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EGTOP/2021

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Quality, Research & Innovation, Outreach
B.4. Organics

Expert Group for Technical Advice on Organic Production

EGTOP

Food VII – Feed V Final Report

The EGTOP adopted this technical report at the plenary meeting of 10 to 12 March 2021.

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

With the Communication from the Commission to the Council and to the European Parliament on a European action plan for organic food and farming adopted in June 2004, the Commission intended to assess the situation and to lay down the basis for policy development, thereby providing an overall strategic vision for the contribution of organic farming to the common agricultural policy. In particular, the European action plan for organic food and farming recommends, in action 11, establishing an independent expert panel for technical advice. The Commission may need technical advice to decide on the authorisation of the use of products, substances and techniques in organic farming and processing, to develop or improve organic production rules and, more in general, for any other matter relating to the area of organic production. By Commission Decision 2017/C 287/03 of 30 August 2017, the Commission set up the Expert Group for Technical Advice on Organic Production.

EGTOP

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

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1. EXECUTIVE SUMMARY

The Group made the following conclusions:

Food

Substance Sulphuric Acid as processing aid for the production of two food products a) Toasted Corn snacks and b) Locust bean gum

The use of Sulphuric acid as a processing aid in the production of corn snacks and locust bean gum is not in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007.
The addition to Annex VIII Section B to Regulation (EC) No 889/2008 is not recommended.

Silicon dioxide as flow agent for use in hot chocolate powder

The group consider that this kind of product is not necessary for health, but the group also considers that addition of silicon dioxide as an anti-caking agent, specifically for cocoa powder in automated drinks dispensing machines, and exclusively for this purpose, is in line with the objectives, criteria and principles of Council Regulation (EC) No. 834/2007, in the case the drinks dispensing machines can carry a wording indicating that the cocoa powder contains silicon dioxide (without violating horizontal labelling legislation).
It therefore recommends addition of silicon dioxide as an additive in Annex VIII Section A of Regulation (EC) No 889/2008 with the specific condition "for use in automated dispensing machines", and restriction to products containing less than 1% of crystalline silica, in addition to the currently permitted uses for spices, propolis and flavourings.

The group would also like to point out to the Commission services the opportunity for further insight on nanoparticles and specifications of these kind of products.

Pine tree extracts containing natural rosin acids (in form of potassium salts)

The group considers pine rosin extracts to be in line with the objectives, criteria and principles of Council Regulation (EC) No. 834/2007.
The addition of pine rosin extracts as a processing aid to Annex VIII Section B of Regulation (EC) No. 889/2008 is recommended with the restriction of use "only for antimicrobial purposes in production of food from plant origin and not only for starch and sugar " and, when available, with the restriction of "from organic production".
The group is not aware of other possible opportunities for similar uses in other sectors, for example in the production of potato starch. However, it seems unnecessary to require other similar sectors to corn starch or sugar production to make separate applications for inclusion in Annex VIII Section B. It may be that such uses could be allowed, by for example using the following wording in annex VIII Section B. Pine rosin extracts, with the following revised condition: With regards to foodstuffs of plant origin:" only for antimicrobial purposes in production of food. When available from organic production ".

Hop extracts containing natural hop alpha acids, hop beta acids and their derivatives (in form of potassium salts)

The group considers hop extracts as a food processing aid in line with the objectives, criteria and principles of Council Regulation (EC) No. 834/2007.
The addition of hop extracts as a processing aid to Annex VIII Section B to Regulation (EC) No. 889/2008 is recommended with the restriction of use "only for antimicrobial purposes in production of food from plant origin and not only for starch and sugar " and, when available, with the restriction of "from organic production".

The group is not aware of other possible similar uses in other sectors, for example in the production of potato starch, but it seems unnecessary to require other similar sectors to corn starch or sugar production to make separate applications for inclusion in Annex VIII Section B. It may be that such uses could be allowed, by for example using the following condition in Annex VIII B:"With regards to foodstuffs of plant origin: only for antimicrobial purposes in production of food. When available from organic production ".

Kaolinitic clay as a processing aid in olive oil extraction processes

The group considers that the use of individual additives, kaolin or bentonite as filtration aids in the processing of olive oil would be in line with the objectives, criteria and principles of Council Regulation (EC) No. 834/2007, only if they meet the specification for additives. However, the mixture known as kaolinitic clay does not appear to meet the specification for use as an additive.

The addition of Kaolinitic clay as a processing aid to Annex VIII Section B to the Regulation (EC) No. 889/2008 is not recommended.

Sodium metabisulphite (pending issue from EGTOP Report FOOD III)

The group considered briefly the request for consideration of the dossier from Belgium requesting removal of sodium metabisulphite with the specific condition "for crustaceans" from Annex VIII Section A to Regulation (EC) No 889/2008. This dossier was submitted for EGTOP Report Food III, but was not discussed due to lack of time.

The group decided that, as the dossier was dated 2014, it was not appropriate to completely review this.

The group recommended that the Commission asks for an updated dossier from Belgium, which should then be submitted, with high priority, to a future subgroup meeting.

CleanSmoke (DE, additional information, pending) (pre-purified smoke (DE))

The group was not able to reach a firm conclusion on whether the process (smoking with pre-purified smoke) or the product (pre-purified smoke) is in line with the objectives, criteria and principles of the organic regulations.

Substance Sucrose Esters (E473)

The use of sucrose esters as a food additive is not in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007. This view is due to the fact that its use would not be labelled so its presence would not be clear to consumers.

The addition of sucrose esters to Annex VIII Section A to Regulation (EC) No 889/2008 is not recommended unless the addition is labelled.

Gellan gum - possibility for making this in organic form.

The group discussed a letter received from an interested party concerning implementation of the requirement in Annex VIII Section A for Gellan gum to be "Only when derived from organic production. Applicable as of 1 January 2022". The letter requested that the implementation should be delayed by two additional years.

The letter states that one substrate for production of gellan gum is not yet available in organic form, but does not identify the substrate or progress and efforts towards making it available in organic form. The group suggests that the delayed implementation to 2022 might be granted by the Commission after receiving by the interested party further details of the substrate and prospects for progress toward making that substrate available in organic form[1].

[1] Commission services: clarification is needed if gellan gum can be considered of agricultural origin under EU law, which is a condition for it to be organic.

Substance Oak extract (feed)

The group is unable to decide on whether the use of oak extract as a feed additive is in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007. The group would like to have more information about the purpose.

Monodicalcium phophates (feed)

If Monocalcium phosphate is produced in a similar chemically way as Monodicalcium phosphate, then Monodicalcium phosphate is a better alternative for feed in aquaculture.
The addition of Monodicalcium phosphate to Annex V and VI of Regulation (EC) No. 889/2008 is recommended. However, the group stresses the need to phase out chemically produced substances, promoting the use of alternatives as they become available.

Velay Green Clay (feed)

The use of the additive "natural mixture of illite, montmorillonite, kaolinite (feed additive No 1g599)", is in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007.

The addition of natural mixture of illite, montmorillonite, kaolinite (feed additive No 1g599) to Annex VI 1. Technological additives d) of Regulation (EC) No 889/2008 is recommended with the mention as "Binders and Anti-caking agent only".

Substance Yeast and Yeast products (feed)

The use of the feed additive "Yeast and Yeast products" as feed material, is in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007, providing the specific product is approved in horizontal legislation and from organic sources when available.

Substance Lutein/Zeaxanthin (feed)

The use of the feed additive Lutein/Zeaxanthin as colourants, including pigments in poultry feed, is not in line with the objectives, criteria and principles of Regulation (EC) No 889/2008.

Substance bentonite (feed)

The use of the feed additive bentonite as feed additive is in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007.

Substance Xanthan gum (feed)

The use of Xanthan gum as a feed additive, is in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007.

The addition of Xanthan Gum to Annex VI to Regulation (EC) No 889/2008 is recommended.

2. CONSIDERATIONS AND CONCLUSIONS

2.1. Substance Sulphuric Acid as processing aid for the production of two food products a) Toasted Corn snacks and b) Locust bean gum

Introduction, scope of this chapter

The assessment of Sulphuric acid relates to the request for inclusion of this substance as a processing aid in Annex VIII Section B (Processing aids used in organic food production).

The dossier was submitted by Spain.

Authorisation in general production and in organic production

Sulphuric acid is authorised by Council Regulation (EU) No 231/2012 regarding food additives & specifically in Regulation (EC) No 1333/2008.

Agronomic use, technological or physiological functionality for the intended use

The dossier includes two separate, but similar processes for which sulphuric acid may be used.

In the production of Toasted corn snacks. In this case sulphuric acid is proposed as a processing aid, early in the process, where the maize is treated with concentrated sulphuric acid to remove the coat of the grain, before neutralisation, washing, drying & frying. Note that further down the dossier refers to the production of corn or pulse based snacks, although no details are given for the production of pulse based snacks.

In the production of Locust bean gum. In this case the dossier reports that sulphuric acid is proposed for use, as a processing aid, early in the process where organically grown beans are treated with concentrated sulphuric acid to remove the seed coat prior to milling and extraction to produce locust bean gum.

Necessity for intended use, known alternatives

For both uses the dossier describes the alternatives currently used to produce organic versions of the products as sulphuric acid is currently not permitted for either purpose. There are alternatives to the use of sulphuric acid in both case. In both cases the removal of outer layers is currently done using heat.

Organic toasted corn snacks and organic locust bean gum are currently available, made without the use of sulphuric acid.

Origin of raw materials, methods of manufacture

Sulphuric acid is produced from sulphur dioxide by the contact process. Sulphur dioxide is produced by burning sulphur. The resultant sulphur dioxide is reacted with oxygen in the presence of catalyst (Vanadium Pentoxide) to produce sulphur trioxide, which when dissolved in water produces sulphuric acid. It is used in mentioned in the dossier that it is used in food grade for both applications.

Environmental issues, use of resources, recycling.

Sulphuric acid is extremely corrosive and toxic in concentrated form (Source: USDA). It must be handled carefully in controlled conditions to avoid violent reactions and toxic gas production, It must be reacted with calcium carbonate to neutralise excess, once used. This results in production of waste calcium sulphate, which must be disposed of. No details of the fate of the excess calcium sulphate in either process are described in the dossier.

Sulphur dioxide, and sulphur trioxide produced as intermediates in sulphuric acid production and sulphuric acid itself are contributors to acid rain if released into the atmosphere.

The dossier reports that the use of sulphuric acid has environmental benefits compared with the currently used processes for production of corn snacks.

Specifically for the production of corn snacks the sulphuric acid step eliminates a subsequent cooking step. This saves energy (50%) and water 20% from the cooking stage. It also reduces corn losses compared to the current process by 30%. The dossier also reports that product improvement is seen by changing to the sulphuric acid process in that the product absorbs 21% less oil than the cooked product reducing oil usage, energy in frying and incidentally a reduction in acrylamide levels of 50%.

Specifically for the production of locust bean gum the dossier does not report or quantify any environmental benefit. It does identify a quality improvement by reducing the generation of toxic materials during combustion and carbonisation of the skin of the locust bean.

Animal welfare issues
None identified or expected from either of the requested processes.

Human health issues
Concentrated sulphuric acid must be considered a hazardous compound for workers. However, correctly handled the risk is low.

Sulfuric acid is considered GRAS[2] when used in certain food production at low concentrations, according to FDA's good manufacturing practices.

The dossier reports for corn based snacks a reduction in 50% of acrylamide compared with similar snacks produced by heating of the corn to remove the outer layer. No documentation is provided to support this claim. The resultant snacks are also reported to contain less fat than the alternative.

The dossier claims unquantified benefits for human health by reducing toxic intermediaries produced as a result of the thermal peeling of the carob beans.

Food quality and authenticity
The dossier claims improved quality of organic corn snacks by enabling reduction in oil content of the finished product and reduced acrylamide levels in the final product.

The dossier claims improved physico-chemical and organoleptic quality in the final locust bean gum produced with sulphuric acid compared with the alternative. (reduced colour and higher viscosity)

Traditional use and precedents in organic production
Sulphuric acid is permitted in Annex VIII Section B of Regulation (EC) No 889/2008 as a permitted processing aid with the specific conditions "Gelatine production" and "Sugar(s) production".

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Sulphuric acid is not listed as permitted in: §205.605 of the USDA National Organic programme as a "Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

Sulphuric acid is an additive authorised in several conventional food (including cider) BUT not for wine

Other relevant issues
The use of sulphuric acid to remove surface coatings of maize, pulses and locust beans may be considered as analogous but opposite to the use of caustic (sodium or potassium) hydroxide to peel

[2] Generally recognised as Safe by USFDA

vegetables. This process has previously been rejected by EGTOP. (EGTOP report Food III) This application related specifically to the peeling of salsify. The following argument was used to reject it.

"The use of chemical methods to peel organic fruit and vegetables in general is not consistent with the expectations of the Group (Article 6(c) of Regulation 834/2007) and there are preferable alternatives available (Article 21.1(i) of Regulation 834/2007). It is also not in line with Article 4(c) of Regulation 834/2007 regarding use of chemical methods. Further the Group is concerned that approval for this specific use will encourage applications for other uses for peeling of organic fruit and vegetables." Ref 2.

