Directorate-General for Agriculture
and Rural Development

Expert Group for Technical Advice on Organic Production

EGTOP

FINAL REPORT

on

Feed VIII and Food IX subgroup

The EGTOP adopted this technical advice at the plenary meeting
of 6-7 March 2024

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

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

EGTOP

The Group's tasks are:

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

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

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

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

ACKNOWLEDGMENTS

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

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EXECUTIVE SUMMARY

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

With respect to feed, the Group recommends the following:

- Lignocellulose should not be included in Annex III sec. A.
- Lecithin should be included in Annex III, part B, to all animal species with the following conditions/limits: only from organic raw materials without solvent extraction unless authorized by organic production and without bleaching step with hydrogen peroxide.
- Ethanol should be included as a processing aid (solvent) in Annex III, part B with the following conditions/limits: only upon demonstration that the availability of protein meals from mechanical extraction is insufficient to fulfil organic animals' nutritional needs; ethanol produced solely by fermentation, the biomass derives from organically produced raw materials; no GMOs are involved at any stage of the production process of the ethanol; and no chemical or physical or chemical-physical process that does not comply with the Reg. 2028/848, including the pretreatment of biomasses and ethanol purification and drying processes. The demand of organic ethanol should be checked for ethanol as a processing aid for food annex V section A2 to keep consistency.
- Single cell proteins from *Trichoderma viride*, Product from *Bacillus subtilis* rich in protein, Single cell proteins from *Aspergillus oryzae*, should be included as a protein sources to all animal species with the following conditions/limits: only from non-GM strain and culture media, Only if produced with natural sources of nitrogen. Only if obtained with organic or without antifoaming agents. If antifoaming agents are used, these must be only from organic production.

With respect to food, the Group recommends the following:

- Buffered vinegar (E267) should be included in Annex V, Part A, Section A1 with the specific conditions: only in the manufacturing process of organic processed food, only if obtained from organic vinegar with addition of Sodium carbonates (E500) or Potassium carbonates (E501) as food additive mentioned in the Regulation 2021/1165, Annex VA, Section A1.

1. BACKGROUND

Several Member States have submitted dossiers under Article 16(3) of Regulation (EU) 2018/848 concerning the possible amendment of Annex IIIA, Annex IIIB, Annex VA to Commission Implementing Regulation (EU) 1165/20213 and in general, on their compliance with the above mentioned legislation.

With regard to feed, Austria requested the authorisation of lignocellulose as feed material, France requested the authorisation of lecithin as feed additive for all animal species, ethanol as processing aid and protein from micro-organisms as feed material.

With regard to food, The Netherlands requested the authorisation of Buffered vinegar (E267).

Therefore, the Group is requested to prepare a report with technical advice on the matters included in the terms of reference.

2. TERMS OF REFERENCE

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

3. CONSIDERATIONS, CONCLUSIONS AND RECOMMENDATIONS

3.1 Feed

The livestock sector faces many challenges in terms of safety and security, climate change and environmental emissions, and public opinion on animal welfare and sustainability. In addition, fluctuations in the international market economy due to recent conflicts in Ukraine and the Middle East are driving the entire production chain towards a necessary increase in sustainability and circularity.
To create the conditions for sustainable farming systems, it is essential to develop science-based management strategies that reduce current dependence on non-renewable resources and secure production in an increasingly unpredictable climate. Such solutions focus on sustainable land use and linking crop and livestock systems as part of a circular and sustainable bio-economy at multiple scales.

3.1.1 Lignocellulose

Introduction, scope of this chapter

The assessment of Lignocellulose (wood fibre) is related to the request for inclusion as feed material in Reg. (EU) 2021/1165, Annex III ("Authorised products and substances for use as feed or in feed production" sec. A "other feed materials"). The substance is to be used as feed material in all animal species - also pets - as an alternative dietary/crude/raw fibre source. The dossier was submitted by Austria.

Authorization in general production

Lignocellulose is listed as a feed material (7.8.1) under Part C (List of feed materials), section 7 (Other plants, algae, fungi and products derived thereof) and described as a "product obtained by means of mechanical processing of raw natural dried wood and which predominantly consists of lignocellulose" in Commission Reg. (EU) 2017/1017 of 15 June 2017 amending Reg. (EU) No 68/2013 on the Catalogue of Feed Materials, as amended for the last time by Reg. (EU) 2022/1104.

7.8.1	Lignocellulose	Product obtained by means of mechanical processing of raw natural dried wood and which predominantly consists of lignocellulose. The natural content of trace elements shall be taken into account	Crude fibre

Authorization in organic production

Wood fibre is listed in Reg. (EU) 2021/1165, Annex V "Authorised products and substances for use in the production of processed organic food and of yeast used as food or feed", Part A "Authorised food additives and processing aids referred to in point (a) of Article 24(2) of Regulation (EU) 2018/848, Section A2 – Processing aids and other products, which may be used for processing of ingredients of agricultural origin from organic production.

Wood fibre	products of plant and animal origin	the source of timber should be restricted to certified, sustainably harvested wood wood used must not contain toxic components (post-harvest treatment, naturally occurring toxins or toxins from micro-organisms)

Agronomic use, technological or physiological functionality for the intended use

Lignocellulose is a complex structure primarily composed of the polymers cellulose (ranging from 35 to 55%) and hemicellulose (polysaccharides, ranging from 20 to 40%), lignin (a phenolic macromolecule, ranging from 10 to 25%), and other components, such as proteins, lipids, and inorganic compounds; it is plant biomass that is available in large amounts, and it is considered a renewable resource (Ojo, 2023). The elemental compositions of most lignocellulosic biomass are classified into major elements (e.g., C, H, O, N, K, and Ca), minor elements (Mg, Al, Si, P, Cl, Na, S, and Fe), and trace elements (e.g., Mn and Ti).
The substance is to be used as feed material in all animal species - also pets - as an alternative dietary/crude/raw fibre source.

