should not be confused with African locust bean *Parkia biglobosa*.

The request was submitted before the new organic regulation (EU) 2018/848 started to apply. The relevant place for inclusion is in regulation (EU) 2021/1165, annex III, part B, (1) Technological additives – (c) Emulsifiers, stabilisers, thickeners, and gelling agents.

The dossier was submitted by France.

Authorisation in general production and organic production

Locust bean gum (E 410) is authorised as a feed additive in the EU according to Regulation (EU) No 231/2012. Accordingly, it is listed in the European Union Register of Feed Additives according to Regulation (EC) No 1831/2003.
Locust bean gum (E 410) is authorised as a food additive in the EU according to Annexes II and III to Regulation (EC) No 1333/2008. It is currently under reauthorisation as a food additive by EFSA, but it is not available yet.
Locust bean gum is already authorised in organic production as a food additive in annex V, part A of Regulation (EU) 2021/1165.

[4] Organic Pet Food Market by Product, Animal Type, and Geography - Forecast and Analysis 2020-2024. Published: Dec 2020; Pages: 120; SKU: IRTNTR45715.

Agronomic use, technological or physiological functionality for the intended use

Locust Bean Gum is widely used in standard wet pet food as a technological aid. It is also part of emulsifying and stabilizing agents, thickeners, and gelling agents.
Synergies include increased viscosity development (guar and cellulose gums) and elastic gel formation (Xanthan Gum or Carrageenan). Locust Bean Gum also is also synergistic with starch. This polymer is not readily soluble in cold water, requiring heat for hydration and activation.

Necessity for intended use, known alternatives

Locust bean gum is necessary to formulate wet pet food as its gelling properties are key in manufacturing jellies, gravies, or mousses.

Non-organic gelling agents are currently not authorised in organic feed. The global volumes are 15, 000 tons globally per year, coming from Europe. Organic locust bean gum exists on the market, but the volume available represents only 1-5% of the total global annual locust bean gum volume. These volumes are too small to supply the whole feed and food organic sector demands.

Locust bean gum authorisation in Organic is key for developing wet pet food in the organic pet food sector. Many consumers, especially cat owners, feed their animals with a mix of dry and wet products. The inability of manufacturers to produce wet organic products because of a lack of authorised gelling agents would prevent consumers from buying organic pet food for their animals to offer them textures variety (dry + wet). Knowing the importance of feeding wet products to maintain a healthy urinary tract in felines is also a question of maintaining good health in cats fed with organic products.

Origin of raw materials, methods of manufacture

The endosperm of the carob fruit seeds is ground to a fine powder and is commercially available in this form as locust bean gum. The clarified gum is obtained by dissolution in hot water and then recovery by precipitation in ethanol or isopropanol. Two different processes are applied. In the acid process, where seeds are heated with sulphuric acid to carbonise the seed coat, the remaining fragments of the seed coat are removed from the clean, pure endosperm by washing and brushing. In the roasting process, the seeds are roasted in a rotating furnace where the seed coat drops off the rest. This process yields a product of a slightly darker colour.

Environmental issues, use of resources, recycling

Information is missing from the dossier. The acid process originates an effluent from the production process. In 2016, nearly 75% of global production came from Portugal, Italy, Spain and Morocco (UN, 2018).

Animal welfare issues

According to the dossier, no adverse effects were reported in 90-day toxicity and carcinogenicity studies in rodents at the highest doses tested. There was no concern regarding the genotoxicity and the reproductive and developmental toxicity of locust bean gum (E 410). The Panel concluded that there is no need for a numerical Acceptable Daily Intake for locust bean gum (E 410). The refined exposure assessment has no safety concern for the general population for its reported uses as a food additive.

Availability of wet products is key in managing feline lower urinary tract health as they help naturally hydrate cats and dilute their urine so that the risk of forming calculus in their bladder is reduced.

Human health issues

Locust bean gum is permitted as a food additive in the EU in accordance with Annex II and Annex III to Regulation (EC) 1333/2008 on food additives. Locust bean gum is a non-carcinogenic, non-toxic, and non-irritant material.

The intended use for dogs and cats does not implicate a problem for human health.

No side effects about locust bean gum reported. Inhalation of locust bean gum powder can cause respiratory problem for manufacturers. However, as for many other food and feed, there have been some incidents of contaminations associated with ethylene oxide (EPA, 2016; EFSA, 2021).

Pet Food quality and authenticity

Processing aid to obtain an adequate texture or cosmetic in wet products using mousse, gravy chunks, or jelly technologies. It compromises the nutritional value of the products but offers a variety of textures that improve product appeal and adequate palatability of products to promote a sufficient food intake to fulfil pets' nutritional needs.
Availability of wet products is critical in managing feline lower urinary tract health as they help to naturally hydrate cats and dilute their urine so that the risk of forming calculus in their bladder is reduced.

Methods identified in the literature for the quantitative chemical analysis of locust bean gum in foods are based on determining the degradation products after hydrolysis (Koswig et al. 1997). Eberendu et al. (2005) described the quantitative determination of saccharides from plant-derived hydrocolloids, including locust bean gum, in food supplements by anion-exchange liquid chromatography with integrated pulsed amperometric detection.

Traditional use and precedents in organic production

Wet organic products already existed on the French market as the French organic standard approved gelling agents. Also in countries where a national standard existed, gelling agents and thickeners were authorised. Therefore there are still, at this moment, organic wet pet food products on these markets using additives such as Carob gum.

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

Locust bean gum is authorised in organic food in Canada (National Standard of Canada, 2020).

Other relevant issues

None

Reflections and conclusions

In this report, the Group recommends the inclusion of three additives (Locust bean gum, Acacia gum and Carrageenan) as emulsifiers, stabilisers, thickeners and gelling agents for pet food. The question should be raised then if all three are needed. In the Group's opinion, all are necessary for organic pet food production and in accordance with the provisions laid down within (EU) 2018/848, article 24.3 (e)(i), "their use is necessary to produce [...] feed because the production [...] of feed is not possible without having recourse to such substances". As well as for food processing (as can be seen in annex V in (EU) 2021/1165) each one of the additives has specific properties, so the gelling agents are not equivalent and are not easily interchangeable. Using one additive or another one depends on the type of pet food (and in accordance with the market demands). There is also often a synergism action between different gelling agents so that a mix of two (or even three) are used together to obtain the desired effect. And, finally, despite the different specific properties, it could be necessary to be able to choose between different alternatives due to scarcity in global market.

The Group considers that the additive should preferably be limited to be obtained only from a roasting process (since the alternative acid process have a bigger environmental impact). However, it is not in the Group's capability to deduce if this limitation is viable due to a lack of information/knowledge of the market for this type of locust bean gum.

Although the EFSA opinion is yet not available, it only concerns locust bean gum as additive in food whereas locust bean gum as feed additive remains authorised in accordance with the current provisions.

The Group concludes also that the authorisation of locust bean gum in pet food production should be accompanied by the condition of being derived from organic production when available. However, the Group has no information on availability of organic locust bean gum at the moment.

Recommendations

The Group recommends adding locust bean gum to the list of authorised feed additives in Regulation (EU) 2021/1165, Annex III, part B (1) TECHNOLOGICAL ADDITIVES as follows:

c) Emulsifiers, stabilisers, thickeners and gelling agents

ID number or functional group	Name	Specific conditions and limits
E 410	Locust bean gum (Carob gum)	only for pet food obtained only from roasting process. from organic production, if available

References for the substance

Carob production in 2016; Crops/World Regions/Production Quantity from pick lists". UN Food and Agriculture Organization, Statistics Division. 2017. Retrieved 26 June 2018.

Eberendu AR, Booth C, Luta G, Edwards JA and McAnalley BH, 2005. Quantitative determination of saccharides in dietary glyconutritional products by anion-exchange liquid chromatography with integrated pulsed amperometric detection. Journal of AOAC International, 88, 998–1007.

EFSA Scientific Opinion - Re-evaluation of locust bean gum (E 410) as a food additive. 10.2903/j.efsa.2017.4646

EPA. 2016. U.S. Environmental Protection Agency. Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) In Support of Summary Information on the Integrated Risk Information System (IRIS). National Center for Environmental Assessment, Office of Research and Development. Washington, DC. EPA/635/R-16/350Fa. https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf

FAO 2016 CAROB BEAN GUM Chemical and Technical Assessment (CTA). Y. Kawamura, J. Smith, M. Rao, - 82nd JECFA

Glicksman, Martin (1963), Utilization of Natural Polysaccharide Gums in the Food Industry, Advances in Food Research, vol. 11, Elsevier, pp. 109–200, doi:10.1016/s0065-2628(08)60065-8, ISBN 978-0-12-016411-0, retrieved 2021-09-20

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2008a. Carob bean gum. Combined Compendium of Food Additives. Monographs 5. Available online: http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2008b. Carob bean gum (clarified). Combined Compendium of Food Additives. Monographs 5. Available online: http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/

Koswig S, Fuchs G, Hotsommer HJ and Graefe U, 1997. The use of HPAE-PAD for the analysis of thickening agents in fruit juice and food analysis. Seminars in Food Analysis, 2, 71–83.

Ministere de l'Agriculture, de l'Alimentation, de la Peche et des Affaires Rurales (2004). Cahier des charges "aliments pour animaux de compagnie" a base de matieres premieres issues du mode de production biologique.

National Standard of Canada. 2020. "Organic production systems: permitted substances lists." (CAN/CGSB-32.311-2020, Corrigendum No. 1, March 2021).

RASFF incidents: https://ec.europa.eu/food/safety/rasff-food-and-feed-safety-alerts/ethylene-oxide-incident-food-additive_en

3.5 Acacia-, Arabic gum

Introduction, scope of this chapter

Acacia gum (also named Arabic gum, *Acacia senegal*) is assessed following a request for authorisation for use in organic pet food production for being consequently listed in the Annex III to Regulation (EU) 2021/1165, part B, 1c.

The same dossier was submitted by several member states

Authorisation in general production

Acacia gum is a feed additive currently authorised for all animal species, with a long history of safe use for decades. It is consequently listed within the "European Union Register of Feed Additives pursuant to Regulation (EC) No 1831/2003" (edition 297 released 24.03.2022) associated with the subclassification "Emulsifying and stabilizing agents, thickeners and gelling agents".

No minimum nor maximum use level is currently defined.

Acacia gum is commonly used in pet food production.

Following the provisions of article 10(2) of Regulation (EC) No 1831/2003, an application, in accordance with article 7, has been submitted. A compliance assessment in accordance with the provisions laid down within that Regulation has been performed within the EFSA in 2013. A new scientific opinion, "Safety and efficacy of a feed additive consisting of acacia gum (gum Arabic) for all animal species (EFSA, 2022). No regulatory decision derived from that opinion is available yet and acacia gum remains authorised in feed in accordance with the current provisions pending that decision.

Authorisation in organic production

Acacia gum is already authorised in organic production, as a food additive, listed in the Annex V, Part A, Section A1 ("Food additives, including carriers"), to Regulation (EU) 2021/1165 in organic products of plant and animal origin (the acacia gum must be derived from organic production). Respectively as an authorised substance for the production and conservation of organic grapevine products of the wine sector (listed in the Annex V, Part D, to Regulation (EU) 2021/1165), possibly derived from organic raw material if available.