Much of the above arguments apply to the current applications, although the availability of preferable alternatives is less clear in the current application.

Lye peeling of fruits is not permitted in any organic standards as far as the group is aware.

Reflections of the Group / Balancing of arguments in the light of organic production principles
The group compared the permitted uses in gelatin and sugar production and considered that they were different to this application due to the fact that sulphuric acid is essential for the two uses already permitted.

Conclusions
The use of Sulphuric acid as a processing aid in the production of corn snacks and locust bean gum is not in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007.

The addition of Sulphuric acid as a processing aid in the production of corn snacks and locust bean gum to Annex VIII Section B of Regulation 889/2008 is not recommended.

2.2. Silicon dioxide as flow agent for use in hot chocolate powder

Introduction, scope of this chapter
Assessment of silicon dioxide as a flow agent for hot beverage delivered in automatic machines.

The request concerns a change of disposition of the substance as a food additive in the Commission Regulation (EC) No 889/2008, in Annex VIII Section A.

The dossier was submitted by the United Kingdom.

Authorisation in general production and in organic production
According to Commission Regulation (EU) No 231/2012, the food additive silicon dioxide (E 551) is defined as 'an amorphous substance, which is produced synthetically by either a vapour-phase hydrolysis process, yielding fumed silica, or by a wet process, yielding precipitated silica, silica gel or hydrous silica.'

Silicon dioxide (E551) is widely used as a flow, anti-caking or anti-foaming agent for powdery foodstuffs in numerous food type (from cheese to chewing gum or salt) in Regulation (EC) N° 1333/2008.

It also usable in dry cereal products for infants food in a limited amount 2000mg/kg Regulation (EU) No 1129/2011.

In organic Regulation (EC) No 889/2008, silicon dioxide is authorised as an anticaking agent (additive) for spices, propolis and flavours.

Agronomic use, technological or physiological functionality for the intended use
According to Fruijtier-Poelloth (2012), 'there are three main types of silicon dioxide (silica, SiO_2) which are all found under the CAS No 7631-86-9, i.e. (i) crystalline silica, (ii) amorphous silica

(naturally occurring or as a by-product in the form of fused silica or silica fume) and (iii) synthetic amorphous silica (SAS) including different forms: silica gel, precipitated silica, pyrogenic (fumed) silica and colloidal silica (silica sol)'.

EFSA panel noted that among these three types of silicon dioxide, synthetic amorphous silica (SAS) is the only one authorised as a food additive (E 551) and that SAS in the form of 'colloidal silica' is not authorised.

This additive is widely used in many sectors including food. 22 000 tonnes have been produced or imported in the EU en 2015. The majority (approximately 80%) of precipitated silica in Europe is used in elastomers. Smaller quantities are used in detergents, cosmetics, polymers, plastics, sealants, paints, coatings and as carrier material, water absorbent, flow agent or bulking agent.

Silicon dioxide is used for fluidising food stuff and to avoid caking in salts and dry spices. It is also a carrier of food flavouring. It can be found in 19 out of 22 food categories in Europe.

Necessity for intended use, known alternatives
Silicon dioxide is very useful for food reconstitution e.g. food in powder to which liquid should be added before consumption (instant coffee, dehydrated soups…).

For automatic dispense of beverage, anti-caking agent is a necessity as the machine should have a fluidised powder to go through the machine pipes. However mechanical blending is a simple alternative to this. It could be possible to deliver powder packs by the automatic machine along with hot water to give the consumer the beverage to blend.

Technological function in food;
The silicon dioxide is used for anticaking, fluidiser and carrier

Origin of raw materials, methods of manufacture
Two different process technologies are used for the manufacture of SAS, (i) the thermal process

resulting in the production of pyrogenic or fumed silica and (ii) the wet process yielding precipitated silica, silica gel or hydrous silica.

• Thermal process

In the information provided to EFSA (CEFIC, 2016b, 2017 (Documentation EFSA)), the production process of pyrogenic (fumed) SAS was summarised as being produced by hydrolysis of volatile chlorosilanes (e.g. tetrachlorosilane) in an oxygen (air)/hydrogen gas flame reactor.

The pyrogenic (fumed) silica forms agglomerates inside the cooling system. The solid particles are separated from the off-gas (contains hydrochloric acid), e.g. by filtering. Afterwards, additional adsorbed hydrochloric acid on the surface of the silica is removed by a de- acidification step. The product is then bagged, filled into containers, or loaded into silo cars. The reaction parameters are kept under strict control to achieve uniform product quality. SiCl4 is converted, in the reactor, to the gaseous phase and reacts completely in a flame (flame temperature > 1,000°C) with the intermediately formed water to form SiO_2 . It is stated that the size of the SiO_2 particles in the reactor are in the range of 5–50 nm which, along the temperature gradient in the reactor, grow into larger aggregates of about 100 nm and then form agglomerates with sizes of 1–250 µm.

• Wet process

Precipitated silica

According to CEFIC (2017 (Documentation provided to EFSA n. 17)), precipitated amorphous silica is manufactured by the precipitation of diluted aqueous alkali metal silicate (e.g. waterglass solution) with a diluted acid (e.g. sulphuric acid or hydrochloric acid) in water. The solid content of the precipitate is typically between 50 and 200 g/L. The precipitate is then filtered, washed to remove salts, dehydrated and milled. After drying the precipitated silica can be milled to achieve the specified particle size distribution. After a period of time (up to 2h), a gelatinous precipitate is formed. The particle size is about 500–600 lm (ECETOC, 2006; ELC, 2009 (Documentation provided to EFSA n. 26)).

Silica gel

Silica gels are produced by the neutralisation of diluted aqueous alkali metal silicates, e.g. waterglass, with a diluted acid (e.g. sulfuric acid). The first step comprises the formation of a hydrosol, produced by the controlled mixing of the sodium silicate solution (waterglass; $Na_2O.x\ SiO_2$, x = 2–4) and diluted mineral acid (usually sulfuric acid, but other acids may also be used). The transformation of the solution into the gel state is characterised by an increase in viscosity and the development of an internal structure with larger aggregates until the complete material reaches a solid state. By controlling the washing, ageing and drying conditions, the functional physical parameters (i.e. porosity, pore size and particle size distributions, degree of aggregation and/or agglomeration, surface areas) are adjusted to produce a range of different silica gel products. Side products such as sodium sulfate are removed in the washing step. After drying, silica gels are milled to achieve the specified particle size distribution. If the pH is reduced to below pH 7 or if salt is added, the chemical subunits tend to fuse together in chains resulting in the formation a gel structure (silica gel). If the pH is kept neutral or alkaline (pH 7–10), then the subunits stay separated, and they gradually grow. These products are called silica sols (Iler, 1979).

Environmental issues, use of resources, recycling
Silica comes from mineral and is obtained by mining. Some SAS production processes use energy and others strong acids. Environmental impacts cannot be excluded for the production of silicon dioxide for food processing purposes.

Animal welfare issues
No raw materials of animal or plant origin are used to product silicon dioxide.

Human health issues
The main issue regarding human toxicity of silicon dioxide concerns the fact that the substance is known to be in a nanoparticular form.

It is considered as GRAS[3] since 1979 but a critical analysis of existing oral repeated dose studies in rodents reveals data gaps and uncertainties limiting their predictive value for the risk assessment of human dietary exposure. Some studies were based on poorly characterised particles in terms of composition, impurities or physico-chemical properties, and most reports lacked an assessment of particle size distribution.

Winkler et al. noticed that adverse effects from food-borne SAS particles cannot be excluded.

Food quality and authenticity
If silicon dioxide is used as an anti caking agent for cocoa powder in automated drinks dispensing machines, but is not available in the list of ingredients, it can be misleading for consumers.

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[3] Generally recognised as Safe (GRAS) by the US FDA

Traditional use and precedents in organic production
Silicon dioxide is already permitted in organic Regulation (EC) No 889/2008 (Annex VIII Section A) for specific purposes, anticaking agent for dry herbs and spices, and for propolis and flavours (carriers).

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
USDA National Organic Program allows silicon dioxide as a defoamer and it is allowed for other uses when organic rice hulls are not commercially available.

JAS standards only authorise silicon dioxide for processed foods of plant origin as gel or colloidal solution.

Silicon dioxide is found in IFOAM norms for organic production and processing but only as a processing aid (use as an additive is not permitted).

Other relevant issues
Silicon dioxide could be formed by particle size in the nano range.

Nanomaterials may have direct or indirect (e.g. silica particles via food) impacts on human health and could therefore pose risks.

Synthetic silica nanoparticles activate dendritic cells and mediate inflammatory reactions in the gut. The next steps are in vivo studies and comparison with human exposure data, which in turn could result in a new definition of food toxicity affecting the digestive system. However, results of this project suggest that concentrations of silica nanoparticles in food additives should be reduced.

Reflections of the Group/ Balancing of arguments in the light of organic production principles
The group considered whether market development of the organic "on the go" market alone, is it enough to authorise this substances ?

The dossier indicates that no suitable alternatives to Silicon Dioxide are possible for this specific use.

EGTOP Report Food IV[4] considered silicon dioxide should not be permitted as a processing aid in food supplements. Furthermore, that group recommended to restrict the potential for use of E551 to products containing less than 1% of crystalline silica. The report also included recommendation to provide workers with information on the health risks and the establishment of a register to monitor health risks.

In addition to that, the group considered that the use in an automated machine could mislead the consumer as there is no accompanying list of additives and processing aids at the point of sale.

The group also wants to raise awareness of the possible presence of nanoparticles, as the new organic regulation states that the production of processed organic food shall be based on the exclusion of food containing, or consisting of engineered nanomaterials and specially any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or

[4] https://ec.europa.eu/info/food-farming-fisheries/farming/organic-farming/co-operation-and-expert-advice/egtop-reports_en

aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.

In this case, the production of nanoparticles seems to be a residual effect of the process

Conclusions

The group consider that this kind of product is not necessary for health, but the group also considers that addition of silicon dioxide as an anti caking agent, specifically for cocoa powder in automated drinks dispensing machines, and exclusively for this purpose, is in line with the objectives, criteria and principles of Council Regulation (EC) No. 834/2007, in the case the drinks dispensing machines can carry a wording indicating that the cocoa powder contains silicon dioxide (without violating horizontal labeling legislation).

It therefore recommends addition of silicon dioxide as an additive in Annex VIII Section A of Regulation (EC) No 889/2008 with the specific condition "for use in automated dispensing machines", and restriction to products containing less than 1% of crystalline silica, in addition to the currently permitted uses for spices, propolis and flavourings.

The group would also like to point out to the Commission services the opportunity for further insight on nanoparticles and specifications of these kind of products[5]

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[5] Commission services: The organic Regulation 848/2018 has only restrictions with regard to 'engineered nanomaterial' as defined in Regulation (EU) 2015/2283 on novel food.

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2.3. Pine tree extracts containing natural rosin acids (in form of potassium salts)

Introduction, scope of this chapter

Assessment of Pine tree extracts containing natural rosin acids (in form of potassium salts) for corn starch production. The assessment relates to the request for inclusion of the substance as a food processing aid in the Commission Regulation (EC) No 889/2008, in Annex VIII Section B.

The dossier was submitted by Austria. (Note, submitted in parallel with a similar application for hop extracts for the same use, considered below).

Authorisation in general production and in organic production

Natural Aleppo Pine resins are used in the production of traditional Greek wines, (retsina) where they predominantly provide some antibacterial effect. They are also used as a base for chewing gum (Coppen and Hone, 1995).

Pine rosin extracts are considered food ingredients when used in wine. For the function described in the dossier they are considered as processing aids, as they fulfil the definition in the Regulation (EC) No 1333/2008: they are not consumed as food in themselves and are intentionally used in corn starch production to suppress growth of bacteria.

Certified organic Pine resins extracted by permitted processes from certified organic pine trees would be permitted in production of organic Retsina wine and in production of organic chewing gum.

Not currently allowed in non-organic form, for any use in organic production.

Agronomic use, technological or physiological functionality for the intended use

Pine tree extracts use within the corn starch industry can be considered an alternative to sulphur dioxide to control bacterial growth.

They are also used in areas such as veterinary hygiene, silage production etc. The active ingredients in pine resin (natural rosin acids) are effective against Gram-positive bacteria such as lactic acid bacteria, bacilli, clostridia, listeria but also other microorganisms (e.g. *M. tuberculosis*).

Nowadays, most rosin is used in a chemically modified form, rather than in the raw state in which it is obtained. It consists primarily of a mixture of abietic- and pimaric-type acids with smaller amounts of neutral compounds.

Necessity for intended use, known alternatives

Sulphur Dioxide is currently used for suppression of bacterial growth in corn starch production. This cannot be used in production of organic corn starch. No other alternatives to the use of pine resins are known for the production of organic corn starch with one exception. This is the use of hop extracts in the same way as the use of pine resins. There is a parallel application for addition of hop extracts to Annex VIII Section B, for use in the corn starch industry, which is also considered by this group. The dossiers presented for both hop extracts and pine resins indicate that the proposal from the corn starch industry is to use the two processing aids alternately to prevent development of bacteria resistant to one or the other.