Necessity for intended use, known alternatives

Suggested minimum and maximum lignocellulose levels according to species group recommended dosage (based on Agromed®) are: Gestating sows: 1-3 %; Lactating sows: 1-1, 5 %; Piglets: 1-3 %; Fattening pigs: 0,5 -1 %; Broilers: 0,8 %; Laying hens: 0,5-1,5 %; Turkeys: 0,8-1,5 %; Dairy cows: 50-60 g/animal/day; Calves: 2 % in starter feed or 20-30 g / animal/day; Pets (Cats, Dogs): 2-4 %; Horses: 1-10 %; Fish: 0,5-1 %; Rabbits: 2-5 %. Method of application: lignocellulose is usually added to compound feed on an average ratio of 1-4 % or serves as a carrier in premixtures, taken from suitable resources, preferably hardwood or annual crop residue.
See "Reflections and conclusions" chapter.

Origin of raw materials, methods of manufacture
See "Environmental issues, use of resources, recycling" section.

Environmental issues, use of resources, recycling

The world's food-producing countries are China, the US, India, Brazil, and Turkey, as they are the largest producers of agricultural waste. Although the most recent global annual lignocellulose production is about 181.5 billion tons, only 8.2 billion tons (4,5%) were used for distinct applications. Large volumes of lignocellulose are obtained from agricultural waste, but only a small fraction is utilized due to unsustainable management practices. This results in excessive emissions of gases and aerosols leading to air pollution, soil fertility deterioration, soil's carbon and nitrogen reduction and a decrease of in-situ microflora and fauna (Singh et al., 2022). This is crucial to understand that a shortage of high-value lignocellulose material from the agricultural sector is hard to be expected.
Thus, it seems that the production process will not have a negative impact on the environment as long as the following conditions are met: a) certified organic production of wood, b) low energy-demanding for drying and grinding methods, and c) the raw materials are sourced locally.

Animal welfare issues

Dietary fibre represents the indigestible fraction of feed or the fractions of the feed that are fermented in the hindgut by microbes. It includes different insoluble carbohydrates that are associated with the cell walls of plants, which are resistant to digestive enzymes. In plants, cell structural components, such as cellulose, hemicellulose, lignin, and pectin. In plants, the levels of structural carbohydrates such as cellulose and hemicellulose increase with plant maturity, resulting in a decrease in plant digestibility. Dietary fibre plays a crucial role in the diets of ruminant animals, as they can ferment a large portion of it. In addition, a certain amount of fibre is necessary to stimulate rumen activity. Dietary fibre has little energy value for non-ruminants, however, it is important for maintaining hindgut health and microbial population in pigs and poultry.

Lignin is a polymer found in the cell walls of plants that consists of polymerised phenolic acids bound to structural carbohydrates. Its presence can limit the amount of energy available to rumen microbes and livestock during digestion due to physical obstruction of enzyme access. The lignin concentration of a plant or an animal feed is inversely related to its digestibility and the energy value that it can provide to an animal: as the lignin content of a feed increases, the digestibility and intake of the feed, as well as the performance of the animal will decrease. Therefore, it is important to consider the lignin concentration when evaluating the quality of a feed.

The problems mentioned in the dossier in poultry - feather pecking (Mississippi State University, 2013) and footpad dermatitis (Shepherd and Fairchild, 2010) - can be avoided in organic livestock management through proper animal management (animal genetics, diet, stocking rate, light/heat exposure, ventilation and bedding) and constant access to grazing areas rich in biodiversity, in line with organic principles.

Human health issues

Lignocellulose originates from a natural origin raw material, but it still can generate concerns regarding: a) the use of pesticides during the organic production of wood, b) the addition of chemicals during the processing, c) the generation of dust during mechanical grinding, pelleting and packaging. These three aspects must be carefully considered in terms of compliance with human health.

Traditional use and precedents in organic production

See "Authorised use in organic farming outside the EU" section.

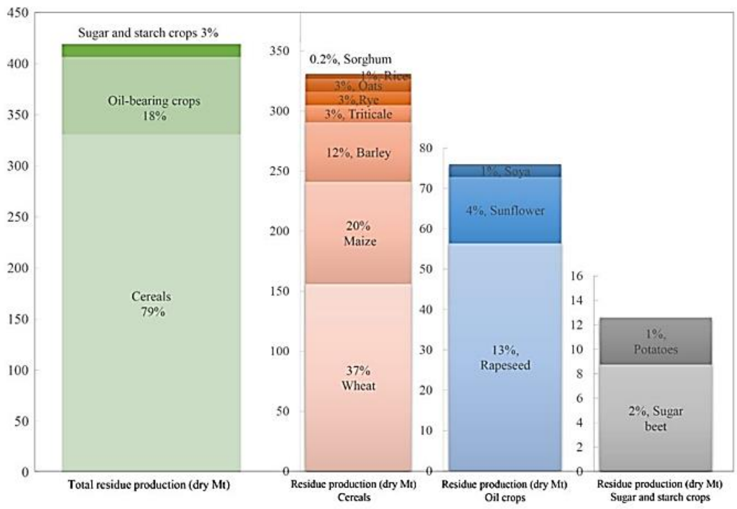
Authorised use in organic farming outside the EU/international harmonization of organic farming standards

Lignocellulose or wood is not authorised for use as feedstuff nor feed additive in Codex Alimentarius - Organically Produced Foods in 2013 (Codex Alimentarius, 2011). Neither is it on the National list of allowed and prohibited substances of the US NOP or on the permitted substances list of the Canadian Organic Standard. The IFOAM Norms (2019) also do not mention lignocellulose as a feedstuff or feed additive.

It is not present in the substances permitted by the Australian National Standard for Organic and Bio-Dynamic (National Standard for Organic and BioDynamic Produce, 2022) nor by the Japanese Agricultural Standard for Organic Feed (Japanese Agricultural Standard for Organic Feed, 2005).