Agronomic use, technological or physiological functionality for the intended use

Acacia gum is widely used within the food industry, especially within the European Union and North America, for the following roles: bulking agent, carrier, emulsifier, glazing agent, stabilizer and thickener (according to the Codex Alimentarius).

The function in pet food production is equivalent in accordance with the sub classification "Emulsifying and stabilizing agents, thickeners and gelling agents" of that feed additive currently authorised for all animal species for "standard" pet food.

Necessity for intended use, known alternatives

Acacia gum is certainly the oldest and best known of all gums, already known and used in antique Egypt. In particular, acacia Arabic is an essential natural emulsifier to prevent sugar crystallization and reduce fat oxidation.

So far, no emulsifier, stabiliser, thickener or gelling agent (except guar gum as a binder and anti-caking agent) is authorised in organic pet food. The authorisation of acacia gum is described as essential because of its specific rheological properties, in particular to contribute to the homogeneity and the machinability of the mix as well as the texture of extruded products.

Origin of raw materials, methods of manufacture

Acacia gum is a dried exudation obtained from the stems and branches of strains of *Acacia senegal* (L) Willdenow or closely related species of Acacia (family *Leguminosae*). The raw gum is a natural exudate obtained by incision of the trunk and branches of acacia trees and is hand-collected; the additive results from a cleaning (generally a sieving) and a purification by dissolution in water to form a syrup, which is filtered, centrifuged, submitted to high temperature and then (spray-)dried.

Environmental issues, use of resources, recycling

Acacia gum is harvested commercially from wild trees, mostly in Sudan (80%) and throughout the Sahel, from Senegal to Somalia. The main producing countries are Sudan, Chad and Nigeria, making 90 % of the worldwide production. NGO's help to develop harvesting and marketing gum arabic in the countries of the Sahel to financially protect more than 500,000 households.

According to the scientific opinion of the EFSA (2022), the use of acacia gum in animal nutrition is considered safe for the environment.

Animal welfare issues

No animal welfare issue is expected due to the following considerations;

- there is a long history of safe use (for decades) in pet food production when acacia gum is used as per necessary (Quantum satis),
- no animal health concern is expected (based on the scientific opinion from EFSA (2017 and 2022)

Human health issues

No concerns.

Pet food quality and authenticity

Acacia gum used in food and pet food manufacturing are not different: same sources and collecting process.

Acacia gum is necessary for the functions reported within the above section "Necessity for intended use, known alternatives". In particular, acacia gum

- is an extrusion improver,
- provides desirable rheological properties to product by stabilizing, thickening and emulsifying the pet food.

It doesn’t compromise the nutritional value of the pet food products but allows a variety of textures that improve product appeal and adequate palatability to promote a sufficient food intake in order to fulfil pets’ nutritional needs.

Traditional use and precedents in organic production

Acacia gum has been authorised and is used in "standard" pet food for decades.

Acacia gum is already authorised in organic production, as a food additive, listed in the Annex V, Part A, Section A1 ("Food additives, including carriers"), to Regulation (EU) 2021/1165 in organic products of plant and animal origin (the acacia gum must be derived from organic production). Respectively as an authorised substance for the production and conservation of organic grapevine products of the wine sector (listed in the Annex V, Part D, to Regulation (EU) 2021/1165), possibly derived from organic raw material if available.

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

Acacia gum is authorised in organic food in Canada (in accordance with the National Standard of Canada (2020). It is also listed in the USDA NOP § 205.606 Non-organically produced agricultural products allowed as ingredients in or on processed products labelled as “organic.” And finally also listed in IFOAM´s Norms in appendix 4-List of approved additives1 and processing / post-harvest handling aids.

There is no specific national rules for organic pet food in Canada nor in the United States of America.

Other relevant issues

None.

Reflections and conclusions

In this report, the Group recommends the inclusion of three additives (Locust bean gum, Acacia gum and Carrageenan) as emulsifiers, stabilisers, thickeners and gelling agents for pet food. The question should be raised then if all three are needed. In the Group's opinion, all are necessary for organic pet food production and in accordance with the provisions laid down within (EU) 2018/848, article 24.3 (e)(i), "their use is necessary to produce [...] feed because the production [...] of feed is not possible without having recourse to such substances". As well as for food processing (as can be seen in annex V in (EU) 2021/1165) each one of the additives has specific properties, so the gelling agents are not equivalent and are not easily interchangeable. Using one additive or another one depends on the type of pet food (and in accordance with the market demands). There is also often a synergism action between different gelling agents so that a mix of two (or even three) are used together to obtain the desired effect. And, finally, despite the different specific properties, it could be necessary to be able to choose between different alternatives due to scarcity in global market.

As acacia gum is already authorised in organic production for food and wine production, there is no reason to object to acacia gum authorisation in organic pet food. It is the most possible natural known gum to support organic pet food production development.
Organic acacia gum would be preferred when available but must not be mandatory because the supply sources of organic acacia gum may not always be permanently sustainable, notably due to:

- the political uncertainty of areas where it is collected, making crop collection and organic certification more challenging
- the seasonal gummosis period for collecting the acacia gum within a worldwide competitive market.

Additionally, the possible scarcity of certified organic acacia gum must not lead to competition between human food use and pet food use; certified organic acacia gum must be preferably allocated to human food production. The Group concludes that due to the potentially limited availability of certified organic acacia gum, the authorisation of acacia gum in pet food production is accompanied by the condition of being derived from organic production, when available.

Recommendations

The Group recommends adding acacia gum to the list of authorised feed additives in Regulation (EU) 2021/1165, Annex III, part B (1) TECHNOLOGICAL ADDITIVES as follows:

c) Emulsifiers, stabilisers, thickeners and gelling agents

ID number or functional group	Name	Specific conditions and limits
E 414	Acacia (Gum arabic)	only for pet food from organic production, if available

References for the substance

EFSA. 2022. Safety and efficacy of a feed additive consisting of acacia gum (gum Arabic) for all animal species (A.I.P.G. Association for International Promotion of Gums). EFSA Journal 2022;20(4):7252.https://doi.org/10.2903/j.efsa.2022.7252.

EFSA. 2017.Re-evaluation of acacia gum (E 414) as a food additive. (EFSA Journal 2017;15(4):4741)https://doi.org/10.2903/j.efsa.2017.4741.

National Standard of Canada "Organic production systems: permitted substances lists." (CAN/CGSB-32.311-2020, Corrigendum No. 1, March 2021).

3.6 Carrageenan

Introduction, scope of this chapter

The assessment of carrageenan is related to the request for the inclusion of it as a feed additive for the manufacture of pet food. The relevant place for inclusion is in Regulation (EU) 2021/1165, annex III, part B, (1) Technological additives – (c) Emulsifiers, stabilisers, thickeners and gelling agent. The dossier was submitted by France.

Authorisation in general production and in organic production

Carrageenan (E 407) is registered as a feed additive for [Pets and other non food producing animals (non-food fur animals)] according to Regulation (EC) 1831/2003. The functional group is category 1: Emulsifying and stabilizing agents, thickeners and gelling agents.

Carrageenan is also already allowed in organic production as a food additive in (EU) 2021/1165 Annex V Part A for products of plant material and milk-based products.

Agronomic use, technological or physiological functionality for the intended use

Carrageenan is a gelling agent extracted from red seaweeds and it can be used as emulsifier, a binder, or for suspension and stabilization in a wide range of products in the food processing, pharmaceutical and cosmetic industries. In food/feed industry it is used as a technical additive that functions as stabiliser, thickening and gelling agent. Carrageenan may be used for most foods, but in organic production it is restricted from food of animal origin (except for milk-based products).

Necessity for intended use, known alternatives

The necessity is as a gelling agent for the manufacture of wet organic cat and dog feed with a firm consistency. The dossier claims that without the authorisation of carrageenan in the organic regulation, wet cat and dog feed will not be able to be produced under the new organic regulation.

Origin of raw materials, methods of manufacture

Carrageenans are extracted from seaweed, from some species of red algae (the Rhodophyceae group). Initially, seaweed were collected from the wild. Today most is produced in aquaculture farms in Indonesia, the Philippines, the United Republic of Tanzania, Malaysia and China. The production of red seaweeds have increased from under 1 million (wet)tonnes in 1980 to over 9 million in 2010 and represents 47% of all cultivated seaweed. The major cultivated red seaweed species are *Kappaphycus* and *Eucheuma*, which are the primary raw materials for carrageenan (FAO, 2013).

The typical production of red seaweed and processes to carrageenan includes the cultivation where the fresh seaweed is produced and harvested; the post-harvest treatment with purifying and drying and the processing where carrageenan is extracted from the raw dry seaweeds (FAO, 2013).

Carrageenan from seaweeds can be processed in two different ways; to refined carrageenan (RC) or semi-refined carrageenan (SRC). The former is a traditional product with a high carrageenan content, suitable for human consumption, but complex and expensive to produce. In this original method - the only one used until the late 1970s-early 1980s - the carrageenan is extracted from the seaweed into an aqueous solution. The seaweed residue is removed by filtration and then the carrageenan is recovered from the solution, as a dry solid containing almost pure carrageenan.

The other, semi-refined carrageenan, is a product with a lower carrageenan content. Initially, it was unfit for human consumption and used primarily for pet food or as raw materials to produce RC. However today, the two forms of the additive are manufactured to meet the specifications set for the food additives carrageenan (EFSA, 2018). In this second method the carrageenan is actually never extracted from the seaweed. Instead the principle is to wash everything out of the seaweed that will dissolve in alkali and water, leaving the carrageenan and other insoluble matter behind. This insoluble residue, consisting largely of carrageenan and cellulose, is then dried and sold as SRC. Due to that the carrageenan does not need to be recovered from solution, the process is much shorter and cheaper.

Environmental issues, use of resources, recycling

According to FAO's Technical paper on Social and economic dimensions of carrageenan seaweed farming (FAO 2013) carrageenan seaweed farming can positively affect the environment because seaweeds could improve the benthic ecosystem and sequester carbon. Another review study (Rimmer, 2021) also highlights that "*seaweed farming can have positive environmental impacts, since it is often associated with reductions in some types of fishing, is*

associated with increased catches of herbivorous fish species, and seaweed farms demonstrate higher abundance and greater species richness of wild, mobile macrofauna than unfarmed areas".

On the negative side, we found that the increase of cultivation of carrageenan seaweed in many countries, as a result of the market demand, can cause that species that are invasive or become invasive are introduced. The need for protocols and quarantines are crucial to avoid this. Other negative environmental impacts can be the destruction of mangroves for materials used in seaweed farming, and impacts on the benthic ecosystem by clearing up the sea floor.

Animal welfare issues

Very recently the EFSA, FEEDAP panel was asked to deliver a scientific opinion on the safety and efficacy of carrageenan as a feed additive for pets and other non-food-producing animals. The panel found that owing the lack of information, they were not in the position to conclude on the safety of the additives for pets and other non-food-producing animals and for the user. Furthermore, they concluded that the additive is efficacious as a gelling agent, thickener and contributes to stabilise canned pet feed but no conclusion could be drawn on the efficacy of the additive as a binder and emulsifier. (EFSA, 2022).