Pine resins are not specifically needed for production of organic corn starch from organically grown maize in that the process is currently undertaken without them in Germany and Austria.

The advantages of using pine resins appear to be that the processing of organic maize can be extended as the problems associated with microbial growth are exacerbated by long processing times due to the internal recycling in the process. The pine resins reduce growth of gram positive bacteria reducing the level of these organisms in the final product. These bacteria also convert starch to carbon dioxide and organic acids. In addition to the direct loss of starch to microbial growth the acids hydrolyse starch further reducing yields. They also can create off flavours in the final product. Bacterial growth can produce gaseous metabolites including carbon dioxide and hydrogen which in turn cause foam production and increased energy use. To counteract these effects organic production is done with increased water throughput to counteract and dilute the acids produced. Levels of pine resins used are reported in the dossier as 50 to 150 ppm

Technological function in food
The pine extracts have no function in food. They are solely processing aids of relevance during the production of corn starch from maize.

Origin of raw materials, methods of manufacture
The extracts are made from conventional pine resin by extraction with steam. Rosin can be also a by-product of turpentine extraction from pine resin. Some additions such as diatomaceous earth and oxalic acid may be made during the extraction (Coppen and Hone, 1995).

Environmental issues, use of resources, recycling
No significant issues of environmental impact would be raised by permitting the use of pine extracts in sugar production.

Animal welfare issues
None. Plant derived material only. Note that by-products of the organic corn starch include corn steep liquor and maize gluten. This latter material is currently derogated at 5% in organic diets for non ruminants as it is high in essential amino acids which are difficult to add to organic feed in organic form. Increased availability of this by-product in organic form would help in this area.

No welfare issues are expected.

Human health issues
Pine resin extracts are permitted under US Federal code of regulations (2018).

No residues of the pine extracts would be transferred into the corn starch, so no human health effects are expected. Similarly no effects on operators in production plants are expected.

As an alternative to sulphur dioxide they represent the possibility to reduce health concerns for workers in the industry.

Pollach et al. (2002) highlight that pine rosin production is a by-product of the production of turpentine oil, which is harmful to the skin and toxic if swallowed. It is included in the European Biocide list. Pollach et al. (2002) also report that rosin acids are toxic to fish.

Food quality and authenticity
No effect on food quality or authenticity is expected.

Traditional use and precedents in organic production
Pine tree resins have been used as a flavouring and microbial stabiliser in wine for a very long time. Resin extracts are not traditionally used. Steam distilled resin extracts are more recent and have no tradition in food production.

They are currently not used in organic corn starch production as they are currently not listed in Annex VIII Section B to Regulation (EC) No 889/2008.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Pine extract containing natural rosin acids, is not listed as permitted in USDA National Organic Program.

Pine extract containing natural rosin acids, is not listed as permitted in IFOAM Norms.

Other relevant issues

No GM concerns as pine trees are currently not being genetically modified as far as the group is aware.

Reflections of the Group / Balancing of arguments in the light of organic production principles
Note that the dossier was submitted with a parallel one for hop extracts for use in organic corn starch production. Both dossiers identify that both hop extracts and pine resin extracts may be used alternately to reduce risk of bacterial strains resistant to one or the other developing due to overuse of a single antimicrobial preparation.

Pine rosin extracts using steam can clearly be organic, providing that the farming and processing are both certified organic.

The use of non-organic pine resin extracts should be restricted to use only for antimicrobial purposes in the processing of foods. sugar production.

The group is aware of the limited availability of organic pine that makes difficult today to limit the use of pine extract for food processing to organic origin. Nevertheless, in the future when availability is in place it should be restricted to organic production.

Conclusions
The group considers pine rosin extract to be in line with the objectives, criteria and principles of Council Regulation (EC) No. 834/2007.

The addition of pine rosin extract as a processing aid to Annex VIII Section B of the Reg. (EC) No. 889/2008 is recommended with the restriction of use “only for antimicrobial purposes in production of foods from plant origin and not only for starch and sugar ” and, when available, with the restriction of “from organic production”.

The group is not aware of other possible opportunities for similar uses in other sectors, for example in the production of potato starch. However, it seems unnecessary to require other similar sectors to corn starch or sugar production to make separate applications for inclusion in annex VIIIB. It may be that such uses could be allowed, by for example using the following wording in annex VIIIB. Pine rosin extract, with the following revised condition: With regard to foodstuffs of plant origin:” only for antimicrobial purposes in production of food. When available from organic production “.

References

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- US Code of Federal Regulations, 2018. Food and Drugs, PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE, Subpart A—General Provisions, §182.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.20

2.4. Hop extracts containing natural hop alpha acids, hop beta acids and their derivatives (in form of potassium salts)

Introduction, scope of this chapter

Assessment of Hop extracts containing natural hop alpha acids, hop beta acids and their derivatives (in form of potassium salts) for inhibition of micro-organisms in corn starch production process.

The assessment relates to the request for inclusion of the substance as a food processing aid in the Commission Regulation (EC) No 889/2008, in Annex VIII Section B.

The dossier was submitted by Austria. (Note, submitted in parallel with a similar application for pine resins for the same use, considered above.)

Authorisation in general production and in organic production

Organic hops are widely used as organic ingredients in organic beers.

Certified organic hop extracts could in theory be made using organic hops as the extraction method described in the dossier does not require any non-permitted solvents; the extraction is performed with liquid carbon dioxide. However, the group is unaware of any production of significant quantities of organic hop extracts in the EU.

Hop extracts are considered food ingredients when used in beer, while for the function described in the dossier they are considered as processing aids as they fulfil the definition in Regulation (EC) No 1333/2008[6], they are not consumed as food in themselves and are intentionally used in corn starch processing to suppress growth of bacteria.

[6] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives

Agronomic use, technological or physiological functionality for the intended use
Hops and hop extracts of various types are used widely in the production of beer, where they predominantly provide bitterness. Other components of the extracts provides hop aroma to beers. They also traditionally provided some antibacterial effect in beers, particularly before the widespread use of pasteurisation.

The active ingredients in hops – natural hop alpha acids (humulones), hop beta acids (lupulones) and their derivatives – are particularly effective against Gram-positive bacteria such as lactic acid bacteria, bacilli, clostridia, listeria but also other microorganisms (e.g. *M. tuberculosis*).

Hop acids were also tested in a range of different other fields of application apart from brewing industry (e.g. animal dietary supplements, pharmaceuticals, veterinary hygiene, dental hygiene, silage production and others) but these uses are not commercially feasible so far as far as the group is aware. Parallel to that, hop acids (termed "natural antibacterial") were introduced to the sugar industry at the beginning of the 1990s as an alternative to formaldehyde and dithiocarbamates (and other conventional chemical products) in order to control bacterial growth in the extraction area. The dossier reports that Hop extracts have recently been introduced to the conventional corn starch sector.

Necessity for intended use, known alternatives
Sulphur dioxide is the normally used antimicrobial product during non organic corn starch production. This cannot be used in production of organic corn starch. No other alternatives to the use of hop extracts are known for the production of organic corn starch with one exception. This is the use of pine resins in the same way as the use of hop extracts. There is a parallel application for addition of pine resins to Annex VIII Section B, which is also considered by this group. The dossiers presented for both hop extracts and pine resins indicate that the proposal from the corn starch industry is to use the two processing aids alternately to prevent development of bacteria resistant to one or the other.

Hop extracts are not specifically needed for production of organic corn starch from organically grown maize in that the process is currently undertaken without them in Germany and Austria.

The advantages of using hop extracts (or pine resin extracts) appear to be that the processing of organic maize can be extended as the problems associated with microbial growth are exacerbated by long processing times due to the internal recycling in the process. The extracts reduce growth of Gram positive bacteria reducing the level of these organisms in the final product. The bacteria also convert starch to carbon dioxide and organic acids. In addition to the direct loss to microbial growth the acids hydrolyse starch further reducing yields. They also can create off flavours in the final product. Bacterial growth produces gaseous metabolites including carbon dioxide and hydrogen which in turn cause foam production and increased energy use. To counteract these effects, organic production is done with increased water throughput to counteract and dilute the acids produced. Levels of hop beta acids used are reported in the dossier as 50 to 150 ppm.

Technological function in food;
The hop extracts have no function in finished corn starch as a food. They are solely processing aids of relevance during the production of starch from maize.

Origin of raw materials, methods of manufacture
The extraction is made with supercritical carbon dioxide and the extracts obtained contain a high proportion of beta acids (lupulones), which are the most effective antimicrobial compounds in hops.

Beta acids have a lower value in the brewing process than the alpha acids, which provide bitterness in beer.

Pollach et al. (2002) mention that the beta acid extract of hops specifically designed for use in the sugar industry is prepared as an alkaline solution, presumably using potassium hydroxide, to produce the potassium salts of the beta acids.

Environmental issues, use of resources, recycling
No significant adverse issues reported. Possible reduced use of energy and water reported in the dossier.

Animal welfare issues
None. Plant derived material only. Note that the by-product of the organic starch production include corn steep liquor and maize gluten which can be used as animal feed. In particular conventional maize gluten is currently derogated for up to 5% of non ruminant (pig and poultry) diets as it contains essential sulphur containing amino acids that are difficult to find in sufficient quantities in organic form. Increased production of organic maize gluten would be expected to be a useful by product of approval of this compound. No welfare issues are expected.

Human health issues
Hop extracts are GRAS[7] (US Code of Federal Regulations, 2012).

No residues of the hop extracts would be transferred into the corn starch and no significant adverse health concerns are associated with hop extracts, so no human health effects are expected. Similarly, no effects on operators in production plants are expected.

As an alternative to sulphur dioxide they may represent the possibility to reduce health concerns for workers in the industry.

Food quality and authenticity
No effect on food quality or authenticity is expected.

Traditional use and precedents in organic production
They are currently not used in organic corn starch production because they are not listed in Annex VIII Section B of Reg. (EC) No 889/2008, specifically for this purpose.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Hop extracts containing natural hop alpha acids, hop beta acids and their derivatives is not listed as permitted in USDA National Organic Program.

Hop extracts containing natural hop alpha acids, hop beta acids and their derivatives is not listed in IFOAM Norms as permitted.

Organic hop extracts can be produced as the process of production is done using supercritical carbon dioxide extraction.

Other relevant issues
No GMO concerns as hops are currently not being genetically modified, as far as the group is aware.

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

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[7] Generally recognized as safe by the US FDA

Note that the dossier was submitted with a parallel one for pine resin extracts for use in corn starch production. Both dossiers identify that both hop extracts and pine resin extracts may be used alternately to reduce risk of bacterial strains resistant to one or the other developing due to overuse of a single antimicrobial preparation.

In the group opinion, the use of non-organic hop extracts in brewing would not help the development of the organic brewing sector. Therefore, the use of non-organic hop extracts should be restricted to only antimicrobial purposes in the processing of food products such as sugar and corn starch.

The group is aware of the issue of availability of organic hops that makes it difficult today to limit the use of hop extract for corn starch production to organic origin. Nevertheless, in the future when availability is in place it should be restricted to extracts from organic hops.

Conclusions

The group considers hop extracts as a food processing aid in line with the objectives, criteria and principles of Council Regulation (EC) No. 834/2007.

The addition of hop extracts as a processing aid to Annex VIII Section B of the Reg. (EC) No. 889/2008 is recommended with the restriction of use “only for antimicrobial purposes in production of foods from plant origin ad not only for starch and sugar” and, when available, with the restriction of “from organic production”.

The group is not aware of other possible similar uses in other sectors, for example in the production of potato starch, but it seems unnecessary to require other similar sectors to corn starch or sugar production to make separate applications for inclusion in Annex VIII Section B. It may be that such uses could be allowed, by for example using the following condition in Annex VIII Section B. With regard to foodstuffs of plant origin: only for antimicrobial purposes in production of foods. When available from organic production .

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- Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives

- US Code of Federal Regulations, 2012. Food and Drugs, PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE, Subpart A—General Provisions, §182.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates). https://www.gpo.gov/fdsys/granule/CFR-2012-title21-vol3/CFR-2012-title21-vol3-sec182-20

2.5. Kaolinitic clay as a processing aid in olive oil extraction processes

Introduction, scope of this chapter

Assessment of kaolinitic clay as a processing aid in olive oil production. The assessment relates to the request for inclusion of the substance as a food processing aid in the Commission Regulation (EC) No 889/2008, in Annex VIII B.

The dossier was submitted by Spain.

Authorisation in general production and in organic production

According to the dossier kaolinitic clay is composed by three type of clay: Kaolinite (85%), Illite (7%) and bentonite (7%).