Other relevant issues

Traces of the topic of "metal contaminated lignocellulosic waste" can be found in the literature (Xiao et al., 2023), especially with regard to lead (Huang et al., 2008), both in Pb mining areas districts and Pb-contaminated soils (high concentrations of Pb found in leaves, stems, and other parts of the plants grown in the polluted areas). Lignocellulosic waste is also used as biosorbent to remove Pb from wastewater and therefore needs proper disposal.
An issue related to the use of lignocellulose in the feed is its country of origin and source. According to a survey (Garcia Condado et al., 2019) we can observe that crop residues are the main feedstock of lignocellulosic biomass from agriculture and are expected to provide a major contribution to the production of advanced biofuels. Additionally, this survey also highlights the good stability of feedstock supply from crop residues in the EU (main sources: cereals, sugar crops and oil crops as in Figure 1), even if the estimated current residue production the feedstocks vary substantially among the main producing countries (mainly: France, Germany, Poland, and Romania). This supports the idea that there is unlikely to be a shortage of lignocellulosic material from the agricultural sector.



Reflections and conclusions

In order to align with organic principles, we must well consider that one of the main differences between conventional and organic livestock farming lies in the possibility that animals in organic farming have access to areas with food value, through daily grazing and browsing activity; in the mandatory forage/concentrate ratio - oriented to the advantage of the former - further stimulates the use of roughage in animal feed. Roughage can include hay, straw and/or silage of clover, alfalfa, ryegrass, oat, corn, cereal, barley, or other crops.
In accordance with the EGTOP Final Report "Feed Mandate II" held in 2015 (EGTOP, 2015), the Group considers that the inclusion of lignocellulose from wood of non-organically grown fruit trees as feed material is not in line with the above mentioned objectives, criteria and principles as it could push towards an intensification of breeding methods, potentially contributing to limiting grazing activity, and because it is considered that there are adequate certified organic sources of dietary/crude/raw fibre at EU level.

Recommendations

The Group does not recommend Lignocellulose to be included in Reg. (EU) 2021/1165, Annex III ("Authorised products and substances for use as feed or in feed production" sec. A "other feed materials").

3.1.2.Lecithin

Introduction, scope of this chapter

The present assessment relates to a request for the extension of the authorisation of lecithins laid down in Reg. (EU) 2021/1165, annex III, part B, to all animal species. The dossier was submitted by France.

Name of the active substance: Lecithins
CAS No.: 8002-43-5

ID numbers as feed additive: 1c322 and 1c322i.

Authorization in general production

Lecithins are authorized as technological additives (emulsifiers) for all animal species under the code 1c322 (lecithin extracted from soybeans) by implementing regulation 2017/1007 of 15 June 2017 amended by regulation 2017/2325 of 14 December 2017 and 1c322i (concerning lecithins, hydrolysed lecithins, de-oiled lecithins and de-oiled hydrolysed lecithins derived from soybean, sunflower or rapeseed) by implementing regulation 2017/2325 of 14 December 2017 and Commission Implementing Regulation (EU) 2018/1980 of 13 December 2018). Lecithins are listed in the European Register of Feed Additives, in accordance with the amended Regulation (EC) No 1831/2003. No maximum limit has been set for lecithins as a feed additive in complete feed.

Authorization in organic production

Lecithins have been authorised since 2009 for use as feed additive in organic farming only if derived from organic raw materials and only in aquaculture. They are listed under Annex III of Regulation (EU) 2021/1165). Lecithins are also authorised as food additives (EGTOP, 2014) and for use in plant protection products.

Agronomic use, technological or physiological functionality for the intended use

Vegetable lecithins are lipids from the phosphoglyceride class, containing primarily Phosphatidyl Choline, lipids composed of choline, a phosphate group, glycerol and two fatty acids. Other lipids are Phosphatidyl Ethanolamine, PE and Phosphatidyl Inositol (Van Nieuwenhuyzen and Mabel, 2008). Lecithins are naturally present in living organisms (plants and animals) and are commonly used as emulsifiers in many areas:

- In products intended for human consumption such as confectionery, chocolate or margarine.
- In products intended for animal feed, such as milk replacers, shrimp feed or pet food
- In pharmaceutical or cosmetic products
- In non-food products such as waxes, paints, or lubricants

The feed additive lecithins is usually used in feedingstuffs for all animal species at levels ranging between 0.1 and 1% of complete feedingstuffs for all animal species (EFSA, 2016).

Necessity for intended use, known alternatives

In the organic livestock farming sector, complementary feed for use in organic farming can be delivered to animals in the form of water-soluble powders or liquids either through the water distribution system or directly to individual animals. A typical example is milk replacers in the form of milk powder.
These products may contain fatty compounds (essential oils, fat-soluble vitamins, fats of interest,…) which are not directly miscible in water. The use of an emulsifier such as lecithins is needed to either manufacture the liquid feed or to allow for a proper mixing with water on the farm. The addition of an emulsifier such as lecithins in the list of additives authorized in organic agriculture will enable to use these complementary feeds in the organic sector.
At present, no emulsifier is included in the list of additives authorized in organic production for food producing animals. Although xanthan gum is listed in Annex III of Regulation 2021/1165 under the functional group “Emulsifiers, stabilisers, thickeners and gelling agents”, it is used only as a stabilizer or thickener in practice. The application for re-authorisation of xanthan gum as feed additive is limited to these two functions only, meaning that it will not be authorized as an emulsifier anymore in conventional farming when the procedure of re-authorisation of xanthan gum is completed.

Origin of raw materials, methods of manufacture

Lecithins authorised as feed additives are produced exclusively from soybeans, rapeseed or sunflower seeds. Lecithins with ID number 1c322 are produced exclusively from soybeans through mechanical or solvent extraction and are dried to a moisture content below 1%. Lecithins with ID number 1c322i are produced exclusively from soybeans, rapeseed or sunflower seeds through mechanical or solvent extraction. Regular liquid lecithins may be further processed by additional solvent extraction steps to remove neutral lipids and thus, to produce de-oiled lecithin powder, or by enzyme treatment to produce the hydrolysed liquid lecithins. Lecithins from rapeseed are only available in the regular liquid form, while hydrolysed and de-oiled lecithins are also available from sunflower and soybean. During the manufacturing process of lecithins may involve a bleaching step with hydrogen peroxide. Organically produced lecithins are produced by mechanical extraction and do not undergo bleaching.