Human health issues

Carrageenan is a food additive also authorised in organic production. The substance was reassessed by EFSA in 2018. The EFSA opinion concluded that there were no concerns with the carcinogenicity of carrageenan and it did not raise a concern with respect to genotoxicity. However, the Panel noted uncertainties as regarding the chemistry, the exposure assessment and biological and toxicological data. Therefore taking into account, considering the lack of adequate data to address these uncertainties, the Panel concluded that the existing acceptable daily intake should be considered temporary. At the same time, the database should be improved within five years after the publication of the opinion.

In any case since this assessment is restricted to carrageenan as a pet food additive it is of no relevance for human health issues.

Pet food quality and authenticity

Carrageenan is widely used in food and pet food and it is efficacious as a gelling agent, thickener and stabiliser.

Traditional use and precedents in organic production

Previous national standards for pet food developed (according to Regulation (EU) 834/2007) by single member states authorised carrageenan. According to Commission services, some of them (e.g. Italy and The Netherlands) since they accepted the same additives that where accepted for organic food production. And some listed it as authorised additives e.g. the French Cahier des charges "aliments pour animaux de compagnie à base de matières premieres issues du mode de production biologique" (2004).

As mentioned above also allowed as food additive.

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

There are no specific national rules for organic pet food in Canada or the United States of America. The National Organic Programme (NOP) at the USDA has since 2004 discussed and formed task force to develop labelling standards for organic pet food but there is nothing in place yet. No other references found or mentioned in the dossier.

Carrageenan is listed as allowed food additive according to the USDA National *list of allowed and prohibited substances*.

It is permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives and processing /post-harvest handling aids (IFOAM, 2014).

Other relevant issues

None.

Reflections and conclusions

In this report, the Group recommends the inclusion of three additives (Locust bean gum, Acacia gum and Carrageenan) as emulsifiers, stabilisers, thickeners and gelling agents for pet food. The question should be raised then if all three are needed. In the Group's opinion, all are necessary for organic pet food production and in accordance with the provisions laid down within (EU) 2018/848, article 24.3 (e)(i), "their use is necessary to produce [...] feed because the production [...] of feed is not possible without having recourse to such substances". As well as for food processing (as can be seen in annex V in (EU) 2021/1165) each one of the additives has specific properties, so the gelling agents are not equivalent and are not easily interchangeable. Using one additive or another one depends on the type of pet food (and in accordance with the market demands). There is also often a synergism action between different gelling agents so that a mix of two (or even three) are used together to obtain the desired effect. And, finally, despite the different specific properties, it could be necessary to be able to choose between different alternatives due to scarcity in global market.

The Group acknowledges that Carrageenan is essential/crucial for the manufacture of canned pet food for cats and dogs. It is in line with Regulation 2018/848 art. 24.1 d and 24 e (i): "…their use [feed additives] is necessary to produce or preserve feed because the production or preservation of feed is not possible without having recourse to such substances."

Recommendations

The Group recommends adding carrageenan to the list of authorised feed additives in Regulation (EU) 2021/1165, Annex III, part B (1) TECHNOLOGICAL ADDITIVES as follows:

c) Emulsifiers, stabilisers, thickeners and gelling agents

ID number or functional group	Name	Specific conditions and limits
E 407	Carrageenan	only for pet food

References for the substance

EFSA. 2018.Re-evaluation of carrageenan (E 407) and processed Eucheuma seaweed (E407a) as a food additive. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). Adopted: 18 March 2018. https://doi.org/10.2903/j.efsa.2018.5238

EFSA 2022. Safety and efficacy of a feed additive consisting of carrageenan for pets and other non-food-producing animals (Marinalg International). EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP). Adopted: 23 March 2022. https://doi.org/10.2903/j.efsa.2022.7285

FAO. 2013. Fisheries and aquaculture technical paper 580. Social and economic dimensions of carrageenan seaweed farming. ISSN 2070-7010

Rimmer, M. A., Larson, S., Lapong, I., et al. Seaweed Aquaculture in Indonesia Contributes to Social and Economic Aspects of Livelihoods and Community Wellbeing
USDA- NOP: § 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)).

3.7 Ammonium chloride

Introduction, scope of this chapter

The following request is for the authorisation of ammonium chloride as an additive in commercial food for cats. The relevant place for inclusion is in Regulation (EU) 2021/1165, annex III, part B, (4) Zootechnical additives. The dossier was submitted by The Netherlands.

Authorisation in general production

Ammonium chloride is authorised as zootechnical additive, functional group acidity regulator, for dogs and cats: Commission Regulation (EU) 2020/354 of 4 March 2020 establishing a list of intended uses of feed for particular nutritional purposes and repealing Directive 2008/38/EC lists E-510 under essential nutritional characteristics "urine acidifying properties" for feed intended for reduction of the risk of renal calculi in ruminants and dissolution of struvite stones and reduction of the occurrence of struvite stones in dogs and cats. It is also listed as a pharmacologically active substance in veterinary medicinal products and it is not subject to maximum residue levels when used in food-producing animals (Commission Regulation (EC) No 7/2010). Within the EU register of Feed additives it is listed under the category *zootechnical additives* and the functional subgroup *other zootechnical additives*. EFSA issued several opinions from 2009 to 2022 on the safety of ammonium chloride used in or on foodstuffs, as reported in references: in the last EFSA opinion, no new evidence was found that would make the FEEDAP Panel reconsider its previous conclusions on the safety of target species, consumers and environment.

Authorisation in organic production

Ammonium chloride is used in cat feed as a urine acidifier, but it is currently not included in the list of substances authorised in organic feed.

Agronomic use, technological or physiological functionality for the intended use

This substance has been mainly used (approximately 70%) as a fertilizer for water paddies in Japan since 70's (but also in China, India, and Southeast Asian countries such as Indonesia, Philippines and Thailand). It seemed to cause concern when assessing the potential eutrophication hazard, including drinking water quality in certain regions. The exposure of nitrite and nitrate to humans has to be assessed through drinking water (in case of persistence, ammonium will be attacked by bacteria and converted to nitrate)

However for this assessment agronomic use not relevant. Ammonium chloride is used in cat pet food as a urine acidifier.

Necessity for intended use, known alternatives

Ammonium chloride is authorised in animal feed and human food (as E 510): in particular, it is currently used in cat feed as a urine acidifier to develop organic dry cat products that are safe for cats' urinary tract.

Origin of raw materials, methods of manufacture

Ammonium chloride is produced by chemical synthesis from ammonia and sodium chloride in water (in the so-called "modified Solvay process" (ammonium chloride–soda ash process)). After the reaction, the product is crystallised and dried. To complete the additive production, a maximum of 0.7 % tricalcium phosphate is added as an anticaking agent because the active substance is hygroscopic. The active substance ammonium chloride contains by specification, a minimum of 99.0 % of ammonium chloride (Chemical Abstracts Service (CAS) no 12125-02-9, molecular weight 53.94, molecular formula NH_4Cl).

Environmental issues, use of resources, recycling

There is no information provided in the dossier about environmental issues linked to ammonium chloride as a pet food for cats. However, there are many studies done for different farm animals. For instance, for lambs for fattening; Ammonium chloride will not be excreted as such but as urea, ammonium, and chloride ions. All these compounds are natural substances in the animal's excreta. Considering the restricted use of the additive in iso-nitrogenous diets for lambs, it will not substantially contribute to the environmental concentration of chlorine or nitrogen. The use of ammonium chloride at the proposed level in feeding stuffs for lambs for fattening does not pose a risk for the environment.

This substance seems to pose hazards to freshwater fish and the marine environment in general: it seems to be able to destroy food chain organisms and gamefish in natural waters (threshold concentrations for fish = 0.5 ppm), showing acute toxicity for three trophic levels of the aquatic organism (algae, invertebrates, and fish). However, the use in the pet food industry does not normally result in contamination of freshwater.

Animal welfare issues

EFSA and the FEEDAP Panel have issued several opinions from 2009 to 2022. It is important to highlight the restriction in time and/or amount or restriction to veterinary treatments when feeding animals with this additive.

For instance, the FEEDAP Panel concludes that ammonium chloride reduces the pH value in the urine of lambs and the formation of urinary calculi. The effective dose is 1 % in complete feeding stuffs, as demonstrated by three studies. This dose and the 1.5-fold overdose affect the mineral balance as it increases renal calcium excretion. Ammonium chloride in a complete diet for lambs for fattening at the maximum dose of 1 % is considered safe for a limited period of feeding (approximately three months).

Furthermore the assessments concludes;
- for an unlimited period of administration 0.5 % ammonium chloride in the complete feed for ruminants should not be exceeded, particularly considering the variety of feeding stuffs with different anion–cation ratios.
- for cats and dogs, 0.5 % ammonium chloride in the complete diet can be considered safe for an unlimited period. But for doses higher than 0.5 % ammonium chloride in complete feed for dogs and cats should be restricted to veterinary treatment.
In cats, 1.5 % of ammonium chloride is generally added to a dry ration. Furthermore, to avoid health risks from long-term feeding of acidifying diets, it is recommended that struvite diets with low base excess be formulated and contain as few alkalizing compounds as possible that must be neutralized by acidifiers.

In addition, ammonium chloride is considered an eye and skin irritant and a potential respiratory sensitiser (fumes), but is not a dermal sensitiser, potentially harmful if swallowed and may cause systemic toxicity by acidosis.

Human health issues

Ammonium chloride will dissociate in the rumen, and the ammonium ion (NH_4+), which is not used for microbial protein synthesis, will cross the rumen wall entering the liver via the bloodstream, where it is converted to urea. The rumino-hepatic circle for protein synthesis can reuse urea. The free proton accounts for the systemic acidifying effect of the substance. In the kidney of healthy animals ammonia (NH_3) is formed de novo by deamination of glutamine and other amino acids and excreted as NH_4^+ with the ultrafiltrate. Due to its relatively poor diffusion potential, a major part of ammonium stays in the urine, decreasing its pH. Since both ions of ammonium chloride will be rapidly excreted, predominantly via the kidney, no residue of the ions or its parent compound is expected in the organs and tissues of the target animal when fed ammonium chloride. A withdrawal period is not considered necessary.

Pet Food quality and authenticity

Not relevant.

Traditional use and precedents in organic production

Ammonium chloride has been used in non-organic cat pet food for almost 40 years, due to its acidification capacity in cats. But as far as we understand it has not been authorised in previous national legislations for organic pet food.

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

No information provided.

Other relevant issues

No other relevant issues available.

Reflections and conclusions

The Group is concerned that the addition of chloride to the diet in the form of ammonium chloride can cause a negative calcium balance in cats (Pastor et al., 1994). If administered without urine controls, acidified dry cat food in subjects with slight pH alterations can cause the opposite: the precipitation of crystals (calcium oxalate uroliths) is favoured by the excessively low pH. The danger is the long-term use, therefore long-term intake is not recommended, except for targeted therapies.

In addition, ammonium chloride is produced by chemical synthesis from ammonia and sodium chloride in water (the so-called “modified Solvay process” may have strong impact on the ecosystem).