The dossier relates to Kaolinitic clay but mentions the specific Einecs Nº .215-286-4 which relates only to Kaolin, (caolinita)

The purity specification for kaolinitic clay is significantly higher than for Kaolin as an additive. (see lead limits) The dossier claims that it could be considered as equivalent to Kaolin. However, the difference in levels is 70mg/kg in Kaolinitic clay vs 5mg/kg in Kaolin.

Aluminium silicate (E559) aka Kaolin is authorised in general food regulation only for food supplement supplied in a solid form. (Regulation 2018/1497).

Bentonite (E558) is authorised in general food regulation only for food supplement supplied in a solid form. (Regulation 2018/1497)

However, E558 and E559 have been discarded from the list of authorised food additives since 2014 for other uses.

Agronomic use, technological or physiological functionality for the intended use

Kaolinitic clay is deemed to increase yield ratio during olive oil extraction and the oil quality.

in the Spanish decree cited in the dossier, kaolinitic clay is used as a co-adjuvant for extraction of virgin olive oil and bentonite as a bleaching agent (decolouration purpose) for refined plant oil.

Necessity for intended use, known alternatives

It seems to improve extraction in quality and quantity but no figures were added to the dossier.

Technological function in food

None

Origin of raw materials, methods of manufacture

The material comes from mining. A Spanish mining site is quoted in the dossier.

Environmental issues, use of resources, recycling

Environmental impact assessment is done on the mining site.

Animal welfare issues

No welfare issues are expected.

Human health issues

Aluminium silicate can be found in nanoparticular size range.

Food quality and authenticity

The dossier claims improved finished product quality.

As a processing aid its use will not be labelled

Traditional use and precedents in organic production
None reported

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Aluminium silicate (E559) is not listed as permitted in USDA National Organic Program.

E558 and E559 are listed in JAS standards and are limited to be used for processed foods of plant origin.

E 559 is not listed as permitted in IFOAM Norms but bentonite is listed in processing aid section only for fruit and vegetable products.

Other relevant issues
No GM concerns

Reflections of the Group / Balancing of arguments in the light of organic production principles
Kaolinitic clay is not E559 and the group suggest to correct the wording in the Annex VI.

Kaolin, (E559) is authorised as additive in EU, eg for use in sugar production and for herbs, spices and seasonings.

Bentonite (E558) is clearly approved for use as a processing aid in organic foods of plant origin & and a sticking agent for organic mead according to Regulation (EU) No 889/2008.

The purity criteria of the mixture Kaolinitic clay, does not meet the requirements of the specification for lead, that applies to the individual additives, E558 and E559. However, it is clear that this application is for the use of the mixture Kaolinitic clay as a processing aid.

The individual component of the kaolinitic clay, Illite, is not approved as an additive on its own and the consequences of its use cannot be assessed.

Conclusions
The group considers that the use of individual additives, kaolin or bentonite as filtration aids in the processing of olive oil would be in line with the objectives, criteria and principles of Council Regulation (EC) No. 834/2007, only if they meet the specification for additives under Commission Regulation (EU) No 231/2012.

However, the mixture known as kaolinitic clay does not appear to meet the specification for use as an additive.

The addition of Kaolinitic clay as a processing aid to Annex VIII Section B of the Regulation (EC) No. 889/2008 is not recommended.

References
COMMISSION REGULATION (EU) 2018/1497 of 8 October 2018 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards food category 17 and the use of food additives in food supplements

https://webgate.ec.europa.eu/foods_system/main/?event=document.view&identifier=17630&documentCrossTable=legislation&documentType=legislation&documentTypeIdentifier=-1

2.6.Sodium metabisulphite (pending issue from EGTOP report FOOD III)

The group considered briefly the request for consideration of the dossier from Belgium requesting removal of sodium metabisulphite with the specific condition "for crustaceans" from Annex VIII Section A of Regulation (EC) No 889/2008. This dossier was submitted for EGTOP report Food III, but was not discussed due to lack of time.

The group decided that, as the dossier was dated 2014, it was not appropriate to completely review this.

The group recommended that the Commission write to Belgium asking for an updated dossier, which should then be submitted, with high priority, to a future subgroup meeting.

2.7. CleanSmoke (DE, additional information, pending) (pre-purified smoke (DE))

Introduction, scope of this chapter

The dossier requests extending the implementation of Article 26 (4)of Regulation (EC) No 889/2008 to smoking with "smoke generated from primary products".

As it is a processing method the purified smoke used for the smokehouse could be seen as a product and be included to Annex VIII Section B (other products) "smoke regenerated from smoke condensate"

The dossier was submitted by Germany

Authorisation in general production and in organic production

The Clean smoke process is authorised as GMP (Good Manufacturing Practices) by Regulation (EC) No 1321/2013.

The new regulation (EU) 2018/848 Annex II Part IV 1.1. stipulates that *"Food additives, processing aids and other substances and ingredients used for processing food and any processing practice applied, such as smoking, shall comply with the principles of good manufacturing practice"*

Agronomic use, technological or physiological functionality for the intended use

The dossier describes the process of smoking with pre-purified smoke from regenerated primary smoked products in the smoke house.

The product is not sprayed or dipped or showered with smoke flavour.

Necessity for intended use, known alternatives

The claims in the dossier are that this process minimises contaminants which are present in traditional smoking methods. It also claims a positive overall environmental impact due to reduced environmental emissions (see below).

Origin of raw materials, methods of manufacture

Origin of raw materials:

The primary smoke production process starts with nature's finest woods from managed and certified forest programs for the construction industry which are beaten and sawn. The sawdust is a high quality by-product in the saw mill. This means that not a single tree is cut or transported for the production of the smoke itself. The untreated sawdust is left to smoulder under controlled conditions. This process avoids the risk of explosion and protects the environment thanks to optimum exhaust air purification.

Methods of manufacture

The smoke is directed into a condenser and sprayed with drinking water to capture it. In the course of multiple filter processes without any chemical additives, the smoke is purified of ash, tar and carcinogenic Polycyclic Aromatic Hydrocarbons (PAHs). Ash and charcoal are collected – the tar sinks down to the bottom. At the end, even the smallest particulates are suspended in the filter. What is left is smoke captured in drinking water, which contains everything a smoked product needs.

The stable smoke is blown into the smoking chamber through tubes and consequently remains in an environmentally friendly closed circuit that significantly reduces CO2 emissions

Environmental issues, use of resources, recycling.
The report of the German Institute of Food Technologies (Sergiy Smetant, Stefan Töpfl 2015) compare three smoking systems (friction, smouldering and clean smoke) in a Life Cycle Assessment (LCA). The results shows that the Clean Smoke Technology lowers e.g. the CO_2 emissions, no emission of NO and CO, less water use compared with the other two techniques.

Animal welfare issues
None

Human health issues
The dossier shows that the stability and microbiological stability of food is the same as with traditional smoking. The only difference is, that the smoke used is purified and therefore less contaminated with PAH. As consumers like healthy organic food, the reduction of PAH is a good argument to use this technique.

Food quality and authenticity
The dossier claims that it is a smoking process as the conventional one. The quality of the final products is the same as with conventional smoking.

Organic products should be healthy according the regulation and contain less contaminants

Traditional use and precedents in organic production
Only the first and the final steps of the process are the same or similar to the traditional process. The step between these two steps, the cleaning step is new.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Smoke flavours are permitted in the US under USDA NOP standards para 205.605 Flavours, using only non-synthetic sources and not be produced using synthetic solvents and carrier systems or any artificial preservative. But, the permission of flavours are not comparable with the process described in the application. It is not a flavour, it is only a process purifying smoke before the smoking process.

Other relevant issues
In the new organic regulation (Regulaion 2018/848 Annex II Part IV 1.1. it is mentioned that … and any processing practice applied, such as smoking, shall comply with the principles of good manufacturing practice. The clean smoking process is authorised as GMP.

In the current regulation processing methods are not defined in detail. Regulation (EC) No 889/2008 mentioned in Article 26(4) that the processing practice applied shall respect the principles of good manufacturing practice. As the requested process is authorised as GMP it should be discussed if the process needs an evaluation by EGTOP – it is permitted now.

The dossier claims that it does not mislead the consumer’s expectation because it is “smoke” and not smoke flavor and it is healthier than traditional smoke. Furthermore, Article 3(c) of Regulation No (EU) 834/2007 highlights in the general objectives that a process should not harm the environment, human health…. The clean smoking process is an innovative process to get smoked products without unwanted substances.

Furthermore the clean smoke process is awarded as “Best Available Technique “ (BAT). In the already published FDM-BREF Conclusions BAT 26 (fish) and BAT 29 (meat) "the use of purified smoke" is classified as the only smoke generation method as "best available technique" for the reduction of air emissions. The technique is recommended as procedure regarding product characteristics and environmental protection.

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

The main document of the dossier was in German so not understandable to most of the group. A range of additional documentation was received in English. This additional documentation included criticism of the original German dossier and of the Expert Group in a document prepared by JAM Consulting.

Discussion about Product or process

As it is not clear whether we have to evaluate the process (smoking) or the product (pre-purified smoke) the discussion was about this fact.

The dossier does not clearly indicate whether the applicant considers that the item under discussion is a process or a product.

Our role in this case is to evaluate whether this application concerns a product, in which case this would be within EGTOP’s current scope, or whether alternatively this may be considered a process in which case it is not within the scope of this particular group.

It is clear that the technique of condensation and cleaning of smoke only relates to the production of a purified extract used as an alternative to traditional smoking. Therefore, it is possible to consider the pre-purified smoke as a product for consideration as to whether or not it meets the criteria for organic production in Regulation (EC) No 834/2007.

General remarks

The group considered that we do not wish to assess this single dossier from the point of view of a process. The group suggests that the Commission should not analyse a single process but review processes for their properties.

The group considered whether it is within our scope to discuss and recommend amendments to articles of Regulation (EC) No 889/2008 (specifically, article 26). However, that would be for the Commission to consider. Our role would be to consider whether the application is within the objectives, criteria and principles for organic production in Regulation (EC) No 834/2007.

Discussion about processing techniques

Processes or techniques are likely to be assessed for the new regulation and criteria for that are to be developed. Smoking techniques are already specifically permitted, so this consideration should be whether the process of use of condensed and purified smoke can be regarded as smoking. It is for the Commission to decide whether, in accordance with horizontal legislation on additives, flavourings or food hygiene the cleanSmoke process as described in the dossier could be regarded as an acceptable variant of the smoking process.

It is clear that the applied process is compliant with GMP and therefore may be compliant both with the requirements of current regulations and Regulation (EC) No 2018/848. As the clean smoking process is authorised as GMP it is permitted and does not need to be discussed by EGTOP.

The regulation does not prescribe how smoking should take place.

Therefore, the group was not able to reach a firm conclusion on whether the process (smoking with pre-purified smoke) or the product (pre-purified smoke) is in line with the objectives, criteria and principles of current organic regulations.

2.8. Substance Sucrose Esters (E473)

Introduction, scope of this chapter

This chapter continues the examination of Sucrose esters (E473) for the surface treatment of organic fruit. In particular, it relates to the request for review of findings of EFTOP Report Food VI (December 2019). That group considered the application of NL for inclusion of this substance as a food additive in Annex VIII Section A of Regulation (EC) No 889/2008.

Additional material was submitted by NL. It consists only of a letter and photocopies of eight articles, scientific papers or parts thereof. Of these only two are in English and one consisted of two photographs only. The letter refers to 9 reports, but only eight were received.

This chapter includes a copy of the report of EGTOP Food VI with further comments and conclusions added. They are highlighted in yellow, to separate them from the previous findings which have been included in full.

Authorisation in general production and in organic production

EU. Sucrose esters (E473) are authorised as a food additive by Regulation (EC) No 1333/2008 in a wide range of food, with purposes including stabiliser and emulsifier. For most of the applications listed there are maximum specified levels. However, for the surface treatment of fruit "*quantum satis*" is permitted. Note that it is not permitted for surface treatment of vegetables. The listing has a footnote which indicates that in non-organic food the treatment with sucrose esters may be combined with other fruit wax treatments.

Sucrose esters (E473) are not authorized in Regulation (EC) No 889/2008.

Agronomic use, technological or physiological functionality for the intended use

The use appears to restrict oxygen access to the fruit, reducing growth of micro-organisms and so reducing spoilage of the fruit in or after storage. Other treatments with compounds such as Sulphur dioxide have different modes of action and are not permitted for organic fruit. Treatment with waxes is the "traditional" method of surface treatment of citrus fruit. The data provided is limited to pears, but appears to have a positive effect over a storage period of 11 days. The data also contains information on the use of plasma gas in the same trial on pears, but the effect is at best marginal.

The further information includes additional information relating to pears, citrus fruits, pineapples, nectarines (photographs only) and cherries. Most are in languages other than English. The letter provides a very brief summary of the results, but in most cases it is not possible to verify that summary from the documentation received.

Necessity for intended use, known alternatives

The use is not necessary for fruit production. However, it may reduce waste, and costs and enable fruit to be stored, on display or in the home for longer before spoilage, resulting in an increasing proportion of the fruit harvest being consumed.

The additional information supports this view for a wider range of fruits.