Environmental issues, use of resources, recycling

Lecithin are products that occur naturally in plants and animals. Once ingested, lecithins are extensively metabolised. Therefore, the use of lecithins in animal feed does not increase their concentration in the environment (EFSA, 2016).

The majority of lecithin is produced from soya. Organically produced lecithin should not be produced from genetically modified soya. Lecithin is a by-product of oil refining. The production of lecithin produced from soya is not the driver of deforestation and its use in animal feed contributes to a circular economy.

Animal welfare issues

Lecithins are safe for all target species (EFSA, 2016). Setting a maximum content for lecithins is not considered necessary. Lecithins are normal constituents of feed materials and animal products, as a nutritional reserve of phospholipids. Lecithins are not expected to produce signs of intolerance under normal feeding conditions. A number of studies in several target species showed that no adverse effects are to be expected at normal inclusion levels.

Human health issues

The use of lecithins in animal nutrition poses no risk to the consumer. Lecithins are authorised as food additives with no maximum content and with ADI not specified. Lecithins are natural constituents of plants and animal products, as components of biological compounds and as a nutritional reserve of phospholipids (eggs, milk). Lecithins in animal products result from dietary sources and de novo synthesis. The metabolic fate of lecithins is common to all animal species, including humans, lysolecithins being intermediate metabolites. Accumulation in animal tissues and products is not expected (EFSA, 2016).

Food quality and authenticity

The small quantities of lecithin added to feed do not affect the quality and authenticity of products of animal origin.

Traditional use and precedents in organic production

Lecithins have been known since the mid-19th century. They were initially extracted from egg yolk before moving to vegetable sources. Little data is available on the organic grade lecithin market. This is a relatively small market compared to the quantities produced conventionally. The main outlets for organic lecithins are the baby food, chocolate, vegetable drinks or margarine industries. Demand for use as feed in organic farming is expected to be much lower than the demand for use in organic food.

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

According to the dossier, lecithins are authorized for organic production in Australia (National Standard for Organic and Bio-Dynamic Produce, 2016) or in the United States (National Organic Program: Amendments to the National List of Allowed and Prohibited Substances, 2012).

Other relevant issues

The manufacturing process of lecithins may involve solvent extraction and a bleaching step with hydrogen peroxide, which is not suitable for use in organic farming.

Reflections and conclusions

Lecithin is a suitable feed additive for use as an emulsifier in feed for all animal species. There is enough supply of lecithin produced according to organic standards available globally, and therefore it is appropriate to limit the authorisation to such lecithin. Attention should be paid in particular to the quality of the oilseeds (organically produced, including non-genetically modified). The lecithin should be derived from organic raw materials without solvent extraction unless authorized by organic production and without bleaching step involving hydrogen peroxide.

Recommendations

The Group recommends the inclusion of Lecithin in Reg. (EU) 2021/1165, Annex III, part B, to all animal species (extension to all animal species) with the following conditions: lecithins derived from organic raw materials without solvent extraction unless authorized by organic production and without bleaching step involving hydrogen peroxide.
Considering all the aspects mentioned above, the Group remarks the need of modification/update of the legislation of aquaculture and a corresponding transitional phase.

ID number or functional group	Name	Specific conditions and limits
1c322 1c322i	Lecithins	only from organic production

3.1.3 Ethanol

The present assessment relates to the request for the inclusion of Ethanol as a processing aid in Annex III B of Reg. (EU) 2021/1165. The dossier was submitted by France.

Other names: Ethylic alcohol

CAS No.: 64-17-5

Molecular Formula: C_2H_6O

Authorization in general production

Processing aids are permitted in feed, and they are defined in the Reg. (EC) No 1831/2003 on feed additives. Ethanol is included in Annex I "Extraction solvents which may be used during the processing of raw materials, of foodstuffs, of food components or of food ingredients", Part I, " Extraction solvents to be used in compliance with good manufacturing practice for all uses" of Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

Authorization in organic production

Ethanol is authorised for the processing of products of plant and animal origin as a solvent and it is included in Annex V "Authorised products and substances for use in the production of processed organic food and of yeast used as food or feed", Part A, "Authorised food additives and processing aids referred to in point (a) of Article 24(2) of Regulation (EU) 2018/848", Section A2, "Processing aids and other products, which may be used for processing of ingredients of agricultural origin from organic production" of Commission Implementing Regulation (EU) 2021/1165.

Agronomic use, technological or physiological functionality for the intended use

Most of the ethanol produced is currently used as a biofuel and industrial solvent, with the remainder used in food and cosmetics or as a disinfectant (Chemanalyst, 2020).

Several grades of ethanol are available on the market, depending on the application: anhydrous ethanol is mainly used for applications where water is undesirable. Ethanol at 96% (v/v) is mainly used for food, cosmetics, or technical uses where water is not problematic. Ethanol used for technical applications is often denatured with additives, making it unsuitable for use as a beverage and, therefore, for food applications in general.

For vegetable oil extraction, dry ethanol (96-99% v/v) is often preferred for vegetable oil extraction due to its higher oil solubility. Ethanol dehydration is generally carried out by advanced distillation technologies, absorption on molecular sieves, or membrane filtration.

Necessity for intended use, known alternatives.