The Group noted no valid alternatives could be found, due to the side effects underlined:

- DL-methionine: Effective in urine acidification: sulphur contained in the molecule of this amino acid is oxidized to sulphates, which are then excreted in the urine and reduce its pH. The studies show that DL-methionine is effective in acidifying urine in cats when administered in the amount of 3%. Possible negative consequences: may lead to a transient decrease in cat's food intake and possible weight loss (administered as a dietary supplement rather than a commercial feed additive, its dose can range from 500 to 1500 mg/cat/day);
Furthermore, DL-methionine is a synthetic amino acid and can therefore not be recommended for inclusion as alternative (see section 3.10).
- Vitamin C seemed to have similar properties to acidifying urine (ascorbic acid) administered to cats at a dose of 400-1000 mg/kg m.c./day. Possible negative consequences: stomach problems caused nausea and vomiting at therapeutic doses.

As a result, ammonium chloride use in cats' feed has been much discussed, regarding the possibility of using only for special nutritional purposes, as reported by Commission Regulation (EU) 2020/354 of 4 March 2020 (list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC), to focus its use properly.

As long as there are no better alternatives, the Group is inclined to recommend the inclusion of ammonium chloride in the list of organic authorised additives for cat food, but with the restriction of *only for feed for special nutritional purposes for cats*.

Recommendations

The Group recommends the inclusion of ammonium chloride to the list of authorised feed additives in Regulation (EU) 2021/1165, Annex III, part B (4) ZOOTECHNICAL ADDITIVES as follows:

ID number or functional group	Name	Specific conditions and limits
4d Other zootechnical additives	Ammonium chloride	only for pet food intended to be used for special nutritional purposes for cats in accordance with Commission Regulation (EU) 2020/354

References for the substance

Commission Decision of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2015. Scientific Opinion on the safety and efficacy of Amoklor (ammonium chloride) as a feed additive for ruminants, cats and dogs. EFSA Journal 2016;14(1):4352, 14 pp. doi:10.2903/j.efsa.2016.4352

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Dusemund B, Fasmon Durjava M, Kouba M, Lopez-Alonso M, Lopez Puente S, Marcon F, Mayo B, Pechova A, Petkova M, Ramos F, SanzY, Villa RE, Woutersen R, Dierick N, Brozzi R, Galobart J, Gregoretti L, Vettori MV and Innocenti ML,2022. Scientific Opinion on the safety and efficacy of the feed additive consisting of ammoniumchloride (Ammonium Chloride AF) for all ruminants, dogs and cats for the renewal of its authorisation(BASF SE). EFSA Journal 2022;20(4):7255, 9 pp. https://doi.org/10.2903/j.efsa.2022.7255

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP); Scientific Opinion on the safety and efficacy of ammonium chloride for bovines, sheep, dogs and cats. EFSA Journal 2012;10(6):2738. [18 pp.] doi:10.2903/j.efsa.2012.2738.

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011. Scientific Opinion on Flavouring Group Evaluation 46, Revision 1 (FGE.46Rev1): Ammonia and three ammonium salts from chemical group 30. EFSA Journal, 9(2):1925.

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP); Scientific Opinion on ammonium chloride (Amoklor) for lambs for fattening. EFSA Journal 2012;10(2):2569. [11 pp.] doi:10.2903/j.efsa.2012.2569.

EFSA (European Food Safety Authority), 2009. Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on Flavouring Group Evaluation 46 (FGE.46)1: Ammonia and two ammonium salts from chemical group 30. The EFSA Journal, 955, 1-34.

Taton GF, Hamar DW and Lewis LD, 1984. Evaluation of ammonium chloride as a urinary acidifier in the cat. Journal of the American Veterinary Medical Association, 184, 433–436.

New Jersey Department of Health. 2016. Hazardous substance fact sheet. Ammonium chloride. https://www.nj.gov/health/eoh/rtkweb/documents/fs/0093.pdf

Ammonium chloride. 2003. SIDS Initial Assessment Report For SIAM 17. UNEP PUBLICATIONS. https://hpvchemicals.oecd.org/ui/handler.axd?id=406084d7-4cb1-473b-a419-961968fe91f6

Fujiwara, F.1976. Ammonium Chloride Fertilizer produced in Japan, 14

Kienzle E., Wilms-Eilers S. 1994. Struvite Diet in Cats: Effect of Ammonium Chloride and Carbonates on Acid Base Balance of Cats Get access Arrow. The Journal of Nutrition, Volume 124, Issue suppl_12: 2652S–2659S. https://doi.org/10.1093/jn/124.suppl_12.2652S

Jank M. 2019. Potent urine acidifiers in feeding cats. Veterinary life, 4: 12-13.

Pastoor, F. J. H., Opitz, R., van 't Klooster, A. T., & Beynen, A. C. (1994). Dietary Calcium Chloride vs. Calcium Carbonate Reduces Urinary pH and Phosphorus Concentration, Improves Bone Mineralization and Depresses Kidney Calcium Level in Cats. The Journal of Nutrition, 124(11), 2212–2222.

3.8 (Ortho-)phosphoric acid

Introduction, scope of this chapter

The following report is based on the request of France for the inclusion of orthophosphoric acid in Annex III, part B, of Regulation (EU) 2021/1165, in the category of (1)Technological additives, Functional group of (a) Preservatives. The applicant also claims the acidifying properties of the additive for the urine of cats.

Authorisation in general production and in organic production

Orthophosphoric acid (Category: Technological additives; Functional group: Preservatives; Code: 1a338) is authorised in the EU until 19 November 2023 by Regulation (EU) n. 1055/2013 for use in feeding stuff for all animal species without restriction on age and levels in feed.

Orthophosphoric acid is authorised as a food additive in the EU (E338) by Regulation (EC) 1333/2008.

Agronomic use, technological or physiological functionality for the intended use

According to ECHA (2022), orthophosphoric acid is used in washing and cleaning products, fertilisers, welding and soldering products, polishes and waxes, plant protection products, pH regulators, and water treatment products.

Regarding food and feed industries, orthophosphoric acid is typically used for pH control in a wide variety of food preparations for humans, including beverages, and it is also used for feed preservation.

Necessity for intended use, known alternatives

Orthophosphoric acid is a widely used feed preservative. As recently reviewed by Perlin et al. (2020), phosphoric acid used in association with organic acids, improves the production performance of weaned piglets. Furthermore, milk replacers, acidified with phosphoric acid-based products, reduced digestive disorders in calves. Including phosphoric

acid-based acidifiers at required levels presents economic benefits like lowering the acidification cost of feed and providing available phosphorus.

In addition to the above-mentioned properties, orthophosphoric acid has a certain ability to lower the urinary pH in the feline species with no long-term adverse effects on animal health (Fettman et al., 1992).

According to the dossier, in the absence of the possibility of using other additives in organic pet food formulations to lower urine pH (e.g., synthetic sulphur amino acids), the urinary acidifying properties of orthophosphoric acid may be useful for the feed industry to formulate organic pet foods that help prevent certain urinary diseases.

Origin of raw materials, methods of manufacture

According to the dossier, orthophosphoric acid is manufactured by two main processes, the wet process and the electrothermal process. In the wet process, phosphate rock is digested with sulphuric, nitric or hydrochloric acids. The phosphoric acid is separated from the insoluble slurry by filtration. However, this process could leave in the acid variable amounts of inorganic impurities that are removed through a solvent extraction purification process to produce the food-grade additive. In the electrothermal process, the phosphate rock, coke and silica are heated in an electric resistance furnace to more than 1 100 °C. The elemental phosphorus is then oxidised to P_4O_{10} and then hydrated. This process leads to a high purity orthophosphoric acid. Only arsenic needs to be removed with an additional purification step.

Environmental issues, use of resources, recycling

The use of orthophosphoric acid in animal nutrition is not expected to pose an additional risk to the environment (EFSA 2013).

Animal welfare issues

Orthophosphoric acid is safe for all animal species when used as a preservative provided that the optimal ratio of Ca:P is maintained. It is considered to be a source of available phosphorus in the diet. Its contribution to the phosphorus supply of animals must be considered when formulating diets or when it is included in water for drinking (EFSA, 2013).

Human health issues

It must be labelled as corrosive to the skin and eyes and should be considered as equally hazardous to the respiratory tract (respiratory sensitiser). These hazards are reflected in the material safety data and appropriate protective measures are recommended (EFSA, 2013).

Pet Food quality and authenticity

Orthophosphoric acid, used as a preservative, is not expected to negatively impact the sensory properties of foods intended for dogs and cats.

Traditional use and precedents in organic production

None

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

According to U.S. NOP standards (2022), Phosphoric acid can be used in the US only for cleaning dairy equipment. In Mexico it can be used as cleaner or sanitizer, provided that measures are taken to prevent contact with organic animals, products and ingredients.

According to the Australian National Standard for Organic and Bio-Dynamic Produce (2016), orthophosphoric acid can be used as a processing aid for plant products (initial sugar cane processing) and for sanitation treatments followed by a rinse of the area/equipment with potable water.

In the Japanese Agricultural Standard for Organic Feeds (2005), no mention is made of the use of orthophosphoric acid in livestock farming, including feeding.

Other relevant issues

None

Reflections and conclusions

The Group notes that the dossier of orthophosphoric acid focuses mainly on the properties of the additive as a urinary acidifier rather than its role as a preservative. The acidifying properties represent a feature of zootechnical additives rather than preservatives. The dossier highlights, furthermore, a prevalent need for its use in organic pet foods linked to its urine acidifying properties. These properties fall within the domain of nutritional additives, a category to which orthophosphoric acid does not belong.

There is an alternative: Ammonium chloride also has urine acidifying properties, and the Group recommends its authorisation (for pet food intended to be used as special nutritional purposes for cats) in this report.

The Group recognises the documented properties of (ortho-)phosphoric acid as a feed preservative; with the purpose mentioned above (that of a preservative), it is presently authorised in the European Union as a feed additive in all animal species. However, the dossier does not clarify the reasons that make it necessary to authorise phosphoric acid as a preservative for organic pet food. The Group sees no necessity, because several other preservatives are already allowed in the production of organic feed.

Based on these considerations, the Group does not recommend that orthophosphoric acid, at present, should be included in the list of authorised additives for pet food in Part B of Annex III to Regulation (EU) 2021/1165.

Recommendations

The Group does not recommend the authorisation of orthophosphoric acid as a feed additive.

References for the substance

Australian National Standard for Organic and Bio-Dynamic Produce (2016) https://www.awe.gov.au/biosecurity-trade/export/controlled-goods/organic-bio-dynamic/national-standard Accessed on 30 April 2022.

ECHA-European Chemical Agency (2022). Orthophosphoric acid. https://echa.europa.eu/it/substance-information/-/substanceinfo/100.028.758 . Accessed 3 May, 2022.

EFSA (2013). Scientific Opinion on the safety and efficacy of orthophosphoric acid for all animal species. EFSA Journal 2013;11(1):3043. DOI:10.2903/j.efsa.2013.3043

Fettman M.J., Coble J.M., Hamar D.W., Norrdin R.W., Seim H.B., Kealy R.D., Rogers Q.R., McCrea K., Moffat K. (1992) American Journal Veterinary Research, 53: 11, 2125-2135.