Origin of raw materials, methods of manufacture

Sucrose esters are made by enzymic combination of sucrose with fatty acids derived from palm oil. Documentation accompanying the application appears to indicate that the application proposed will use organically certified Sucrose esters. However, this would not be within the scope of EU organic regulation as Sucrose esters may not be of agricultural origin. Further, it is not absolutely clear whether both the Sucrose and the palm oil would be organic or just the sucrose.

The letter confirms that the operator will only use sucrose esters produced from lauric acid from coconut oil rather than from palm oil. It is not clear how this will apply to possible competitors.

Environmental issues, use of resources, recycling.

On the positive side this treatment could significantly reduce spoilage of fruits, reducing waste, transport etc. creating a significant, although unquantified environmental saving. However, the production of palm oil in particular is environmentally damaging and organic production of palm oil alone does not necessarily address the main concerns of deforestation.

The additional information confirms that the sucrose esters produced by the company supporting the application are produced from coconut oil, rather than from palm oil. This removes the concern over palm oil sustainability and deforestation, but it is not clear whether all sucrose esters are produced from coconut oil or whether it could also be produced from palm oil. This concern must be addressed or the conditions allowing this product should include the requirement that the lauric acid element must come only from sustainable coconut plantation. The letter does not provide any further information relating to the use of certified organic ingredients to make the sucrose esters, although this was mentioned in the intitial dossier.

Animal welfare issues

None

Human health issues

The permitted levels of Sucrose esters were modified downwards by the EFSA in 2017 as a result of evidence that for some uses, especially soft drinks and baked goods the levels consumed could exceed the ADI. Ref: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5087.

In 2012, the EFSA committee considered data and concluded that the surface treatment of fruit lead to a maximum contribution of 0.25% of the ADI. Ref: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2658

The letter points out that the fact that the conditions for use on fruit include the provision for sucrose esters to be used at "*quantum satis*" indicates that the EFSA has deemed that there will be no human health concerns with the use of sucrose esters as a fruit surface treatment.

Food quality and authenticity

The treatment of fruit with Sucrose esters may improve the quality of fruit purchased and consumed due to the reduction in spoilage. However, in a manner similar to surface waxes the treatment cannot be considered as authentic as it cannot normally be detected by the consumer and current legislation does not require its use to be labelled. The public may be unlikely to consume organic fruit when labelled as surface treated with sucrose esters.

The letter does not address the fact that the application of sucrose esters to the surface of fruit is not clear to the consumer and therefore this major concern expressed by EGTOP Food VI group is not removed or affected by the letter.

The letter confirms the view that in terms solely of quality of fruit consumed the addition of sucrose esters will provide some improvement.

Traditional use and precedents in organic production

While fruit has long been treated with waxes to improve appearance and shelf life there is no tradition of using sucrose esters to support this use.

The letter claims that sucrose esters are an improvement over the traditional use of waxes to improve shelf life of fruit as it does not provide an artificial shine

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

Sucrose esters are not listed in USDA National Organic Program as permitted additives. Ref: https://www.ecfr.gov/cgi-bin/textidx?c=ecfrandSID=9874504b6f1025eb0e6b67cadf9d3b40andrgn=div6andview=textandnode=7:3.1.1.9.32.7andidno=7#se7.3.205_1605 Sucrose esters are not listed in IFOAM Norms as permitted additives in Appendix 4 Table 1. Ref: https://www.ifoam.bio/sites/default/files/ifoam_norms_july_2014_t.pdfOther relevant issues

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

The group expressed concerns over the use of Sucrose esters as an additive.

Also concerns regarding labelling. The use may have to be labelled as this is an additive, depending on horizontal legislation[8]. Unlabelled use would not make it clear to the consumer that they were consuming Sucrose esters, both for fruit where the skin is consumed such as pears, cherries etc. and when using the zest of citrus fruits etc. Its use is questionable also from the authenticity perspective, as, especially without clear labelling, consumer may be misled on the product freshness. The classification of this compound as a post-harvest treatment or food additive is not entirely clear.

The letter provides no further information on the above concerns.

No information was provided on use of this additive on other fruits, particularly stone fruits. The group is aware that this use could be beneficial, particularly in certain climatic areas and for certain fruits. However, the dossier contained insufficient information to make an informed decision.

The letter and accompanying documentation support the view that the application of sucrose esters to fruit including pears, cherries, nectarines and pineapples has a positive effect on shelf life of those fruit.

No formal request for approval of plasma gas has been received. However, there is documentation with the application for Sucrose esters which includes information on plasma gas. This provides little to recommend its use and certainly does not provide sufficient information to allow this group to consider it as a dossier. The previous recommendation of EGTOP Food III that "In the Group's opinion, a decision should be taken as soon as these results are available to create certainty in the food industry" is not fulfilled by the information received and so that recommendation stands.

The letter confirms that plasma gas is to be the subject of further dossiesrs in the future and does not need to be further considered in this application.

Conclusions

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[8] Commission Services : fresh fruit treated with additives do not need to be labelled

The use of sucrose esters as a food additive is not in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007. This view is due to the fact it would be misleading as to the true nature of the product. This is aggravated by the fact that use would not be labelled so its presence would not be clear to consumers.

The addition of sucrose esters to Annex VIII Section A of Regulation (EC) No 889/2008 is not recommended unless the condition is labelled

2.9.Gellan gum - possibility for making this in organic form.

The group discussed a letter received from an interested party concerning implementation of the requirement in Annex VIII Section A for Gellan gum to be “Only when derived from organic production. Applicable as of 1 January 2022”. The letter requested that the implementation should be delayed by two additional years.

The letter states that one substrate for production of gellan gum is not yet available in organic form, but does not identify the substrate or progress and efforts towards making it available in organic form. The group suggests that the delayed implementation to 2022 might be granted by the Commission after receiving by the interested party further details of the substrate and prospects for progress toward making that substrate available in organic form.

2.10. Substance Oak extract (feed)

Introduction, scope of this chapter

The assessment of Oak extract relates to the request for inclusion of this substance as a feed additive in Annex VI (feed additives used in animal nutrition).

The dossier was submitted by Slovenia.

CAS- number 71011-28-4

Authorisation in general production and in organic production

Oak extract is listed in the European Union Register of Feed Additives pursuant to Regulation (EC) No 1831/2003 in Annex I List of additives 2 b Natural products – botanically defined *Quercus robur L., Q. pedunculata Ehrh*: Oak wood English cresote / extract CAS 71011-28-4 CoE 390 EINECS 275-129- 0

Agronomic use, technological or physiological functionality for the intended use

There are few scientific literatures discussing oak extract.

Van et al (2018) started from the hypothesis that hop and oak extracts have been found to possess anti-methanogenic and protein-sparing effects in the rumen. For that, an *in vitro* incubation with ruminal fluid was conducted to study the effects of increasing inclusions of hop pellets and oak extracts, alone or in combination, on ruminal fermentation parameters. Van et al (2018) found that the combination of hop pellets and oak extracts reduced total volatile fatty acid (VFA) production compared with the control (no additive), whereas these additives alone had no effect. The acetate/propionate ratio decreased with the combination of hop pellets and oak extracts, as compared to the control, whereas these additives alone had no effect. Hop pellets at the highest dose alone or in combination with oak extracts reduced the methane (CH_4) production, as compared to the control. The CH_4/VFA molar ratio was lower than the control for hop pellets at the highest dose combined with oak extracts, whereas the additives used alone had no effect. Ammonia N concentration was reduced by oak extract treatments at the highest dose alone or in combination with hop pellets, as compared to the control.

Van et al (2018) concluded that hop pellets and oak extracts altered in vitro rumen fermentation with some responses being non-linear when used in combination.

Herremans et al. (2020) evaluated the effects of oak tannin extract (OTE) added in forage before ensiling on dairy cows fed at 92% of their digestible protein requirements. Six multiparous lactating Holstein cows were used in a crossover design (two treatments x two periods). The control treatment (CON) was based on a diet including 50% of grass silage, whereas the experimental treatment (TAN) included grass silage sprayed with OTE (26 g/kg DM) just before baling. Milk yield (on average 24 kg fat protein corrected milk per day) was not affected, but both milk and rumen fatty acids profiles were impacted by OTE. Nitrogen intake (415 g N per cow per day) and nitrogen use efficiency (NUE; 0.25 on average) were not affected, but a shift from urine (-8% of N intake relatively to control, P = 0.06) to faecal N (+5%; P = 0.004) was observed with the TAN diet (P <= 0.05). Nitrogen apparent digestibility was thus reduced for TAN (-3%; P <= 0.05). The effect of OTE on ruminal and milk FA profiles suggests an impact on rumen microbiota. Nitrogen isotopic discrimination between animal proteins and diet (Delta N-15) was evaluated as a proxy for NUE. While no differences in NUE were observed across diets, a lower Delta N-15 of plasma proteins was found when comparing TAN v. CON diets. This finding supports the concept that Delta N-15 would mainly sign the N partitioning at the metabolic level rather than the overall NUE, with the latter also being impacted by digestive processes. The results agree with a N shift from urine to faeces, and this strategy can thus be adopted to decrease the environmental impact of ruminant protein feeding (Herremans et al., 2020).

Smailagic et al.(2020) assessed antimicrobial activities of the 11 wood extracts: oak (*Quercus petraea (Matt.) Liebl., Q. robur L., and Q. cerris L*.), mulberry (*Morus alba L*.), myrobalan plum (*Prunus cerasifera Ehrh*.), black locust (*Robinia pseudoacacia L*.), and wild cherry (*Prunus avium L*.).Wood samples were the most active against Methicillin-resistant

Staphylococcus aureus (MRSA), S. aureus and S. pyogenes. The lowest MIC and MBC values were detected in mulberry extract against MRSA. Activities were also distinguished against MRSA (extracts of non-seasoned sessile oak, Turkey oak, black locust and mulberry) and S. aureus (Turkey oak and all sessile oak extracts).

Necessity for intended use, known alternatives
Natural wood extracts have a long term of use in organic farming (in animal husbandry) for zootechnical and health supporting effects (especially in stress condition (weaning) for piglets, calves and rabbits) and for wine and cognacs refining. Furthermore, the oak tree has a long history of medicinal use. It is anti-inflammatory, antiseptic, astringent, haemostatic and tonic. The Oak bark is useful in the treatment of chronic diarrhoea, dysentery, intermittent fevers, haemorrhages.

So other Natural wood extract could be alternatives.

Origin of raw materials, methods of manufacture
Selected Oak wood (*Quercus sp*.) is crushed into particles of certain dimensions and extracted by means of hot soft water without any additives or preservatives (T=116°C, pressure = 1,2 bar, t = 8 h). The solution obtained by extraction is condensed in the systems of vacuum evaporators (from 4 % - 50 %), the 50 % solution is further dehydrated in a spray dryer (T=220°C) to the final market powder form.

The technological process is regulated with a strong HACCP and GMP principles.

Environmental issues, use of resources, recycling
Come from oak tree

Animal welfare issues
None

Human health issues
None

Food quality and authenticity
None

Traditional use and precedents in organic production
None

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Oak extract is not listed in USDA National Organic Program.

Oak extract is not listed in IFOAM Norms as permitted.

Other relevant issues

Reflections of the Group / Balancing of arguments in the light of organic production principles
The dossier explains that natural wood extracts have a long term of use in organic farming (in animal husbandry) for zootechnical and health supporting effects (especially in stress condition (weaning) for piglets, calves and rabbits) and for wine and cognacs refining. Furthermore, the oak tree has a long history of medicinal use. It is anti-inflammatory, antiseptic, astringent, hemostatic and tonic. The Oak bark is useful in the treatment of chronic diarrhea, dysentery, intermittent fevers, hemorrhages.

The dossier is not clear on the reason for the request or on the possible benefits of the addition of oak extracts, or even the species for which the application is made other than the general reference to piglets, calves, rabbits etc. There is no details on the mode of application. Also there is nothing in the literature saying that oak extract has better or even the same properties compared with other kinds of wood extracts. It is not clear whether the application covers oak wood or oak bark or both.

Given the low number of publications and the minor effects of the addition of oak extract on animals, the group is not convinced of the usefulness of recommending the addition of oak extract to Annex VI of Regulation (EC) No 889/2008.

With the information available the group has not been able to verify the effectiveness of the oak extract.

A detailed submission covering all of the points above would enable the group to further assess the application for oak extracts.

Conclusions
The group is unable to decide on whether the use of oak extract as a feed additive is in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007. The group would like to have more information about the purpose.

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2.11. Monodicalcium phosphates (feed)

Introduction, scope of this chapter

The assessment of Monodicalcium phosphate relates to the request to amend Annexes V and VI concerning feed materials, additives/processing aids and certain substances used in animal nutrition Regulation (EC) No 889/2008.

The dossier was submitted by France.

Authorisation in general production and in organic production

Monodicalciumphosphate is authorised by Regulation (EC) No 68/2013 amended by Regulation (EU) 2017/1017 on the Catalogue of feed materials. Monodicaclciumphosphate is listed in the feed material catalogue under section 11 Minerals and products derived thereof as point 11.2.3.