The main vegetable protein meals used in animal feed are by-products of oil extraction. The current solution for producing high quality organic oils is mechanical pressure, which does not allow the recovery of the entire lipid fraction (70-90% yield). Although cold-pressed oilseed cakes are rich in protein and represent a good source of plant proteins, the degradation of the residual lipid fraction could challenge their nutritional and sensory properties, especially during long-term storage. Conversely, meals obtained from solvent extraction can be stored longer, helping achieve 100% organic protein feeding. This objective requires, in fact, the continuous availability on the EU market of sufficient quantities of high quality, high-protein density feed. According to the dossier, the above considerations support the request to include ethanol of plant origin among the processing aids (solvents) authorised for organic feed production.

Origin of raw materials, methods of manufacture

Historically, ethanol can be produced from petroleum (ethylene oxidation) or from biomass sources (fermentation). However, the current trend is towards the massive use of biomass sources due to reduced manufacturing costs compared to the oil-based process.

Bioethanol (that is ethanol produced from biomass) is obtained after the fermentation of sugars by yeasts. In first-generation ethanol, the sugars are obtained from sugar plants (sugar cane, sugar beet, etc.) or starchy crops (wheat, maize, etc.). Second-generation ethanol uses non-food products or agricultural waste as raw material to avoid competition with food production.

As a volatile substance, analytical methods mainly rely on gas chromatography to determine purity or to quantify residual solvents in feed/food. There are currently no norms or standards for the quantification of ethanol in oilseed materials. However, the methods are comparable to standardized methods used for common solvents (e.g., hexane), and their implementation should not be a problem for the industry.

Environmental issues, use of resources, recycling

As recently reviewed by Soleymani Angili et al. (2021), a wide range of LCA studies have been conducted to measure the sustainability of bioethanol production. The differences in the methodological assumptions, technical and agricultural issues applied by the authors made it difficult to compare the LCA results. In other words, it is not possible to compare with a high degree of certainty the influence of each component of the methodology on the results, as different technical and agricultural parameters are also involved in the results of the studies.

From a general standpoint, using agricultural practices with low environmental impact to produce the biomass and applying targeted pre-treatments to the biomass can enhance the sustainability of the whole ethanol production process.

Animal welfare issues

No animal welfare issues are expected.

Human health issues

No human welfare issues are expected.

Food quality and authenticity

No modifications of food quality or authenticity are expected.

Traditional use and precedents in organic production

The use of protein meals derived from the extraction of the lipid fraction with solvents is a common practice in animal nutrition.

Ethanol is currently used as a "solvent" in the production of organic foodstuffs (Annex V - section A2 Regulation 2018/848).

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

According to the OMRI Products List (2024), ethanol is entered among Processing Agricultural Ingredients and Processing Aids with restrictions (alcohol used as an ingredient in a product labelled as 'organic' must be produced and handled organically) in the US.

In Canada it is authorised as a Processing Ingredients and Aids if of organic origin, and with restriction if synthetic.

According to the US National List of Allowed and Prohibited Substances for organic production, ethanol of synthetic origin is prohibited as a feed additive (§ 205.603).

According to the Australian National Standard for Organic and Bio-Dynamic Produce (2022), food grade ethanol is permitted as a processing aid for plant products (solvent).

Other relevant issues

None

Reflections and conclusions

The EGTOP Group notes that the dossier, although aimed at authorization for a processing aid for protein meals destined to feed production, also refers to the production of oil intended for human consumption.

According to Regulation 2018/848, Part V, Processed feed production rules: “Any feed materials used or processed in organic production shall not have been processed with the aid of chemically synthesised solvents”.

The Group noticed that ethanol is authorized as solvent in Annex V of Regulation 2021/1165. It also noticed that the EGTOP, in its report adopted on 20-21th June 2012, recommended that “Ethanol, gelatine, vegetable oils and rice meal should only be used in organic form, even if they are listed in Annex VIII B to Commission Regulation (EC) No 889/2008.” For the sake of consistency, it would be appropriate to authorise ethanol under the same conditions.

Ethanol obtained through the fermentation of sugars in plant materials by yeast or bacteria can be regarded as a natural product, i.e. not as a "chemically synthesised solvent", and complying with Reg 2018/848 provided that:

1. Ethanol is produced solely by fermentation
2. The biomass derives from organically produced raw materials;
3. No GMOs are involved at any stage of the production process;
4. No chemical or physical or chemical-physical process that does not comply with Reg. 2028/848, including the pretreatment of biomasses and ethanol purification and drying processes.

Recommendations

The EGTOP Group recommends including ethanol as a processing aid (solvent) in annex III B of Reg. (EU) 2021/1165 with the specific conditions:

1) It is used only upon demonstration that the availability of protein meals from mechanical extraction is insufficient to fulfil organic animals' nutritional needs;

2) The specific conditions set out here are to be applied in addition to the conditions of the authorisations under Regulation (EC) No 1831/2003: 1) ethanol produced solely by fermentation, 2) the biomass derives from organically produced raw materials, 3) No GMOs are involved at any stage of the production process; 4) No chemical or physical or chemical-physical process that does not comply with the Reg. 2028/848, including the pretreatment of biomasses and ethanol purification and drying processes.

Name	Specific conditions and limits

Ethanol	Only if the following conditions are met: 1) ethanol produced solely by fermentation, 2) the biomass derives from organically produced raw materials, 3) No GMOs are involved at any stage of the production process; 4) No chemical or physical or chemical-physical process that does not comply with the Reg. 2028/848, including the pretreatment of biomasses and ethanol purification and drying processes.

3.1.4 Protein from micro-organisms

1. **Single cell proteins from *Trichoderma viride*, Product from *Bacillus subtilis* rich in protein, Single cell proteins from *Aspergillus oryzae***

Introduction, scope of this chapter

The present assessment relates to a request for the authorisation for all animal species of single cell proteins (SCP) from *Trichoderma viride*, Product from *Bacillus subtilis* rich in proteins and SCP from *Aspergillus oryzae* as feed material into the lists of authorised non-organic products and substances referred to Article 24(7) of Reg. (EU) 2018/848. The relevant place for inclusion is in Reg. (EU) 2021/1165, Annex III, part A (2) Other feed materials. The dossier was submitted by France. This is the first application for authorisation of a feed material of bacterial origin in organic farming.