Japanese Agricultural Standard for Organic Feeds (2005) https://www.maff.go.jp/e/policies/standard/specific/organic_JAS.html#Organic%20Standards Accessed on 30 April 2022.

OMRI Products List (2022) https://www.omri.org/omri-search?page=1&query=&exactMatch=false&types=category Accessed on 30 April 2022.

Pearlin B.V., Muthuvel S., Govidasami P., Villavan M., Alagawany M., Farag M.R., Dhama K., Gopi M. (2020) Role of acidifiers in livestock nutrition: a review. Journal of Animal Physiology and Animal Nutrition, 104: 558-569. DOI: 10.1111 / jpn.13282

3.9 Taurine

Introduction, scope of this chapter

The following report is based on the request of France for the inclusion of Taurine an in Annex III, part B, of Commission Implementing Regulation (EU) 2021/1165, in the category of Nutritional additives, functional group of "Vitamins, pro-vitamins and chemically well-defined substances having a similar effect" to fulfil the nutritional needs of dogs and cats.

Authorisation in general production

Taurine (CAS No. 107-35-7 / Flavis No. 16.056), ID n. 2b16056, as feed additive is authorised in the EU up to 15

March 2028 by Commission Implementing Regulation (EU) 2018/249 in the category of "Sensory additives", functional group "Flavoring compounds", for all animal species without specifications concerning the age of the animals and the maximum and minimum levels in mg/kg complete feeding stuffs.

Taurine, ID n. 3a370, as a feed additive is authorised in the EU up to 26 May 2025 by Commission Implementing Regulation (EU) 2015/722 as a feed additive for *Canidae*, *Felidae*, *Mustelidae* and carnivorous fish in the category of "Nutritional additives", functional group "Vitamins, provitamins, and chemically well-defined substances having a similar effect", without specifications concerning the age of the animals and the maximum and minimum levels in mg/kg complete feeding stuffs.

Authorisation in organic production

According to Regulation (EU) 2018/848 the Commission may authorise as feed additives trace elements, vitamins, or pro-vitamins of natural origin, except in cases where products or substances from such sources are not available in sufficient quantities or qualities or where alternatives are not available; (Art. 24, letter (e) point (ii)).

Agronomic use, technological or physiological functionality for the intended use

Taurine is a unique beta–amino-sulfonic acid that is not incorporated into large proteins but is found as a free amino acid in tissues or as a constituent of small peptides. Most mammals synthesize it from methionine and cysteine during normal sulphur amino acids (SAA) metabolism. The myocardium and retina contain high concentrations of free taurine, and these two tissues are able to concentrate taurine to levels that are 100-fold to 400-fold greater than those found in plasma. Taurine is conjugated with several compounds and is involved in many aspects of metabolism.
It's most important roles are in bile acid conjugation, retinal function, and normal functioning of the myocardium.
Taurine is also necessary for healthy reproductive performance in dogs and cats (Case et al., 2011).

Necessity for intended use, known alternatives

Cats can synthesize only small amounts of taurine and so require a dietary source of taurine to meet daily needs. This inability is partially the result of the cat's low specific enzymatic activity. The domestic cat uses only taurine for bile-salt formation and, in contrast to other animals, cannot convert to conjugation of bile acids with glycine. When the taurine supply is limited, resulting in a continual requirement for taurine to replace faecal losses occurring from the incomplete recovery of bile salts by the enterohepatic circulation (Case et al., 2011).

Studies have shown that the bioavailability is lower when cats are fed a heat-treated canned food. To maintain adequate taurine status, a heat-processed wet cat food must contain approximately 2 to 2.5 times more taurine than a dry extruded food; the latter should contain 0.1 % DM taurine (FEDIAF, 2021).

The dog also uses only taurine to conjugate bile acids, but provided that the diet contains adequate protein and SAA, dogs can synthesise adequate taurine to meet their metabolic needs. However, in recent years, the high prevalence of dilated cardiomyopathy (DCM) in certain breeds and families of dogs, along with evidence of low plasma and whole-blood taurine levels in some of these dogs, has led researchers to examine taurine status as a potential underlying cause of DCM (Case et al., 2011).

Feeding stuffs of animal origin except milk products are rich in taurine, e.g. fish DM 1 000–9 000 mg/kg; poultry meat DM 1 000–8 000 mg/kg, beef DM 200–2 000 mg/kg; and meat and bone meal 90–1 100 mg/kg (Spitze et al., 2003).

According to the information provided in the dossier, no natural purified Taurine source is available. Heat processing and canned food processing reduce Taurine bioavailability, thus determining the need to supplement pet foods with Taurine. Furthermore, the applicant draws attention to the possible deficiency of Taurine in vegan and vegetarian diets intended for dogs.

Origin of raw materials, methods of manufacture

According to the dossier, Taurine is synthesised starting from ethylene oxide and sodium bisulphite. Subsequently, liquid ammonia and sulphuric acid are added. The product is then decolourised, purified, crystallised, centrifuged, dried, sieved and blended with the carrier to obtain the additive.

Environmental issues, use of resources, recycling

Several species of bacteria and fungi are known to degrade taurine (e.g. to sulphate/sulphide, ammonia, acetate and carbon dioxide). The use of taurine as an additive in animal nutrition is not expected to increase the concentration in the environment substantially. Therefore, a risk to the environment resulting from the use of taurine in animal nutrition is not expected (EFSA, 2012).

Animal welfare issues

Feline central retinal degeneration (FCRD) is the first clinical deficiency syndrome recognized as being caused by taurine deficiency in cats. Although it is not the only underlying cause in cats, a deficiency of taurine results in the development of dilated cardiomyopathy (DCM). A concomitant degeneration of tapetum lucidum may also occur. Taurine is also necessary for normal functioning of the myocardium. Finally, taurine is required for normal reproductive success in queens (entire female cats). The effects of taurine deficiency on reproduction appear to be related to fetal development rather than an effect on the queen's estrous cycle or ability to ovulate (Case et al., 2011).

Unlike the cat, dogs fed diets containing adequate levels of protein and SAA can synthesize enough taurine to meet their needs.

In dogs, diets low in protein, taurine, and sulphur-containing amino acid precursors have been associated with taurine-deficient DCM. Low protein diets designed to manage urate stones were associated with DCM. This may be due to low protein diets being low in essential and nonessential amino acids or vital precursors for carnitine and taurine synthesis. When these diets were supplemented with taurine and l-carnitine, the clinical signs of DCM were reversed. (McCauley et al., 2020).

Human health issues

Taurine is considered a skin and eye irritant and skin sensitiser, and hazardous if inhaled (EFSA, 2012).

Pet Food quality and authenticity

Taurine is not expected to negatively impact the sensory properties of feed intended for dogs and cats.

Traditional use and precedents in organic production

Taurine was allowed in organic pet foods in France according to the French Cahier des Charges on organic pet food, issued by the French Ministere de l'Agriculture, de l'Alimentation, de la Peche et des Affaires Rurales (2004).

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

According to the USDA National List of Allowed and Prohibited Substances (2022), synthetic vitamins for enrichment or fortification when FDA approved may be used as feed additives in livestock production (§ 205.603 Synthetic substances allowed for use in organic livestock production. Point d.3.). However, it should be noted that the USDA regulation does not contain specific rules regarding the substances authorised or prohibited in the formulation of pet foods. In 2013 NOSB (US National Organic Standard Board) recommended that Taurine should be allowed in organic food for dogs and cats.

The Japanese Agricultural Standard for Organic Feeds (2005) allows feed additives (except for those produced by using antibiotic and recombinant DNA technology), substances derived from natural substances without being chemically treated. In case of difficulty in obtaining those feed additives, the use of similar agents to described food additives are permitted only for supplementing nutrition and effective components in feeds.

According to the Australian National Standard for Organic and Bio-Dynamic Produce (2016), feed supplements of non-agricultural origin can include minerals, trace elements, vitamins or pro vitamins. If these are to be sourced from origins other than natural sources, their use must be authorised by the certifying body.

On the basis of international regulations and recommendations, there are no reasons that could preclude the authorisation of the use of synthetic Taurine in food for dogs and cats.

Other relevant issues

None

Reflections and conclusions

Taurine is essential for cats, and its deficiency is related to heart disease in dogs. Technological treatments such as extrusion and canned food production reduce the bioavailability of taurine present in raw materials of animal origin.

The Group is aware that there are currently no known sources of taurine as an alternative to the feed additive presently authorised in the EU that is obtained by chemical synthesis. However, the Group is concerned about allowing chemically synthesized substances in organic farming and processing.

The Group highlights that from the analysis of the principal horizontal organic regulations, in the absence of natural alternatives, the use of vitamins or pro-vitamins, even of a synthetic nature, necessary for the maintenance of animal health and welfare can be authorised. Failure to supplement dog and cat food with exogenous taurine would have a significant negative impact on the organic pet food market.

In conclusion, the Group is inclined to recommend that taurine should be authorised, although it is chemically synthesized. However, its use should be limited to those conditions where it is strictly necessary.

Recommendations

The Group recommends the inclusion of taurine to the list of authorised feed additives in Regulation (EU) 2021/1165, Annex III, part B (3) NUTRITIONAL ADDITIVES as follows:

a) *Vitamins, pro-vitamins and chemically well-defined substances having similar effect*

ID number or functional group	Name	Specific conditions and limits
3a370	Taurine	only for cat and dogs not from GMO origin not from synthetic origin, if possible

References for the substance

Australian National Standard for Organic and Bio-Dynamic Produce (2016) https://www.awe.gov.au/biosecurity-trade/export/controlled-goods/organic-bio-dynamic/national-standard. Accessed on 30 April 2022.

Case L.P., Hayek M. G., Leighann D., Foess Raasch M. (2011) Canine and feline nutrition. 3rd Edition Mosby Elsevier, Maryland Heights, Missouri ISBN: 978-0-323-06619-8

EFSA. Scientific Opinion on the safety and efficacy of Taurine as a feed additive for all animal species. EFSA Journal 2012: 10(6):2736. DOI:10.2903/j.efsa.2012.2736
FEDIAF (2021). Nutritional Guidelines for Complete and Complementary Pet Food for Cats and Dogs. https://drive.google.com/file/d/1aRrX08am_7tuLOb2Nget2mLKnSC8D_7W/view Accessed on 2 May 2022.

Japanese Agricultural Standard for Organic Feeds (2005)
https://www.maff.go.jp/e/policies/standard/specific/organic_JAS.html#Organic%20Standards Accessed on 30 April 2022.

McCauley S.R., Clark S.D., Quest B.W., Streeter R.M., Oxford E.M. (2020) Review of canine dilated cardiomyopathy in the wake of diet-associated concerns. Journal of Animal Science, 98: 6, 1-20. DOI: 10.1093/jas/skaa155

Ministere de l'Agriculture, de l'Alimentation, de la Peche et des Affaires Rurales (2004). Cahier des charges "aliments pour animaux de compagnie" a base de matieres premieres issues du mode de production biologique.

OMRI Products List (2022) https://www.omri.org/omri-search?page=1&query=&exactMatch=false&types=category Accessed on 30 April 2022.

NOSB (2013). April 2013 NOSB Recommendation.
https://www.ams.usda.gov/rules-regulations/organic/petitioned-substances/amino-acids-pet-food Accessed on 14 May 2022.