It is not listed in Regulation (EC) No 889/2008 in Annex V (3. Feed Materials of mineral origin; 3.4 Phosphorus).

Agronomic use, technological or physiological functionality for the intended use

Calcium (Ca) and phosphorus (P) are two of the most abundant minerals in the body, which is why they are essential in formulating feed and ration balancing tests for farm animals.

Due to the abundance of these minerals in the body, it is important to understand the function and how to meet requirements to insure that deficiencies and toxicities are not a concern. The main function of both calcium and phosphorus is skeletal. Nearly 99% of the calcium in the body if found in the skeleton, while 80% of the phosphorus is in bones and teeth.

In general, roughages provide adequate amounts of Ca in the diet, especially if there are legumes in the mix. We are most likely to see a Ca deficiency shortly after calving (bovines) when the cow's Ca loss due to lactation exceeds Ca intake. Ca is also important for poultry production (egg shells and bones). On the other hand, phosphorus deficiency is the most prevalent deficiency throughout the world, as roughages, which are the primary feed for ruminants, are a poor source of P. A P deficiency can lead to many problems including reduced growth and feed efficiency, decreased appetite, reduced reproduction efficiency, decreased milk production, and weak or fragile bones (f.e. in broilers).

In animal production, calcium and phosphorus are added in most feeding rations. In certain production phases this is indispensable.

In animal nutrition, monodicalcium phosphate is used for targeted supplementation of the feed with the important elements calcium and phosphorus.

Necessity for intended use, known alternatives

In organic feeding the phosphorus listed in Regulation (EC) No 889/2008 in Annex V (3. Feed Materials of mineral origin; 3.4 Phosphorus): defluorinated dicalcium phosphate and defluorinated monocalcium phosphate are the main alternatives.

Dicalcium phosphate (DCP) is obtained from rock phosphates by digestion with mineral acids. It is then purified and neutralised. As a pure carrier of calcium and phosphorus, it is used in mineral feeds and compound feeds specifically to supplement the two minerals. It contains 21% calcium and 16% phosphorus. In animal nutrition, the product is used for targeted supplementation of the feed with the important quantity elements calcium and phosphorus as required.

Monocalcium phosphate (MCP): Technically pure calcium phosphate. Monocalcium phosphate is chemically produced as a highly available calcium and phosphorus carrier.

Monocalcium phosphate is a mineral straight feed containing 16% calcium and 22% phosphorus.

Monodicalcium phosphate (MDCP) is chemically produced as a highly available calcium and phosphorus carrier. Monodicalcium phosphate (MDCP) is a mineral straight feed consisting of equal parts of monocalcium phosphate and dicalcium phosphate and containing 22% calcium and 22% phosphorus. In animal nutrition, the product is used for targeted supplementation of the feed with the important elements calcium and phosphorus.

Advantages of listing monodicalcium phosphate: more targeted administration of calcium and phosphorus depending on the basic feed. More flexibility for farms and compound feed producers.

The dossier states that mineral feed manufacturers are very sensitive to raw material reactivity (increase of temperature due to exothermic reaction between different minerals in the resulting mixes) as it can inactivate some temperature sensitive ingredients and thus causes economical losses. MDCP, due to its molecular composition has a medium reactivity whereas MCP has a high reactivity and DCP a low reactivity.

Origin of raw materials, methods of manufacture
Product obtained chemically and composed of dicalcium phosphate and monocalcium phosphate ($CaHPO_4$. $Ca(H_2PO_4)_2 \times H_2O$) $0.8 < Ca/P < 1.3$

MDCP production could consist of six processes:

Phosphate ore mining. Phosphate ore (P_2O_5 ¼ 22%) was mined mainly by the help of explosives, excavating machinery and drilling machine.

Phosphate ore beneficiation: To get a qualified phosphate concentrate (P_2O_5 ¼ 30%), the mined phosphate needs to be pretreated.

Sulfuric acid synthesis process

Phosphoric acid synthesis process.

MDCP synthesis process. MDCP was produced with the use of chemical methods. In this method, the input raw materials were extraction phosphoric acid synthesised in previous step. It reacted in two stages system with calcium carbonate. The production was subjected to drying after neutralisation, crystallisation or granulation (Smol et al., 2019). During this process, the obtained MDCP product included the monocalcium phosphate (MCP, $Ca(H_2PO_4)_2$) and dicalcium phosphate (DCP, $CaHPO_4$).

Sodium fluorosilicate synthesis process

Environmental issues, use of resources, recycling
Compared with other feed phosphates, the use of MDCP has a good bioavailability of phosphorus, lower phosphorus pollution and economic benefits (Lamp et al., 2020). With the scarcity of phosphorus resources and the reinforcement of environmental awareness, it is expected to take the largest market share in domestic feed phosphate market. Although chemical feedgrade MDCP has advantages for animal husbandry, its production also generates negative impacts on the environment, such as heavy metal pollution, air pollution and radioactivity pollution (Zhang et al., 2017). Therefore, the environmental impacts of the MDCP production need to be considered.

A study by Zhou et al. 2020 found that the predominant environmental impact identified was human toxicity, followed by fossil depletion, marine ecotoxicity, and particular oxidant formation. The cause of these negative environmental impacts is electricity consumption during manufacturing.

The digestibility of monodicalcium phosphate is better than that of dicalcium phosphate but worse than that to monocalcium phosphate (Bikker et al, 2016).

Animal welfare issues
Monodicalcium phosphate delivers phosphorous and calcium to the animals' diet. It secures correct bone mineralisation and has also other metabolic functions: energy utilisation and transfer, protein synthesis, maintenance of osmotic pressure and acid base balance.

Human health issues
Use of monodicalcium phosphate has no known effect on human health.

Food quality and authenticity
Monodicalcium phosphates on the EU market are produced under FCA (feed chain alliance)/ GMP+ / HACCP principles. Main place of production is China.

Traditional use and precedents in organic production
No.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
MDCP is not listed in USDA National Organic Program as permitted.

The submitter of the dossier mentioned, that monodicalcium phosphate is used and registered for organic farming in the USA.

MDCP is not listed in USDA National Organic Program as prohibited additive.

Monodicalcium phosphate is not listed in IFOAM Norms as permitted.

Other relevant issues
None

Reflections of the Group / Balancing of arguments in the light of organic production principles
The main argument for listing the MDCP product is the more resource-efficient use of calcium and phosphorus in animal feed to optimise formulation of feeds.

It is a feed of mineral origin which is not of natural origin, but is chemically well defined.

Digestability of MDCP sits between the other two permitted phosphate compounds.

One very specific study about Life Cycle Analysis (LCA) of MDCP, was found but no complete comparison to the already listed compounds MCP and DCP could be found regarding the energy used during production. Therefore, it is not evident, whether the manufacturing of MDCP is worse or better, than the others.

However, it is clear that in use there could be a resource efficiency advantage in using MDCP over the other two permitted compounds to optimise phosphorous ratio, reducing total useage of phosphorous in the feed.

Conclusions
If Monocalcium phosphate is produced in a similar chemically way as Monodicalcium phosphate, then Monodicalcium phosphate is a better alternative for feed in aquaculture.

The addition of Monodicalcium phosphate to Annex V and VI of Regulation (EC) No. 889/2008 is recommended. However, the group stresses the need to phase out chemically produced substances, promoting the use of alternatives as they become available..

References

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2.12. Velay Green Clay (feed)

Natural mixture of illite, montmorillonite, kaolinite (feed additive No 1g599)

Introduction, scope of this chapter

The assessment of Velay Green Clay “Natural mixture of illite, montmorillonite, kaolinite” (feed additive No 1g599) relates to the request for inclusion of this substance as a feed additive in Annex VI (feed additives used in animal nutrition) Commission Regulation (EC) No 889/2008.

The dossier was submitted by France.

CAS Number of the 3 active substances:

Illite: 106958-53-6

Montmorillonite: 1318-93-0

Kaolinite: 1318-74-7

EC Additive identification: No 1g599 [Regulation (EU) No 2019/10]

Authorisation in general production:

Velay green clay is authorised by Register of Feed Additives pursuant to Regulation (EC) No 1831/2003 as No 1g599 (Reg. No 2019/10)

https://ec.europa.eu/food/sites/food/files/safety/docs/animal-feed_additives_eu-register_1831-03.pdf

Technological feed additive

Functional groups: Binders and Anti-caking agent

Listed as “natural mixture of illite, montmorillonite, kaolinite”

From the dossier

Velay Green Clay was also granted Ecocert certification since 2010 (periodic renewal) for use in organic farming [Annex 2] as:

- Additives and processing aids,

- External animal hygiene,

- Litter, slurry treatments,

- Physical barrier.

This certification stays valid until 30 June 2020.

Authorisation in organic farming:

E559 Kaolinitic clays, free of asbestos is listed in Annex VI (d) binders and anti-caking agents

Agronomic use, technological or physiological functionality for the intended use

Binders: substance which increases the tendency of particles of feedstuffs to adhere

Anti-caking agent: substance that reduces the tendency of individual particles of a feedstuff to adhere

From the dossier

Since antiquity, clays are known and used for many curative uses but also for washing clothes, making pottery, tablets for writing etc. It is even used by ancient Egyptians for mummification because of its antiseptic and purifying properties. It was part of the pharmacopoeia for Chinese, Greeks and Romans.

Green clay is a natural product derived from sedimentary rock. The main uses of this natural green clay are: argilotherapy and cosmetic. French green clay is a substance that is used for external cosmetic treatments as well as some internal applications by practitioners of alternative medicine.

Clay is used as an organic plant protection product.

Necessity for intended use, known alternatives

The potential use is not described in the dossier submitted

The applicants claimed that no alternative is known as green clay is not approved in organic farming.

Origin of raw materials, methods of manufacture

Velay Green Clay is a natural mixture of illite-montmorillonite-kaolinite. These 3 components belong to the phyllosilicates family.

Name of active substances: Illite $K(Al,Fe)_2AlSi_3O_{10}(OH)_2 \times H_2O$, Montmorillonite $Na_x[(Al_{2-x}Mg_x)Si_4O_{10})(OH)_2]$, Kaolinite $Al_2(OH)_4(SiO_5)$

Velay Green Clay is extracted and produced in France for all European countries, both geographically and politically.

Production method

Quarry – mining process – drying process – selection by induction – controls of dioxin and heavy metals (Pb, Cd, As, Hg) - packaging in big bags or filling up tankers – delivery to customers.

No chemicals have been used during the manufacturing process.

Based on 6 different production batches tested, all results are below the regulated levels in heavy metals. The same conclusion can be drawn for dioxins, dioxin-like PCBs, non-dioxin-like PCBs.

Various measures to reduce negative environmental impacts are described by the applicant.

Environmental issues, use of resources, recycling
Velay Green Clay has no impact against the environment as this is a natural product from soil origin.

Animal welfare issues
Abstract of EFSA FEEDAP Panel, 2016:

The additive, a natural mixture of illite, montmorillonite and kaolinite with a minor amount of calcite and sanidine, is intended to be used as a technological additive (functional groups: binders and anticaking agents) in feedingstuffs for all animal species. The additive is safe in complete feed for cattle for fattening at a maximum concentration of 50,000 mg/kg and at a maximum concentration of 20,000 mg/kg for piglets and pigs for fattening. No conclusions can be drawn for all the other animal species/categories. The additive is not genotoxic. As the additive is essentially not absorbed from the gut lumen, the Panel on Additives and Products or Substances used in Animal Feed considers that use of the additive in animal nutrition is safe for consumers of food products from animals fed diets containing the additive. The additive is not an irritant to the eyes and the skin and it is of low toxicity by the inhalation route. No systemic toxicity is expected following dermal exposure. Due to its nickel content, the additive should be considered a potential dermal and respiratory sensitiser. The components of the additive are natural constituents of soil. Consequently, the use of the additive in animal nutrition will not pose a risk to the environment. The additive is effective as an anticaking agent and a binder at an inclusion rate of 50,000 mg/kg complete feed.

Human health issues
See abstract of EFSA FEEDAP Panel, 2016 XX

Food quality and authenticity
See abstract of EFSA FEEDAP Panel, 2016 XX

Traditional use and precedents in organic production

Kaolinite is already present in organic feeding.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Illite-montmorillonite-kaolinite is not listed in USDA National Organic Program as permitted.

Illite, montmorillonite and kaolinite are not listed in USDA National Organic Program as prohibited additive.

Kaolin is listed in IFOAM Norms as permitted in Appendix 4. Illite and Montmorillonite are not listed as permitted.

Other relevant issues
None

Reflections of the Group / Balancing of arguments in the light of organic production principles
There are no apparent reasons not to approve the product. The mixture is natural and without any chemical process behind it. It is mined in Europe.

The application is for a special product from a specific area. For general approval as an additive, all regional mineral mixtures must be registered.

Therefore, the addition of the technical description of the mixtures of the minerals, rather than the specific trade name should be considered.