Authorization in general production

Trichoderma viride and *Aspergillus oryzae* are classified as fungi in the taxonomy and SCP of *Trichoderma viride* and SCP of *Aspergillus oryzae* are listed under ID number 12.1.9 in Part B of the Annex of the EU Catalogue of feed materials Regulation (EC) No 68/2013 as lastly amended by Reg. (EU) 2022/1104. *Bacillus subtilis* is a bacteria and Product from *Bacillus subtilis* rich in proteins is listed under ID number 12.1.10 in Part B of the Annex of the same EU Catalogue of feed materials.

Authorization in organic production

The SCP from *Trichoderma viride*, Product from *Bacillus subtilis* rich in proteins and SCP from *Aspergillus oryzae* are not authorised in organic production. There are no specific production rules for micro-organisms to be produced under organic farming conditions except for yeast. Article 24(1)(c) of Regulation 2018/848 foresees that feed material of microbial origin may be authorised for use in organic farming and included in Reg. (EU) 2021/1165, Annex III, Part A (2) Other feed materials.

Agronomic use, technological or physiological functionality for the intended use

The SCP generally refers to the edible biomass of unicellular microorganisms. It can be the whole biomass or protein extracts from single or mixed cultures of different microbial groups, including algae, bacteria, yeasts/fungi and others. SCP can be used as animal feed or human food and consumed whole or applied as a supplement (Onyeaka et al., 2020).

The SCP from bacteria and fungi contain high quantities of proteins (between 50 and 65% for bacterial biomass and between 30 and 45% for fungi - see Table 1) and contribute to the protein content of livestock rations. Their amino acid composition makes them potent alternative protein sources for animal consumption (Onyeaka et al., 2020). The feed materials can be used in compound feed (mineral, complementary or complete) or mixed into the ration on the farm. They are mainly intended for use in ruminants and equine diets. There is no safety limitation to the incorporation of these microbial biomass and the levels can vary from 0.5% to 5% in the complete diet depending on the species, stage of development and composition of the other diet ingredients.

Table 1. Nutritional compositions of microorganisms (% dry weight) (Kalaichelvan and Arulpandi, 2019).

Microorganisms	Protein	Fat	Ash	Nucleic Acid
Fungi	30-45	2-8	9-14	7-10
Algae	40-60	7-20	8-10	3-8
Yeast	45-55	2-6	5-10	6-12
Bacteria	50-65	1-3	3-7	8-12

Necessity for intended use, known alternatives

The demand for organic raw materials, particularly those rich in protein, is increasing while the supply on the EU market has faced difficult agronomic conditions with reduced yields in recent years . As a result, protein rich feed materials such as organic oilseed expellers are mainly imported from China, India and Black Sea countries (EU Commission, 2023). Due to geopolitical tensions worldwide, the security of these sources is no longer guaranteed. It is therefore necessary to find alternative protein sources to reduce the vulnerability of the EU organic livestock sector. Reducing the dependency in proteins has become a key objective for the European Union both regarding the conventional and the organic protein market, including feed, and is ear-marked as a clear objective in the EU Commission action plan on organic farming, which specifies that, “In addition to increasing the availability of locally sourced feed proteins, alternative sources of protein for feed should be found to ensure sustainable and diversified animal nutrition.” (EU Commission, 2021).

The products resulting from fermentation are developed for use in animal feed because of their good availability. They represent an interest in organic animal feed because of their natural composition (quantity and quality of the protein. Their use is increasing in traditional livestock production because of their high protein content and the contribution of essential nutrients for farm animals.

The inclusion of the three fermentation products in the ration makes it possible to reduce the proportion of protein-rich feed such as soya by substitution. Alternatively, the protein content of the diet can be increased by adding these fermentation products.

At present, the only SCP authorized in organic farming are organically produced yeast and yeast products or, when not available, non-organically produced yeast and yeast products when not available from organic production (entries 12.1.5 and 12.1.12 of the EU Catalogue of Feed Materials) as listed in Annex III of Regulation 2021/1165.

Compared to yeasts, SCP from fungi have a lower protein content but a higher fat content and are also rich in vitamins while bacteria are higher in proteins and may be produced with feedstock of lower value.

Origin of raw materials, methods of manufacture

For the production of SCP from *Trichoderma viride*, Product from *Bacillus subtilis* rich in proteins and SCP from *Aspergillus oryzae* for use in organic farming, the strains are cultivated in a medium consisting mainly of non-GMO plant-based ingredients. These include molasses, sugar syrup, alcohol, distillery residues, cereals and starch products, fruit juice, whey, lactic acid, sugar, plant fibre hydrolysates and fermentation nutrients such as ammonia or mineral salts.

The defoamer is used in quantities of less than 0.01%. The antifoam compounds are either consumed by the cultures during fermentation or they are inert compounds that have no effect on the culture.

Once the fermentation is completed, the bacterial and fungal strains used are inactivated/killed by heat. The fungal strains of Aspergillus oryzae and Trichoderma viride grow between 25 and 28°C. They are unable to grow above 37°C and are thus inactivated. These fungal strains are heated to 47°C for 6 hours and are thus inactivated. For the strain, the fermentation time is 24 hours which is not sufficient for the culture to produce heat resistant spores. Thus, only the vegetative cells are present and are inactivated during 6 hours of drying while preserving all the beneficial activities of the metabolites. The fermentation products can be in dry or liquid form.

The inactivation phase is controlled by culturing the dried fungal fermentation extracts on nutrient media such as PDA (potato dextrose agar) or YPD (yeast extract peptone dextrose agar) at 25°C for 96 to 120 hours. The bacterial fermentation extract is cultured on NA (nutrient agar) or TVC (total viable count) agar at 30°C for 96 to 120 hours. The absence of growth of the fermentation extracts on these nutrient media allows for the control of their total inactivation.