Spitze AR, Wong DL, Rogers QR and Fascetti AJ, 2003. Taurine concentrations in animal feed ingredients; cooking influences taurine content. Journal of Animal Physiology and Animal Nutrition, 87, 251–262. DOI: 10.1046/j.1439-0396.2003.00434.x

Slamova R., Trckova, M., Vondruskova H., Zraly Z., Pavlik I. (2011) Clay minerals in animal nutrition. Applied Clay Science, 51: 395-398. DOI: 10.1016/j.clay.2011.01.005

3.10 Methionine

Introduction, scope of this chapter

The following report is based on the request of The Netherlands for the inclusion of DL-Methionine in Annex III, part B, of Commission Implementing Regulation (EU) 2021/1165, in the category of Nutritional additives, functional group of "Amino acids, their salts and analogues" to fulfil nutritional needs of dogs and cats and reduce urinary pH in cats.

Authorisation in general production

DL-methionine technically pure (3c301), Sodium DL-methionine liquid (3c302), Hydroxy analogue of methionine (3c307), Calcium salt of hydroxy analogue of methionine (3c3108) as feed additives are authorised in the EU up to 12 June 2023 by Commission Implementing Regulation (EU) N. 469/1013, category "Nutritional additives", the functional group "Amino acids, their salts and analogues" for all animal species without specifications concerning the age of the animals and the maximum and minimum levels in mg/kg complete feeding stuffs.

Agronomic use, technological or physiological functionality for the intended use

Proteins that are highly digestible and contain all the essential amino acids in their proper proportions relative to the animal's needs are considered high-quality proteins. The following 10 amino acids have been identified as being essential for growing puppies and kittens: arginine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, and valine. The degree to which a dog or cat can use dietary protein as a source of amino acids and nitrogen is affected by the digestibility and the quality of the protein included in the diet. The essential amino acid in greatest deficit in a certain protein source is called the limiting amino acid because it will limit the body's ability to use it. The three amino acids that are most often limiting for dogs and cats are methionine, tryptophan, and lysine. Methionine is usually the first limiting amino acid in most commercial pet foods containing animal tissues and plant protein sources (Case et al., 2011).

For dietary purposes, the sulphur amino acids (SAA) methionine and cysteine are grouped since methionine is used by the body to synthesize cysteine and approximately half of the methionine requirement can be met with dietary cysteine. On the other hand, cysteine, a dispensable amino acid, may become indispensable if there is not enough methionine to provide for the total sulphur (methionine + cysteine) requirement. Cats have a higher need for SAA (methionine and cysteine) when compared with most other mammals for felinine (a urinary feline pheromone) production maintenance of a thick hair coat, high methylation reactions, and taurine synthesis.
Inorganic sulphate and taurine are major end products of sulphur-containing amino acid metabolism in mammals (Nakamura et al., 2002).

According to EFSA (2012), DL-Met and its sodium salt and hydroxy analogue of methionine and its calcium salt are effective dietary sources of methionine for protein synthesis in monogastric animals (including fish). The hydroxy analogues show a somewhat lower bio-efficacy than the DL-Met forms.

Necessity for intended use, known alternatives

Animal tissues typically contain high biological value proteins; often, all 10 essential amino acids AAs are provided in sufficient quantities with high digestibility. In contrast, the biological value of plant proteins for pet foods has been questioned because their AA profiles may be incomplete, particularly with methionine or lysine limiting amino acids (Dodd et al., 2018). To reduce the risk of such deficiencies, synthetic amino acids are added to conventional plant-based pet foods but not organic ones. Furthermore, dietary supplementation with methionine, which causes a lowering of urinary pH, is an effective tool for preventing and managing some forms of urolithiasis especially in cats (Funaba et al., 2001).

Origin of raw materials, methods of manufacture

The products are manufactured by chemical synthesis starting from methyl-thio-propionic aldehyde (MTPA) and hydrogen cyanide (HCN) in the presence of a catalyst purified MTPA and HCN are obtained by chemical synthesis using raw materials of petrochemical origin.

Environmental issues, use of resources, recycling

Methionine is a physiological and natural component in animals and plants. Like its salts and the hydroxy analogue, it is not excreted as such (but as urea/uric acid, sulphate and CO2). The use of methionine, its analogue and its salts in animal nutrition would not lead to any localised increase in the concentration in the environment. It is concluded that the use of these products as feed additives does not represent a risk to the environment (EFSA, 2012).

Animal welfare issues

Methionine is an essential amino acid both for dogs and cats and, consequently, its deficiency can cause a wide range of symptoms. Puppies fed a methionine deficient diet experience decreased food intake, weight loss and evidence of dermatitis (Milner, 1979). Inadequate intake of sulphur amino acids without supplemental taurine has also been associated with the development of taurine deficient cardiomyopathy (Torres et al., 2003; Backus et al., 2006), and pigmented gallstones (Christian and Rege, 1996) in adult dogs. Feeding a methionine deficient diet to kittens resulted in weight loss, lethargy, abnormal ocular secretions severe perioral and foot pad lesions (Teeter et al., 1978; Rogers and Morris, 1979; NRC, 2006).

Human health issues

None of the products are considered to present a significant inhalation risk. DL-Methionine is considered non-irritant to skin and eyes and has no sensitisation potential. DL-Methionine sodium salt is considered to be corrosive to skin and eyes. The hydroxy analogue of methionine (HMTBa) irritates the skin and is corrosive to the eyes. The calcium salt of HMTBa, HMTBa-Ca, is irritant to the eyes. The absence of dermal sensitisation potential demonstrated for HMTBa is considered relevant for HMTBa-Ca (EFSA, 2012).

Pet Food quality and authenticity

DL-methionine technically pure, Sodium DL-methionine liquid, Hydroxy analogue of methionine, Calcium salt of hydroxy analogue of methionine are not expected to negatively impact the sensory properties of foods intended for dogs and cats.

Traditional use and precedents in organic production

According to Regulation (EU) 2018/848, synthetic amino acids shall not be used in organic animal feeding (Annex II, part II, 1.4.1 f).

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

The examination of the international organic legislation shows a generalized attitude of discouragement or prohibition towards the supplementation of feed with synthetic amino acids. Regarding the various forms of synthetic methionine as feed additives, their use is restrictively permitted in some countries only in poultry species at well-defined levels.

According to U.S. NOP standards (2022) includes the following forms only: DL-methionine, DL-methionine-hydroxy analog and DL-methionine-hydroxy analog calcium. Does not include D-methionine or L-methionine. For use only in organic poultry production at the following pounds of synthetic 100 percent methionine per ton of feed in the diet, maximum rates as averaged per ton of feed over the life of the flock: Laying chickens-2 pounds; broiler chickens-2.5 pounds; turkeys and all other poultry- 3 pounds (NOP Reference 205.603(d)(1). With respect to Mexico LPO standards the use of synthetic methionine is limited to the maximum levels per ton of feed: laying hens and broiler chickens shall have no more than 2 pounds per ton of feed; turkeys and all other poultry shall have no more than 3 pounds per ton of feed (LPO Guidelines Article 81).

In 2013 NOSB (US National Organic Standard Board) concluded that in organic pet food production the manufacturers could meet the required levels of Arginine, DL-Methionine, Cysteine, L-Lysine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, and Valine with organic agricultural ingredients.

Canada COR standard states that when biological sources of methionine are not commercially available for use in monogastrics feeding, as an exception to 5.1.2 (32.311) and 1.4 a) of CAN/CGSB-32.310, all sources of methionine may be used.

According to the Australian National Standard for Organic and Bio-Dynamic Produce (2016) amino acids isolates, with the exception of methionine for poultry, are prohibited in livestock feeding

The Japanese Agricultural Standard for Organic Feeds (2005) does not specifically mention amino acids in livestock feeding. It is allowed only to use feed additives (except for those produced by antibiotic and recombinant DNA technology), which are natural substances, or those derived from natural substances without being chemically treated. In case of difficulty in obtaining those feed additives, similar agents to described food additives are permitted only for supplementing nutrition and effective components in feeds.

Other relevant issues

None

Reflections and conclusions

The Group states that the organic EU regulation does not allow the use of synthetic amino acids in feed. However, the Group identified a certain gap in the new organic regulation, EU 2018/848, where feed for pets now is part of the general requirements for all organic feed production. This gap depends on the fact that the prohibition for synthetic amino acids is mentioned in Annex II, part II: Livestock production rules and Part III: Production rules for algae and aquaculture animals but not in Part V: Processed feed production rules. This leaves pet food production without a clear statement. The Group recommends to close this gap (see chapter below).

The Group also noted an inconsistency in the dossier. In the first part, *Requested inclusion, name of the additive/substance* DL-methionine is mentioned but the remaining part of the dossier also refers to DL-methionine sodium salt, its analogues and the salts of its analogues which, in the EU Register of Feed Additives, have identification codes other than DL-methionine.

Methionine may become deficient in pet foods containing high levels of ingredients of vegetable origin. The Group recognises the importance of methionine as essential amino acid and its properties as a urine acidifier in dogs and cats. Animal-derived foods and some seeds contain high levels of methionine, so well-balanced pet foods should contain sufficient amounts of the native amino acid.

However, in light of the provisions of Regulation (EU) 2018/848, being the additives DL-methionine (as well as the other above mentioned) amino acids of synthetic origin, whose supplementation may become advisable only in particular formulations (high vegetable /vegan diets; feed intended for particular nutritional purposes), it cannot be recommended.

Recommendations

The Group does not recommend the authorisation of DL-methionine (as well as DL-methionine sodium salt, its analogues and the salts of its analogues) as a feed additive.

References for the substance

Backus R.C., Ko K. S., Fascetti A. J., Kittleson M. D., MacDonald K. A., Maggs D. J., Berg J. R., Rogers Q. R. (2006) Low Plasma Taurine Concentration in Newfoundland Dogs is Associated with Low Plasma Methionine and Cyst(e)ine Concentrations and Low Taurine Synthesis. J Nutr 136:2525-2533. DOI: 10.1093/jn/136.10.2525

Case L.P., Hayek M. G., Leighann D., Foess Raasch M. (2011) Canine and feline nutrition. 3rd Edition Mosby Elsevier, Maryland Heights, Missouri ISBN: 978-0-323-06619-8

Christian JS and Rege RV. (1996) Methionine, but not taurine, protects against formation of canine pigmented gallstones. J Surg Res 61:275-281. DOI: 10.1006/jsre.1996.0116

Dodd A.S., Adolphe J. L., Verbrugge A. (2018) Plant-based diets for dogs. JAMA 253: 11, pp 1425 – 1432. DOI: 10.2460/javma.253.11.1425

EFSA (2012) Scientific Opinion on DL-methionine, DL-methionine sodium salt, the hydroxy analogue of methionine and the calcium salt of methionine hydroxy analogue in all animal species; on the isopropyl ester of methionine hydroxy analogue and DL-methionine technically pure protected with copolymer vinylpyridine/styrene in dairy cows; and on DLmethionine technically pure protected with ethylcellulose in ruminants. EFSA Journal 10(3):2623.