Conclusions
The use of the additive “natural mixture of illite, montmorillonite, kaolinite (feed additive No 1g599)”, is in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007.

The addition of natural mixture of illite, montmorillonite, kaolinite (feed additive No 1g599) to Annex VI 1(d) of Regulation (EC) No 889/2008 is recommended with the mention as Binders and Anti-caking agent only.

References

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2016. Scientific opinion on the safety and efficacy of a natural mixture of illite, montmorillonite and kaolinite (Argile Verte du Velay) as a feed additive for all animal species. EFSA Journal 2016;14(1):4342, 18 pp. doi:10.2903/j.efsa.2016.4342

2.13. Substance Yeast and Yeast products (feed)

Introduction, scope of this chapter

Request for the addition of all yeasts and yeast products authorised under the general regulations for possible examination by the EGTOP group with a view to their inclusion in Annex V (feed materials) of Regulation (EC) No 889/2008.

The dossier was submitted by France.

Authorisation in general production and in organic production

Yeasts and yeast product is authorised by COMMISSION REGULATION (EU) 2017/1017 of 15 June 2017 amending Regulation (EU) No 68/2013 on the Catalogue of feed materials points 12.1.5 Yeasts [brewers' yeast] All yeasts obtained from Saccharomyces cerevisiae, Saccharomyces carlsbergensis, Kluyveromyces lactis, Kluyveromyces fragilis, Torulaspora delbrueckii, Cyberlindnera jadinii, Saccharomyces uvarum, Saccharomyces ludwigii or Brettanomyces ssp. on substrates mostly of vegetable origin such as molasses, sugar syrup, alcohol, distillery residues, cereals and products containing starch, fruit juice, whey, lactic acid, sugar, hydrolysed vegetable fibres and fermentation nutrients such as ammonia or mineral salts and points 12.1.12 Yeasts products All yeasts parts obtained from Saccharomyces cerevisiae, Saccharomyces carlsbergensis, Kluyveromyces lactis, Kluyveromyces fragilis, Torulaspora delbrueckii, Cyberlindnera jadinii, Saccharomyces uvarum, Saccharomyces ludwigii or Brettanomyces ssp. on substrates mostly of vegetable origin such as molasses, sugar syrup, alcohol, distillery residues, cereals and products containing starch, fruit juice, whey, lactic acid, sugar, hydrolysed vegetable fibres and fermentation nutrients such as ammonia or mineral salts.

Yeasts are authorised by Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control in Annex VIIIa , Products and substances authorised for use or addition in organic products of the wine sector referred to in Article 29 (c), Points 5, 15 and 21: Use — Yeasts.

Agronomic use, technological or physiological functionality for the intended use

Yeasts are single cell, eukaryotic microorganisms classified in the fungal kingdom. These microscopic fungi are generally about 3–4 µm in size, have a nuclear membrane and cell walls. Animals have been fed various forms of yeast and yeast derivatives for more than 100 years (Shurson, 2018)

Yeasts are found in abundant quantities and are almost everywhere in the environment. They have been isolated from fruit, honey, soil, water, and plant stems, leaves, and flowers, and are naturally present in common feed ingredients such as grains, grain co-products, silage, and hay fed to animals. Most species of yeast are neither harmful nor beneficial to humans and animals. A few genera of yeasts are known to be pathogenic (*Candida, Cryptococcus, Torulopsis, and Trichosporon*;), while some species (*Saccharomyces cerevisiae, Kluyveromyces marxianus, Candida utilis*) provide beneficial effects. There are about 60 different genera of yeasts, which are comprised of about 500 different species. Yeast species vary in their cellular morphology, metabolism of different substrates, and reproduction processes. However, only a few of these species are used commercially. Commercial applications for yeast include the production of alcoholic beverages (i.e. beer, wine, and spirits), non-alcoholic beverages (i.e. root beer, kvass, kombucha, kefir, mauby), bread and pastry baking, bioremediation, industrial ethanol production, nutritional supplements, probiotics, aquarium hobbies (to generate carbon dioxide for support plant growth in aquaria), food additives and flavoring agents, scientific research, and genetically engineered biofactories. *Saccharomyces cerevisiae* is the predominant species used in food, beverage (distilled spirits and beer), and fuel ethanol production processes, where selected strains convert glucose and sucrose to ethanol. Other commercially important yeast strains include *Kluyveromyces marxianus* (whey yeast) which uses glucose and lactose in milk as its substrates, and *Candida utilis* (Torula yeast) which uses xylose and glucose in wood pulp from paper manufacturing as substrates (Shurson, 2018)

Dried yeast (AAFCO – 96.1 Primary Dried Yeast or Dried Yeast; IFN 7-05-533 Yeast primary dehydrated), brewer's dried yeast (AAFCO – 96.4 Brewers Dried Yeast; IFN 7-05-527 Yeast brewers dehydrated), brewer's liquid yeast (AAFCO – 96.10 Brewers Liquid Yeast; IFN 7-20-878 Yeast brewers liquid), Torula dried yeast (AAFCO – 96.7 Torula Dried Yeast or Candida Dried Yeast; IFN 7-05- 534 Yeast torula dehydrated), and whey yeast are considered to be nutritional yeast products because they consist of yeast biomass of dead yeast cells and are fed for their nutritional value (Dubey et al., 2010). Dried yeast is expensive and is mainly used in the food G.C. Shurson Animal Feed Science and Technology 235 (2018) 60–76 62 industry as a nutritional supplement (Dubey et al., 2010). Brewer's yeast is commonly used in the animal feed industry as a specialty amino acid, vitamin and mineral supplement. Torula yeast (*Candida utilis*) also contains high concentrations of protein, minerals, and vitamins and it is used as an additive to a wide variety of processed foods (Bekatorou et al., 2006). Historically, Torula yeast was also used in animal feeds, but today, most of it is used by food manufacturers. Although whey yeast was commonly available and used in the feed industry for many years, very little is produced and available today (Shurson, 2018).

Numerous yeast supplements and yeast-containing feed ingredients are produced, marketed and used in animal feeds as nutrient sources, probiotics, providers of nutraceutical compounds (i.e. β-glucans, mannanoligosaccharides, nucleotides), or serve unique nutritional functions (i.e. Se yeast and Phaffia yeast). A large number of scientific studies have generally shown that yeast and its derivatives, may provide beneficial effects on animal growth performance and health, especially when animals are reared in suboptimal hygienic conditions or are experiencing a disease challenge. It is essential that nutritionists understand the inherent differences between these products, along with their potential role in providing desired potential effects when added to animal feeds. While numerous analytical methods have been developed and compared (Shurson, 2018).

Necessity for intended use, known alternatives

The use of yeasts and yeast products from other species than *Saccharomyces cerevisiae* and *Saccharomyces carlsbergensis* will enable feeding of animals with natural ingredients with well described nutritional and/or functional benefits. It could lead to reduced dependency on non-organic protein sources such as non EU soy.

Origin of raw materials, methods of manufacture

Yeasts are produced by fermentation with natural yeasts species that have not been genetically modified. At the end of the fermentation process, yeasts are heat treated to be inactivated/killed. Products can be dried or liquid. Fermentation is performed on substrates mostly of vegetable origin such as molasses, sugar syrup, alcohol, distillery residues, cereals and products containing starch, fruit juice, whey, lactic acid, sugar, hydrolysed vegetable fibres and fermentation nutrients such as ammonia, mineral salts and/or vitamins.

Yeast products are produced by fermentation with natural yeasts species that have not been genetically modified. The fermentation process is the same as that of yeasts. At the end of the fermentation process, yeasts are heat treated to be inactivated/killed. The inactivated yeast are further processed to remove the inner or the outer parts and to extract the targeted yeasts fractions. Products are dried. Environmental issues, use of resources, recycling

Animal welfare issues
Numerous yeast supplements and yeast-containing feed ingredients are produced, marketed and used in animal feeds as nutrient sources, probiotics, providers of nutraceutical compounds (i.e. β-glucans, mannanoligosaccharides, nucleotides), or serve unique nutritional functions (i.e. Se yeast and Phaffia yeast). A large number of scientific studies have generally shown that yeast and its derivatives, may provide beneficial effects on animal growth performance and health, especially when animals are reared in suboptimal hygienic conditions or are experiencing a disease challenge. It is essential that nutritionists understand the inherent differences between these products, along with their potential role in providing desired potential effects when added to animal feeds.

Human health issues
The major beneficial effects of yeasts are probiotic effects, biodegradation of phytate, folate biofortification and detoxification of mycotoxins. However, there are other reported effects such as enrichment of foods with prebiotics as fructooligosaccharides, lowering of serum cholesterol, antioxidative properties, antimutagenic and antitumor activities etc (Moslehi-Jenabian, 2010). Saccharomyces cerevisiae, which according to EFSA (The European Food Safety Authority) has a QPS (Qualified Presumption of Safety) status is the most common yeast used in food fermentation where it has shown various technological properties. (EFSA 2005)

Food quality and authenticity
Not applicable

Traditional use and precedents in organic production
Yeasts and yeast products have been used for decades as feed materials in animal nutrition.

Yeasts and yeasts products are either produced as primary products for the feed industry or are co-products from the fermentation industry (e.g. brewery)

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Yeast is listed in USDA National Organic Program in §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)).”: Yeast—When used as food or a fermentation agent in products labeled as “organic,” yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented..

Yeast and yeast product is not listed in USDA National Organic Program as prohibited feed additive.

Yeast is not listed in IFOAM Norms as permitted.

Other relevant issues
None

Reflections of the Group / Balancing of arguments in the light of organic production principles
Concerns were expressed over the possibility of GM substrates, ingredients or additives. This should be prevented otherwise the risk of GM DNA carry over into animal feed is present.

Organic substrates may be possible. Organic yeasts is available for food.

Currently only *Saccharomyces cerevisiae and Saccharomyces carlsbergensis* are permitted as feed additives in organic production.

The group is aware that there is consideration of a yeast product high in B vitamins for animal feed. The regulatory status of this product at this time is unclear.

Yeast may in the future also provide feed ingredients high in specific amino acids, which will reduce the need for derogations for non organic protein sources for non ruminants and also for the use of fish oil and fish meal.

A wide range of yeast products is approved as feed ingredients in conventional agriculture. The group is in favor to use "Yeast and Yeast products" from organic sources when available.

Conclusions
The use of the feed additive "Yeast and Yeast products" as feed material, is in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007, providing the specific product is approved in horizontal legislation and from organic sources when available.

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2.14. Substance Lutein/Zeaxanthin (feed)

Introduction, scope of this chapter
The assessment of Lutein/Zeaxanthin relates to the request for inclusion of this substance as a feed additive in Annex VI (feed additives used in animal nutrition) of Regulation (EC) No 889/2008, suggesting the addition of the statement "Only if derived from organic raw materials".

The dossier was submitted by France.

Lutein:

CAS number 127-40-2

E 161b

Zeaxanthin:

CAS number 144-68-3

E 161h

Authorisation in general production and in organic production
Lutein/Zeaxanthin is cited in the List of the authorised additives in feeding stuffs (1) published in application of Article 9t (b) of Council Directive 70/524/EEC concerning additives in feeding stuffs (2004/C 50/01) in CHAPTER III: LIST OF OTHER ADDITIVES AUTHORISED FOR AN UNLIMITED PERIOD as colourants, including pigments Point 1. Carotenoids and xanthophylls

Lutein/Zeaxanthin is authorised by COMMISSION IMPLEMENTING REGULATION (EU) 2020/1097 of 24 July 2020 concerning the authorisation of lutein-rich and lutein/zeaxanthin extracts from Tagetes erecta as feed additives for poultry (except turkeys) for fattening and laying and for minor poultry species for fattening and laying. The substances specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'colourants: (ii) substances which, when fed to animals, add colours to food of animal origin', are authorised as feed additives in animal nutrition subject to the following conditions: the authorised substances specified in the Annex shall not be used in water for drinking

Agronomic use, technological or physiological functionality for the intended use
Pigmentation is an important factor in consumer acceptance and perceived quality of broilers. The color of poultry skin is provided by carotenoid pigments present in the diet of birds that are deposited in the skin and subcutaneous fat. Carotenoids are a group of more than 500 pigments spread throughout the plant and animal kingdom. Poultry use carotenoids for pigmentation oft he skin and the yolk, and these substances are also involved in growth metabolism and fertility. Some carotenoids serve as precursors for the synthesis of vitamin A, and some provide protection against damaging reactions in the body, acting as physiological antioxidants, and thus enhancing the immune response. Poultry cannot synthesise these compounds and must obtain carotenoids from their diets. The amounts and availability of carotenoids in poultry feed ingredients fluctuate considerably. It has therefore become common practice in the poultry industry to add carotenoids to the feed to assure the necessary amount for pigmentation but also for optimal health, because a number of these compounds have vitamin A activity. To achieve the desired color, feed producers usually combine a yellow carotenoid (apo-ester, lutein, zeaxanthin) and a red one. One of the more widely used sources of yellow pigments is the flower petals of marigolds (*Tagetes erecta*), which contain up to 2,000 ppm of carotenoids. Healthy poultry absorb pigments from their diet, which are transported in blood to the subcutaneous fat tissues and skin, where they are stored. Feed carotenoids occur in natural compounds in about 60 to 90% trans form and 10 to 30% cis form. When evaluated in vitro, the trans isomer is a more effective pigment than the cis isomer because of the redder hue and greater stability (Perez-Vendrell, et all, 2001)

Carotenoids are absorbed in the intestine and transported to the liver of birds, in which they are incorporated into triglyceride-rich low-density lipoproteins to be transported to the ovary or the target tissues (fat, skin) by the blood stream. In the past, it has been assumed that absorption of esterified carotenoids by birds would be facilitated compared to free carotenoids . It may be expected that deposition of single carotenoids in yolks and tissues is increasing with increasing contents in diets, but the relation may not be linear. In general, deposition rates of artificial carotenoids are higher than of natural ones. Several studies exist in which deposition rates have been determined for nearly all approved carotenoids. For egg yolk, estimated deposition rates for β-apo-8′-carotenal vary between 29% and 39%; for ethyl ester of β-apo-8′-carotenoic acid between 51% and 62%; for lutein between 4.4% and 23% (average of 7 %); for zeaxanthin about 23% (average of 25

%); for capsanthin between 7% and 29%; and for citranaxanthin between 13% and 15% (Grashorn, 2016)

The marigold flower extract is the main source of lutein and its stereoisomer zeaxanthin (Landi et al, 2018; Skřivan, 2015).