Environmental issues, use of resources, recycling

The production of SCP for animal feed use involves bioreactors requiring energy. However, it does not require land and most feedstocks used as growing medium are non edible co-products or residues from crop processing industries. The use of these substrates, which are relatively easy to obtain, makes SCP production desirable as it does not put pressure on the production of crops for human food or animal feed (Onyeaka et al., 2020).

SCP contributes also to reduce the EU dependency on third countries for the supply or protein sources, mostly in the form of imported oilseed meals thereof soybean meal.

Animal welfare issues

Bacillus subtilis and *Aspergillus oryzae* are authorized as digestibility enhancers further to assessment by EFSA (2018). No negative impact on animal health has been reported in relation to the use of the three fermentation products in the animals' diets.

Human health issues

Aspergillus oryzae, *Bacillus subtilis* and *Trichoderma viride* have been used for many years in the food industry. Their use as feed is not expected to impact on the safety of animal products.

Food quality and authenticity

Fermentation is a natural process that has been used by mankind in the production of foodstuffs for centuries. The use of fermented products is therefore compatible with food authenticity and quality.

Traditional use and precedents in organic production

Fermentation products have been used for decades and have been authorized at the Community level since 1982 by Directive 82/471/EEC in the generic group "protein products obtained from micro-organisms of the following groups Bacteria and lower fungi ", without distinction of strains. This Directive has been repealed and there is no longer a procedure for authorization of microbial biomass for feed use. The content of the annex of Directive 82/471/EEC was transferred under the first version of the EU Catalogue of Feed Materials in 2010 under Chapter 12 *Products and by-products obtained by fermentation using inactivated micro-organisms, resulting in the absence of living micro-organisms in the product*", whose structure has been improved with specification of the strains of the micro-organisms.

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

In the U.S., the Organic Materials Review Institute (OMRI) allows "Fermentation Products" ("Livestock Products by Category," updated December 5, 2020) to be used in accordance with the National Organic Program standards. As such, fermentation products are eligible for organic production in the US subject to USDA certification.

In the United States, the National Organic Program (NOP), USDA CFR §205.237 (Animal Feed) has established that any non-synthetic substance not prohibited by §205.604 may be used as a supplement or feed additive. Furthermore, organic feed operators can feed their animals with products from fermentation according to §205.605 as non-synthetic supplements. Several products derived from the fermentation of Aspergillus oryzae and Bacillus subtilis are marketed and used in organic livestock production in the United States.

Other relevant issues

None

Reflections and conclusions

Single cell proteins *from Trichoderma viride*, Product from *Bacillus subtilis* rich in proteins and Single cell proteins from *Aspergillus oryzae* may be regarded as useful sources of proteins for organic farming as they can contribute to bridge the protein feed supply gap. They must be produced from non-genetically modified strains and with a non-GM substrate composed of co-products from food processing of organic origin. However, any anti-foaming agent use in the manufacturing process would require a specific authorisation as feed processing aid in Annex III of Regulation 2021/1165.

Recommendations

The Group recommends to authorise for all animal species the use of single cell proteins from *Trichoderma viride*, from *Bacillus subtilis* rich in proteins and single cell proteins from *Aspergillus oryzae* with the following conditions:

Only from non-GM strain and culture media

Only if produced with no synthetic nitrogen sources.

Only if obtained with organic antifoaming agents or without antifoaming agents.

Number in feed materials catalogue	Name	Specific conditions and limits
ex 12.1.9	Single cell proteins from *Trichoderma viride* and *Aspergillus oryzae*	Only from non-GM strain and culture media Only if produced with no synthetic nitrogen sources Only if obtained with organic or without antifoaming agents
12.1.10	Product from *Bacillus subtilis* rich in protein	Only from non-GM strain and culture media Only if produced with no synthetic nitrogen sources Only if obtained with organic antifoaming agents or without antifoaming agents

3.2 Food

3.2.2 Buffered vinegar (E267)

Introduction, scope of this chapter

The assessment of Buffered vinegar (E267) relates to the inclusion in Annex V, Part A, Section A1 – food additives, including carriers of Regulation (EU) No 2021/1165. Specifically, the applicant requests the inclusion of Buffered vinegar (E267) as a preservative and acidity regulator for use in organic foodstuffs of plant and animal origin. The dossier was submitted by the Netherlands.

Authorisation in general production and in organic production

Buffered vinegar (E267) is include in the list of authorised food additives in Regulation (EC) No 1333/2008. Its specifications are laid down in Regulation (EU) No 231/2012.

Buffered vinegar (E267) is listed in Group I in Part C of Annex II to Regulation (EC) No 1333/2008 among food additives with an Acceptable Daily Intake (ADI) 'not specified' or for which is required and for which a nureical ADI was not considered necessary. It is authorised for use in many foods in accordance with the *quantum satis* principle as defined in Article 3(2), point (h) of that Regulation.

Agronomic use, technological or physiological functionality for the intended use

Buffered vinegar (E267) is a preservative and acidity regulator (food additive) specifically formulated for its technological effect that ensures good quality and safety of foods. Instead, normal vinegar (normal food ingredient) without buffering would negatively affect the quality of food. Most vinegars have a low pH of around 3.0, which affects the colour, taste, and texture of foods, as well as their ability to retain water retention.

Necessity for intended use, known alternatives

While traditional vinegar has preservative properties, it is not suitable for inclusion in many food products due to the low pH, which can have several undesirable effects on the final product. Buffered vinegar is a sustainable and, in many cases, a more effective preservative than the currently approved alternatives, such as lactic acid (E270) and sodium lactate (E325), especially in cases where yeasts, moulds and gram-negative bacteria cause problems with the shelf life and safety of food products.

On the other hand, in some specific cases, buffered vinegar cannot function as an alternative to lactic acid and lactate, e.g. in the case of certain gram-positive microorganisms and spoiling lactic acid bacteria. Some species are more sensitive to buffered vinegar, and some are more sensitive to salts of lactic acid.