Funaba, M., T. Yamate, Y. Narukawa, K. Gotoh, T. Iriki T., Hatano Y., Abe M. 2001. Effect of supplementation of dry cat food with D, L-methionine and ammonium chloride on struvite activity product and sediment in urine. The Journal of Veterinary Medical Science, 63, 337–339. DOI: 10.1292/jvms.63.337

Milner J.A. Assessment of indispensable and dispensable amino acids for the immature dog. J Nutr 109:1161-1167. DOI: 10.1093/jn/109.7.1161

Nakamura H., Kajikawa R., and Ubuka T. (2002) A study on the estimation of sulfur-containing amino acid metabolism by the determination of urinary sulfate and taurine. Amino Acids 23: 427–431 DOI: 10.1007/s00726-002-0208-9

NOSB (2013). April 2013 NOSB Recommendation.
https://www.ams.usda.gov/rules-regulations/organic/petitioned-substances/amino-acids-pet-food Accessed on 14 May 2022.

NRC (2006). Nutrient Requirements of dogs and cats. National Academy Press, Washington. ISBN 0-39-08628-0.

Rogers Q. R. and Morris J.G. (1979) Essentiality of amino acids for the growing kitten. J Nutr 109:718-723. DOI: 10.1093/jn/109.4.718

Teeter R.G., Baker D. H., Corbin J. E. (1978) Essentiality of methionine in the cat. J Anim Sci 46:1287-1292. DOI: https://doi.org/10.2527/jas1978.4651287x

Torres CL, Backus R.C., Fascetti A.J., Rogers Q.R. (2003) Taurine status in normal dogs fed a commercial diet associated with taurine deficiency and dilated cardiomyopathy. J Anim Physiol Anim Nutr 87:359-72. DOI: 10.1046/j.1439-0396.2003.00446.x

3.11 Disodium dihydrogen diphosphate (SAPP)

Introduction, scope of this chapter

Disodium dihydrogen diphosphate (SAPP) is assessed following a request for authorisation for use in organic pet food production. The request refers to listing the feed material in the Annex III, part A, (1) Feed materials of mineral origin, to Regulation (EU) 2021/1165.

Synonyms of disodium dihydrogen diphosphate are disodium diphosphate, disodium dihydrogen pyrophosphate, sodium acid pyrophosphate (SAPP) and disodium pyrophosphate.

The dossier was submitted by The Netherlands.

Authorisation in general production

Disodium dihydrogen diphosphate is a feed material within the European Union, currently listed within the "Catalogue of feed materials" (position "11.3.27" within the section titled "11. *Minerals and products derived thereof*") with the description "Disodium dihydrogen diphosphate ($Na_2H_2P_2O_7$)".

It is also a food additive (E 450 (i)) authorised within the European Union. The specification for that additive is laid down within the Annex to the Regulation (EU) No 231/2012.

Authorisation in organic production

Disodium dihydrogen diphosphate is not currently authorised either in organic food or in organic feed within the European Union.

Agronomic use, technological or physiological functionality for the intended use

Pyrophosphates have been used for decades in pet food (especially cat food) in order to improve palatability and ensure the consumption of complete and nutritionally balanced food. Disodium dihydrogen diphosphate is an essential pyrophosphate to enhance the palatability of pet food.

Using disodium dihydrogen diphosphate in pet food is popular by increasing the palatability and appeal of pet food. Therefore disodium dihydrogen diphosphate contributes to properly feed the pet when it is part of a complete and nutritionally balanced pet food. Formulating complete pet food and reaching satisfactory organoleptic profile can be challenging. Disodium dihydrogen diphosphate is an asset in the formulation.

The absence of disodium dihydrogen diphosphate from the list of feed materials of mineral origin approved in organic feed induces a competitive disadvantage for organic pet food, preventing the development of such products in contradiction with the goals of the organic production policy brought into play with Regulation (EU) 2018/848.

Last but not least, disodium dihydrogen diphosphate contributes to the calcium / phosphorus ratio necessary for a proper, nutritionally balanced, complete pet food.

Necessity for intended use, known alternatives

Please refer to the above "Agronomic use, technological or physiological functionality for the intended use" section.

Origin of raw materials, methods of manufacture

According to the dossier submitted for the assessment, disodium dihydrogen diphosphate is manufactured by partial neutralization of phosphoric acid (H_3PO_4) with sodium hydroxide (NaOH) or sodium carbonate (Na_2CO_3) to form monosodium phosphate (NaH_2PO_4) which is then dehydrated at approximately 250° C to form disodium dihydrogen diphosphate ($Na_2H_2P_2O_7$).

According to the data available within the scientific opinion from the EFSA (2019), calcium and magnesium phosphates are produced commercially from phosphoric acid with calcium oxide or calcium hydroxide respectively magnesium oxide or magnesium hydroxide. Both mono- and disodium phosphates are prepared commercially by neutralisation of phosphoric acid using sodium carbonate or sodium hydroxide. The three sodium diphosphates are produced commercially by the neutralisation of phosphoric acid with sodium hydroxide, mixed in the required proportions for the specific product (1:1 sodium hydroxide:phosphoric acid for disodium dihydrogen diphosphate), whilst phosphoric acid is produced commercially from phosphate rock.

Environmental issues, use of resources, recycling

No concern considering the amount used in pet food and also the production methods including the related monitoring system.

Animal welfare issues

No animal welfare issue is expected:

- there is a long history of safe use (for decades) in pet food production when disodium dihydrogen diphosphate is used as per necessary (*Quantum satis*, with the lower inclusion level to achieve the targeted palatability effect whilst respecting the proper calcium / phosphorus ratio),
- no animal health concern is expected (EFSA, 2019) where the following main relevant conclusions for animals may be found;
    - the acute oral toxicity of all evaluated phosphates is very low with LD_{50} values generally exceeding 2,000 mg/kg body weight;
    - for the short-term and sub-chronic toxicity, bone demineralisation, the release of calcium, calcification of the kidney and tubular nephropathy may be observed with high phosphate loads (a NOAEL for kidney effects corresponding to 116 mg phosphorus /kg body weight per day is reported),
    - phosphate is not genotoxic;
    - phosphates do not have any carcinogenic potential,

- exposure to phosphates do not present any risk for reproductive or developmental toxicity.

It is reminded within the above quoted scientific opinion that phosphate is essential for all living organisms: in particular,

- the intracellular activity of phosphate ions participates in acid base balance,
- phosphate is intrinsically involved with regulation of metabolic processes via phosphorylation of proteins and supplying energy by means of nucleotides triphosphates (e.g. ATP, GTP, CTP and UTP) which serve as energy depots supporting protein and polysaccharide synthesis, ion pumps, cell signalling, muscle contractility,
- phosphate is also a component of second messengers such as cyclic adenosine monophosphate (cAMP), inositol polyphosphates (IP3) and cyclic guanine monophosphate (cGMP),
- phosphate is fundamental for the structure and function of DNA and ribonucleic acid (RNA),
- phospholipids are part of cell membrane structure where they affect the membrane fluidity and function.

Human health issues

Disodium dihydrogen diphosphate is a food additive (E 450 (i)) authorised within the European Union.

There is no human health concern when disodium dihydrogen diphosphate is used in pet food. Due to its powder form, sodium dihydrogen diphosphate has to be appropriately handled at the factory level.

Food quality and authenticity

Disodium dihydrogen diphosphate used in pet food is generally the food additive (E 450 (i)). Therefore it complies with the specification laid down within the Annex to the Regulation (EU) No 231/2012.

The use of disodium dihydrogen diphosphate offers adequate palatability of products to promote a sufficient food intake to fulfil pets' nutritional needs. The FEDIAF's "Nutritional Guidelines for Complete and Complementary Pet Food for Cats and Dogs" provides for recommended calcium / phosphorus ratios.

Traditional use and precedents in organic production

Disodium dihydrogen diphosphate is used in "standard" pet food for decades.

Other phosphates are already authorised in organic feed within the European Union: dicalcium phosphate, monocalcium phosphate, calcium-magnesium phosphate, magnesium phosphate, monosodium phosphate, calcium sodium phosphate, monoammonium phosphate (listed within the Annex III, Part A, to Regulation (EU) 2021/1165).

Additionally monocalcium phosphate is authorised as a raising agent in organic food (self-raising flour), listed within the Annex V to Regulation (EU) 2021/1165.

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

Disodium dihydrogen diphosphate is authorised in organic food in Canada (National Standard of Canada, 2020) for use as a leavening agent and in dairy products. There is no specific national rules for organic pet food in Canada nor in the USA.

Other relevant issues

None.

Reflections and conclusions

The manufacturing process to obtain disodium dihydrogen diphosphate is certainly a chemical synthesis (although a quite "simple" acid-based chemical reaction) and may consequently be perceived far from the principle of organic production aiming at promoting the use of materials of natural origin. However, the authorisation of a feed material

of mineral origin which is not derived from a natural source may be granted when it is not available in sufficient quantities or qualities or where alternatives are not available in accordance with the provisions laid down in article 24, paragraph 3(e)(ii). As an example there are already other phosphates, such as monosodium phosphate, authorised in organic feed although they may be produced by chemical reaction (generally by neutralization of orthophosphoric acid by sodium hydroxide). Furthermore, dicalcium phosphate, derived from bones or inorganic sources, is also already authorised in organic feed although the production process described in Annex X, chapter II, section 6, to Regulation (EU) No 142/2011, includes hydrochloric acid and lime use.

The Group highlights that, although other phosphates are already authorised in organic feed, disodium dihydrogen diphosphate has a unique palatability effect, especially for cats.

Disodium dihydrogen diphosphate is necessary for consistent palatability in pet food and proper pet feeding. Refusal would compromise the development of organic pet food in contradiction with the goals of the organic production policy brought into play with Regulation (EU) 2018/848.

Recommendations

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

Number in feed catalogue	Name	Specific conditions and limits
11.3.27	Disodium dihydrogen diphosphate	only for pet food

References for the substance

Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Consolidated 20220417).

EFSA. 2019. Re-evaluation of phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452) as food additives and the safety of proposed extension of use", (EFSA Journal 2019;17(6):5674). https://doi.org/10.2903/j.efsa.2019.5674 .

National Standard of Canada. 2020. "Organic production systems: permitted substances lists." (CAN/CGSB-32.311-2020, Corrigendum No. 1, March 2021).

3.12 Pentasodium triphosphate (STPP)

Introduction, scope of this chapter

Pentasodium triphosphate (STPP) is assessed following a request for authorisation in organic pet food production. The request refers to listing the feed material in the Annex III, part A, (1) Feed materials of mineral origin, to Regulation (EU) 2021/1165.

Synonyms of pentasodium triphosphate are; sodium tripolyphosphate (STPP), sodium triphosphate (STP) and pentasodium tripolyphosphate.

Although the name "Triphosphate" is provided for within the specification from the JECFA Monograph (FAO, 2006), such a short name does not seem appropriate in order to avoid any possible confusion with "Pentapotassium triphosphate" which also exists (a similar comment is valid for the short name "Tripolyphosphate" abbreviated to TPP).

Other names provided for within the submitted dossier are not reported here because they are not very relevant compared with the names generally included within the European regulations, in particular Regulation (EU) No 231/2012 and Regulation (EU) No 68/2013.

The dossier was submitted by The Netherlands.

Authorisation in general production

Pentasodium triphosphate is a feed material within the European Union, currently listed within the "Catalogue of feed materials"(position "11.3.19" within the section titled "11. *Minerals and products derived thereof*") with the description "Sodium tripolyphosphate ($Na_5P_3O_{10} \times n\ H_2O$; n = 0 or 6)".

It is also a food additive (E 451 (i)) authorised within the EU. The specification for that additive is laid down within the Annex to the Regulation (EU) No 231/2012.

Pentasodium triphosphate may beanhydrous or hexahydrate. Both forms are considered equivalent for that assessment.

Authorisation in organic production

Pentasodium triphosphate is not currently authorised either in organic food or in organic feed within the EU.

However pentasodium triphosphate was authorised in organic pet food for dogs and cats under Dutch National Legislation (Regeling Diervoeders 2012; art. 5) as part of the category of “minerals” (in a specific addition under Dutch legislation, supplementing Annex VIII Part A of Commission Regulation (EC) No 889/2008).

Agronomic use, technological or physiological functionality for the intended use

The following data are provided within the submitted dossier:

- when used in food or feed production, polyphosphates increase the amount of bound water, increase the strength of the meat particles binding in processed meat products (stability) and have a buffering capacity;
- for "wet" ("canned") pet food (i.e. pâtés and chunks in gravy or in sauce) for cats and dogs, triphosphates are the most efficient; pentasodium triphosphate separates myosin and actin, which increased the reactive surface and increases the functionality;
- pentasodium triphosphate is widely used in "wet" pet food ("general production") to produce acceptable cat and dog food.
- pentasodium triphosphate has a unique water-binding capacity that makes it highly suitable to produce stable "wet" cat and dog food in the form of "patée" and chunks in gravy or sauce; water separation is undesirable in such products because it can lead to the loss of vital (water-soluble) nutrients that are essential for nutritionally complete pet foods.

Last but not least, pentasodium triphosphate contributes to the calcium / phosphorus ratio necessary for a proper, nutritionally balanced, complete pet food.

Necessity for intended use, known alternatives

Pentasodium triphosphate is widely used in "wet" pet food ("general production") to produce acceptable cat and dog food, especially thanks to its unique water-binding capacity that makes it highly suitable to produce stable "wet" cat and dog food in the form of "patée" and chunks in gravy or sauce. Its contribution to the texture of pet food products is essential since such products are made from "by-products" which are both nutritious and palatable to pets but may be insufficiently texturizing to lead to a product "appetizing" for the pet owner (anthropomorphism), especially as the high cooking-level treatment in accordance with the European pet food safety regulations may produce an adverse effect. Therefore pentasodium triphosphate is a necessary contributing material to achieve the appropriate texture.

According to the justifications developed within the submitted dossier,

- no alternative substance with the same capabilities has been found yet to replace pentasodium triphosphate,
- the few possible options available for human food (such as specific amino acids, polysaccharide mixes, fibres or minerals like sodium salts) are currently not allowed to be used in organic feed production,

- anyway preventing water dissociation by other means than using pentasodium triphosphate would require long and uncertain development, considerable investments to modify production lines and alter the production processes, just to compensate only one of the pentasodium triphosphate's functions,
- impossibility to use pentasodium triphosphate in organic pet food although it is authorised for "general production"
    - would drastically reduce the possibility to produce an acceptable organic wet pet food,
    - would be a high additional hurdle which would reduce again the ability of organic pet food manufacturers to compete with other manufacturers and would consequently compromise the development of organic pet food in contradiction with the goals of the organic production policy brought into play with Regulation (EU) 2018/848.

Origin of raw materials, methods of manufacture

The dossier submitted for the assessment is referring to the manufacturing processes described within the scientific opinion of EFSA (2019), as regards the origin and production method of pentasodium triphosphate, with an "in short" outline (however with a possible confusion between polyphosphates and triphosphates on the end of the explanations).

According to the data available within the above named EFSA opinion;

- calcium and magnesium phosphates are produced commercially from phosphoric acid and either calcium oxide or calcium hydroxide, and either magnesium oxide or magnesium hydroxide, respectively,
- both mono- and disodium phosphates are prepared commercially by neutralisation of phosphoric acid using sodium carbonate or sodium hydroxide,
- pentasodium triphosphate and pentapotassium triphosphate are produced commercially by the neutralisation of phosphoric acid with sodium or potassium hydroxide, respectively, whilst phosphoric acid is produced commercially from phosphate rock.

Environmental issues, use of resources, recycling

No concern considering the amount used in pet food and also the production methods including the related monitoring system.

Animal welfare issues

No animal welfare issue is expected:

- there is a long history of safe use (for decades) in pet food production when pentasodium triphosphate is used as per necessary (*Quantum satis*, with the lower possible inclusion level to achieve the targeted effect whilst respecting the proper calcium / phosphorus ratio),
- no animal health concern is expected according to EFSA (2019), where the following main relevant conclusions for animals may be found;
    - the acute oral toxicity of all evaluated phosphates is very low with LD50 values generally exceeding 2,000 mg/kg body weight;
    - for the short-term and sub-chronic toxicity, bone demineralisation, the release of calcium, calcification of the kidney and tubular nephropathy may be observed with high phosphate loads (a NOAEL for kidney effects corresponding to 116 mg phosphorus /kg body weight per day is reported),
    - phosphate is not genotoxic;
    - phosphates do not have any carcinogenic potential,
    - exposure to phosphates do not present any risk for reproductive or developmental toxicity.

It is reminded within the above quoted EFSA opinion that phosphate is essential for all living organisms: in particular,

- the intracellular activity of phosphate ions participates in acid base balance,
- phosphate is intrinsically involved with regulation of metabolic processes via phosphorylation of proteins and supplying energy by means of nucleotides triphosphates (e.g. ATP, GTP, CTP and UTP) which serve as energy depots supporting protein and polysaccharide synthesis, ion pumps, cell signalling, muscle contractility,
- phosphate is also component of second messengers such as cyclic adenosine monophosphate (cAMP), inositol polyphosphates (IP3) and cyclic guanine monophosphate (cGMP),

- phosphate is fundamental for the structure and function of DNA and ribonucleic acid (RNA),
- phospholipids are part of cell membrane structure where they affect the membrane fluidity and function.

Human health issues

Pentasodium triphosphate is a food additive (E 451 (i)) authorised within the European Union. There is no human health concern when pentasodium triphosphate is used in pet food.

When it comes as a powder, pentasodium triphosphate has to be appropriately handled at the factory level.

Food quality and authenticity

Pentasodium triphosphate used in pet food is generally the food additive (E 451 (i)). Therefore it complies with the specification laid down within the Annex to the Regulation (EU) No 231/2012.

There is a long history of safe use (for decades) in pet food production. According to the explanations put forward within the dossier, pentasodium triphosphate is used for the beneficial effects on the pet food quality by helping pH stabilization, oxidation reduction and water dissociation prevention, mainly in wet pet food whilst water dissociation can lead to the loss of vital (water-soluble) nutrients that are essential in nutritionally complete pet food.

Pentasodium triphosphate also contributes to the calcium / phosphorus ratio necessary for a proper, nutritionally balanced, complete pet food.

Traditional use and precedents in organic production

Pentasodium triphosphate is used in "standard" pet food for decades.

Other phosphates are already authorised in organic feed within the EU: dicalcium phosphate, monocalcium phosphate, calcium-magnesium phosphate, magnesium phosphate, monosodium phosphate, calcium sodium phosphate, monoammonium phosphate (listed within the Annex III, Part A, to Regulation (EU) 2021/1165).

Additionally monocalcium phosphate is authorised as a "raising agent" in organic food (self-raising flour), listed within the Annex V to Regulation (EU) 2021/1165.

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

Pentasodium triphosphate is authorised in organic food in Canada (National Standard of Canada, 2020) for use in dairy products. There is no specific national rules for organic pet food in Canada nor in the USA.

Other relevant issues

None.

Reflections and conclusions

The manufacturing process to obtain pentasodium triphosphate is certainly a chemical synthesis (although a quite "simple" acid-based chemical reaction) and may consequently be perceived far from the principle of organic production aiming at promoting the use of materials of natural origin. However, the authorisation of a feed material of mineral origin which is not derived from a natural source may be granted when it is not available in sufficient quantities or qualities or where alternatives are not available in accordance with the provisions laid down in article 24, paragraph 3(e)(ii). As an example, there are already other phosphates, such as monosodium phosphate, authorised in organic feed although they may be produced by chemical reaction (generally by neutralization of orthophosphoric acid by sodium hydroxide), Furthermore, dicalcium phosphate derived from bones or inorganic sources is also already authorised in organic feed although the production process described in Annex X, chapter II, section 6, to Regulation (EU) No 142/2011, includes hydrochloric acid and lime use.

The dossier requests the authorisation of pentasodium triphosphate only for cat and dog food. However, the Group considers that it should be authorised for any pet food, especially for other pet mammals and ornamental birds, for the sake of consistency with the authorisation of other phosphates.

Pentasodium triphosphate is necessary because of its particular beneficial effect on pet food texture, refusal would compromise the development of organic pet food in contradiction with the goals of the organic production policy brought into play with Regulation (EU) 2018/848.

Recommendations

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

Number in feed catalogue	Name	Specific conditions and limits
11.3.19	Sodium tripolyphosphate; [Penta sodium triphosphate]	only for pet food

References for the substance

Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Consolidated 20220417).

ECHA, (European Chemical Agency). Dossier relating to pentasodium triphosphate.

EFSA. 2019. Re-evaluation of phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452) as food additives and the safety of proposed extension of use", (EFSA Journal 2019;17(6):5674). https://doi.org/10.2903/j.efsa.2019.5674 .

FAO. 2006. Monograph for Pentasodium Triphosphate. Joint FAO/WHO Expert Committee on Food Additives, (JECFA).

National Standard of Canada. 2020. "Organic production systems: permitted substances lists." (CAN/CGSB-32.311-2020, Corrigendum No. 1, March 2021).

REGULATORY GAP- SYNTHETIC AMINO ACIDS IN FEED PROCESSING

In the Group´s understanding, synthetic amino acids are not allowed in organic production according the EU regulations for organic production. This applies regardless if the feed is for livestock consumption or organic labelled pet food. However, since food for pets now is part of the general requirements for all organic feed production a gap in the basic act of organic production (EU) 2018/848 has been identified. This depends on the fact that the prohibition for synthetic amino acids is only mentioned in Annex II, part II: Livestock production rules and Part III: Production rules for algae and aquaculture animals but not in Part V: Processed feed production rules. To mention it only in the feeding sections was sufficient until 2021, when the feed processed was only intended for livestock and aquaculture animals. But since 2022, when feed processing also comprehends pet food, not mentioning the prohibition in Part V results in leaving pet food production without a clear statement.

The Group recommends that this gap is closed.

Recommendations

In part V, point 2, of Annex II of regulation (EU) 2018/848, the following should be added: Synthetic amino-acids shall not be used in the production of processed feed.

5. MINORITY OPINIONS

None

6. LIST OF ABBREVIATIONS / GLOSSARY

7. 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).