The ideal solution can be a separate preservative or a combination. Sodium nitrite (E250) and potassium nitrate (E252) are only authorised in meat products under specific restricted conditions. Buffered vinegar does not function as a full alternative for nitrites and nitrates, as the latter especially and very effectively control pathogenic Clostridium species, but it can be part of an alternative solution.

Sodium metabisulphite and sulphur dioxide are allergenic substances and are restricted to a limited range of food products.

Citrates (sodium and calcium), sodium ascorbate/ascorbic acid and malic acid do not show strong enough inhibition of microorganisms to extend microbial shelf life significantly, apart from the effect of lowering the pH or acidity of the food.

Origin of raw materials, methods of manufacture

Buffered vinegar is a liquid or dried product prepared by adding buffering agents to vinegar. The buffering agents used are sodium/potassium hydroxides (E524-E 525) and sodium/potassium carbonates (E 500-E 501). The vinegar is compliant with the European Standard EN 13188:2000 and is exclusively obtained from an agricultural organic source origin (except wood/cellulose) by double fermentation, alcoholic and acetous.

Environmental issues, use of resources, recycling.

The use of organic certified preservatives such as buffered vinegar results in longer shelf life of organic food products which has a positive impact on the reduction of food waste. Tackling food waste is one of the key action points of the European Commission's Farm to Fork Strategy as part of the European Green Deal.

Animal welfare issues

Not applicable, since the application of buffered vinegar will be in food.

Human health issues

According to the dossier, buffered vinegar is a more effective preservative than other preservatives currently approved in the EU. It will therefore be more effective in providing safe food.

Food quality and authenticity

Buffering vinegar allows vinegar to be used for preserving function while ensuring good food quality. Buffered vinegar does not have the sensory impact on foods other preservatives have, such as sodium lactate, which has been shown to provide off-taste with increasing concentrations and can discolour food at high concentrations. Buffered vinegar is effective in improving cooking yield, which will directly benefit the consumer.

According to the requirements established in Regulation (EU) No 1169/2011, it will be labelled as “preservative: buffered vinegar”. This labelling clearly communicates what ingredient is inside the product being consumed, the functional reason it is added, and the use of the word “buffered” provides a clear differentiation from traditional organic vinegar.

Traditional use and precedents in organic production

Buffered vinegar is used by the global food industry for the preservation of various food products.

In Europe, buffered vinegar has been placed on the market for many years as a food ingredient. In 2019, some European Member States authorities challenged the status of buffered vinegar when used in foodstuffs. On 17 November 2020, the SCoPAFF (Standing Committee on Plants, Animals, Food and Feed Section Novel Food and Toxicological Safety of the Food Chain) statement on the “Status of buffered vinegar” was published. It considers the use of “buffered vinegar”, where it delivers a technological effect in the foods to which it is added, an intentional use as a food additive. Buffered vinegar is specified as a product where the pH is adjusted to be higher than 4.9 through the use of or addition of acidity regulators. Buffered vinegar was authorised as a food additive with the Commission Regulation (EU) 2023/2086 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of buffered vinegar as a preservative and acidity regulator.

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

In the US, buffered vinegar products are placed on the market as vinegar and positioned as an ingredient. Organic buffered vinegars have been used in organic food processing under the National Organic Program (NOP).

In Canada, in conventional food production, it is allowed the use of the modified vinegar defined as a liquid or spray-dried mixture containing acetic acid and one or more of potassium acetate, potassium diacetate, sodium acetate or sodium diacetate, prepared by adding potassium bicarbonate or sodium bicarbonate, potassium carbonate or sodium carbonate, or potassium hydroxide or sodium hydroxide to vinegar.

Other relevant issues

None

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

According to the dossier, efficacy data is available to demonstrate that buffered vinegar can significantly reduce *Listeria monocytogenes* counts in various food applications.

Nitrites and nitrates are used in the production of organic meat products such as cured meats for a number of reasons: for their anti-microbial and antioxidant properties, to form and stabilise the red cured meat colour and to form the cured flavour. Since the use of nitrite is not desirable, mainly because of the health risks associated with it that deserve consideration according to several publications. The Group consider that buffered vinegar could possibly replace nitrites and be an alternative additive used in certain organic meat to provide some of the functions of nitrite in organic cooked cured meats.

Regarding the buffering agents proposed, we should consider that in Regulation 2021/1165, ANNEX V, PART A, SECTION A1, there are only the following food additives that Applicant proposed for buffering:

E 500/ Sodium carbonates/ products of plant and animal origin

E 501/ Potassium carbonates/ products of plant origin

E 524/ Sodium hydroxide/ ‘Laugengebäck’ flavourings/ surface treatment, acidity regulator

Regarding the buffered vinegar as dried product, in the dossier there is no information supporting the compliance with the regulation 2018/848, for example the flow chart and description of the manufacturing.

Conclusions

The EGTOP Group recommends the inclusion of the Buffered vinegar (E267) in the liquid form in Annex V Part A Section A1 – food additives, including carriers of Regulation (EU) No 2021/1165.

Regarding the buffered vinegar as a dried product, the Group will assess this form after receiving information supporting compliance with Regulation 2018/848.

Recommendations

The EGTOP Group does recommend the inclusion of liquid form of Buffered vinegar (E267) in Annex V, Part A, Section A1 – food additives, including carriers of Regulation (EU) No 2021/1165 with the specific condition: The buffering agents should be limited to the food additive mentioned in the Regulation 2021/1165, Annex V, Part A, Section A1:
Sodium carbonates (E500)
Potassium carbonates (E501)

ID	Name	Specific conditions and limits
E 267	Buffered vinegar	Only in the manufacturing process of organic food products Only if obtained from organic vinegar with addition of sodium carbonates (E500) or Potassium carbonates (E501) as food additive mentioned in the Regulation 2021/1165, Annex VA, Section A1

4. MINORITY OPINIONS

None

5. LIST OF ABBREVIATIONS / GLOSSARY

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7. ANNEX