In one experiment, Marigold flower extract (MFE), was added to the diets of hens at different concentrations (0, 150, 250, and 350 mg/kg of diet) to determine the effects of MFE on hen performance, physical characteristics of egg quality, and carotenoid content of the egg yolk of hens housed in enriched cages. Additionally, the highest dose of MFE (350 mg/kg) was tested under commercial poultry conditions and compared with a feed mixture with added synthetic carotenoids and a control diet without synthetic carotenoids. The highest hen-day egg production ($P = 0.005$) and egg mass production ($P = 0.010$) was found in hens fed a diet supplemented with MFE at 150 mg/kg. The performance characteristics, however, were not influenced by MFE under commercial conditions. When the dose of MFE was increased, increased values were observed for DSM Yolk Colour Fan ($P < 0.001$), redness ($P < 0.001$), yellowness ($P < 0.001$), ratio of redness and yellowness ($P < 0.001$), and decreased for lightness ($P = 0.036$). In the commercial study, the synthetic carotenoids decreased the value of yellowness ($P < 0.001$) compared with the control group. The lutein and zeaxanthin content in yolk increased by approximately 11.5 and 5.9 mg/kg dry matter, respectively, after the MFE addition of 350 mg/kg. Supplementation with synthetic carotenoids significantly ($P < 0.001$) decreased the α-tocopherol content in egg yolk. Skřivan et al (2015) concluded that MFE is a suitable natural alternative for increasing the xanthophyll contents in eggs compared with the commercially used synthetic carotenoids.

An other experiment had for objective to evaluate the efficacy of two types of marigold: natural SME-10 (in which the lutein:zeaxanthin ratio was 90:10) and a new formulation SME-25 (characterised by a lutein:zeaxanthin ratio of 75:25, which alone could provide a more orange color tonality) on practical broiler grower diets based on a standard diet (maize-wheat-soybean). This experiment was conducted using 960 1-day-old, sexed broilers of Ross 308 strain from 1 to 43 day to evaluate if SME-25 could produce pigmentation equivalent to the current addition of conventional SME-10 plus canthaxanthin (CTX). The SME-10 was supplemented at different levels and also was added or mixed with different levels of CTX, wheeras SME-25 was used alone, because of its higher zeaxanthin proportion. The treatments consisted of a nonpigmented control (T1), a combination of 35 ppm of yellow xanthophylls (YX) from SME-10 + 5 ppm of CTX (T2), a combination of 32 ppm of YX from SME-10 + 2 ppm of CTX (T4), and one treatment with 40 ppm of YX from a new SME-25 (T3). There were no significant treatment effects on chicken performance. All color parameters (Minolta coordinates, Roche color fan scores, Rank test) presented significant differences ($P < 0.0001$) because of dietary pigments on shanks and breast skin. Birds fed the SME-25 diet had less pigmentation than those fed equivalent quantities of a combination of SME- 10 + CTX. Lutein and zeaxanthin from the SME-25 product had lower deposition rates in skin and fat tissues than those from the SME-10 product. This finding seems to be related to the ratio of zeaxanthin stereoisomer RR (optically active) vs. RS that was found in tissues from the SME-10 product (97.8%:2.2%), whereas with SME-25 this ratio was 16.0:84.0%. These results suggest that inclusion of only the SME-25 product could not replace the current addition of SME-10 and CTX combinations (Perez-Vendrell, et al, 2001).

Necessity for intended use, known alternatives

Pigmentation of egg yolks and poultry tissues (mainly skin and fat) directly reflects the contents of carotenoids in the feed of birds. In most countries of the World, consumers prefer pigmented egg yolks, whereas pigmented poultry tissues are less desired. Especially in the southern part of Europe, eggs with a golden-orange tone of yolks are preferred. This is achieved by supplementing feeds of birds with both yellow and red carotenoids. For this purpose, nine carotenoids are approved as feed additives in the European Union, five natural and four artificial products, six with a yellow color and three with a red color (Grashorn, 2016).

Only in few countries, like Austria and Mexico, consumers prefer broilers with pigmented skin, whereas in most countries “white” broiler (skin without pigmentation) is prevailing. Despite this general preference, specialty products with yellow skin exist in several countries. Examples are organic broilers and the corn chicken in France. Especially, most consumers expect a yellow touch of the skin for organic broilers as this reflects the extensive production conditions. Furthermore, this indicator allows the distinction of organic chicken meat from the conventionally produced one. The corn chicken is produced as a specialty product in France. The higher fat content is associated with a better sensory quality (Grashorn, 2016).

Alternatives such as growing flowers in the range may help, to colour egg yolks and skin, but the birds eat different amounts. Also currently maize and maize extracts are fed, to organic but they do not produce the dark colours desired by growers according to this application.

Origin of raw materials, methods of manufacture

Total carotenoids (TC): ≥ 60 kg/kg

Lutein: 37% of TC

Zeaxanthin: 36% of TC

Lutein in obtained from a saponified extract of *Tagetes erecta* (dried flowers petals) obtained via extraction and saponification.

Saponification of natural pigmenting products from paprika and *tagetes erecta* improves pigmentation efficiency of these products, that is why pigment producers include this step in the production process of pigments (Galobart & al, 2004). In fact, most of the natural carotenoids that are relevant for poultry pigmentation occur in free form, but the lutein in *Tagetes* petals occur mainly as diesters of palmitic and of myristic acids. Feed carotenoids are absorbed in their free form; thus esterified hydroxycarotenoids have to be saponified before they are absorbed. (Perez-Vendrell, et al, 2001).

Environmental issues, use of resources, recycling

None

Animal welfare issues

It was shown that lutein-depleted birds have greater inflammatory responses (Meriwether et al 2010).

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) evaluated (i) lutein from a saponified extract from Tagetes erecta obtained via extraction and saponification (lutein not less than 85% of total carotenoids (TC)) and (ii) lutein/zeaxanthin extract from Tagetes erecta obtained via extraction, saponification and isomerisation (lutein not less than 45% and zeaxanthin not less than 35% of TC). The maximum proposed use level of 80 mg TC from saponified Tagetes extract/ kg complete feed for chickens for fattening and laying hens is safe for these animal categories. This conclusion can be extrapolated to minor poultry species for fattening and laying. The conclusions on saponified Tagetes extract for poultry for fattening and laying are extended to the saponified/ isomerised Tagetes extract. The maximum use level of the saponified/isomerised Tagetes extract in breeding minor poultry should not exceed 50 mg TC/kg feed, considering the toxicological potential of zeaxanthin on reproduction. The saponified Tagetes extract is not genotoxic. This conclusion is extended to the saponified/isomerised Tagetes extract. Consumer exposure related to the consumption of animal products is very low compared to the exposure from other sources. The active substance is a viscous paste and may be irritant to skin and eyes; no exposure by inhalation is expected. In the absence of data, the Panel cannot conclude on the safety for the user of commercial preparations. The use of Tagetes extracts in poultry feed raised no concern for the environment. Tagetes extracts at levels up to the proposed maximum use level of 80 mg TC/kg complete feed have the potential to colour the egg yolk of laying hens and the skin of chickens for fattening. This conclusion is extended to minor poultry species for laying and for fattening. The use of the additive in feed and water for drinking is considered bioequivalent (EFSA, 2019).

Human health issues

In humans, the lutein and zeaxanthin are believed to function in two ways: firstly, as an antioxidant, thereby protecting from oxidative damage, and secondly as a filter of ultraviolet light. Evidence shows that the consumption of lutein and zeaxanthin is related to a lower incidence of age-related macular degeneration (AMD) and cataracts. Lutein is also able to protect skin from UV-induced damage and may reduce the risk of cardiovascular disease. Furthermore, there is strong epidemiologic evidence that lutein can protect against the development of certain types of cancer. Additionally, lutein has been indicated to improve the immune response. Lutein and zeaxanthin are also becoming increasingly important in the nutraceutical market since they are now understood to play a significant role in eye health, preventing cataract and macular degeneration. Generally, these two xanthophylls are not considered toxic and are relatively safe for human consumption. They are the macular carotenoids creating the macular pigment at the back of the eye. Brain lutein concentrations have been shown to be lower in mild cognitive impairment patients than in those with normal cognitive function (Langi et al, 2018)

Food quality and authenticity

There are concerns over the authenticity of egg yolks and bird skin coloured by feeding additives solely for this purpose.

Traditional use and precedents in organic production

Pigmentation of the egg yolk and the skin of the poultry is not a traditional use of additives, although other additives and feed ingredients may have had this effect in the past.

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

Lutein/Zeaxanthin are not listed in USDA National Organic Program

Lutein/Zeaxanthin are not listed in IFOAM Norms as permitted

Other relevant issues

In most countries and regions of the world, consumers are interested in pigmented egg yolks also. Information on color preferences of egg yolks is quite limited. There exists a survey of DSM performed in the late 1990s indicating a clear difference in color preferences of egg yolks in Europe between northern and southern countries. It is remarkable that, especially in southern countries, eggs with intensely colored (golden-orange) yolks are preferred. Obviously, consumers correlate a better quality and a more intense taste with a darker yolk color. In contrast to southern Europe, the majority of consumers worldwide prefer brighter yolks. Consumers purchasing organic eggs generally accept paler yellow yolks (Grashorn, 2016).

The yellow-orange colour of chicken skin is often associated with better quality of the product, which is linked differently to each consumer's diet (corn), farming (outdoor chicken) and animal in good health, freshness and high nutritional value (Hernandez, 2005). A sudden change in the appearance of the product, even without a change in smell or taste, makes the product totally unacceptable (Williams, 1989).

In Europe, in different countries (Germany, Spain, Italy, France and Great Britain), a study conducted by Roche (Beardswort & Hernandez, 2004) showed that the intensity of yellow is one of the most important organoleptic selection criteria with shell resistance and albumen consistency. When the consumers interviewed have the choice, they will preferably take eggs with the most intense yellow color. Other studies also show this trend in other countries outside Europe: Ethiopia (Senbeta & al, 2015), Brazil (Spada & al, 2016), Canada (Bejaei & al, 2011) and Turkey (Demircan & al, 2018).

Further research has also been initiated in other countries to assess consumer preferences in France, Spain, China and South Africa this time on chicken meat. Whatever the country of the study, when the consumer has the choice, the colour of the chicken skin remains one of the first criteria of purchase (Chiraze et al, 2007 – Lapierre & al, 2005) : his preference goes in priority to the most yellow chickens, because associated with a quality image of the product and that, even if the cost is higher.

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

Key issues were the claimed demand of consumers and the possible benefits on human and animal health.

It was noted that the compounds are ultimately derived from natural origin, by chemical methods.

Significant time has been spent discussing colouring of egg yolk. It is not necessary, natural or authentic.

Report of German study where organic consumers do not require a strongly yellow coloured egg yolk (Grashorn, 2016). In Switzerland egg farmers use organic paprika powder to give some colour. This is considered more authentic than giving an extract.

Similar views are reported from organic consumers in France.

Similar discussions in Italy. Studied the addition of colours relating to the physiological requirement of the birds.

The group considered that these issues are similar to the issues relating to colouring of the flesh of salmon and trout, by feeding of shrimp shell, or Phaffia yeast. These carotenoids are essential for the life of the fish, so the addition to fish feed is allowed only during the essential phase of growth.

This does not appear to be the case for poultry in the current application. The scientific literature does not show consistent improvement of health of the poultry, by addition of these carotenoids.

The group is aware of cases of over colouring, where levels had to be reduced so that consumers became used to normally coloured yolks.

Conclusions

The use of the feed additive Lutein/Zeaxanthin as colourants, including pigments in poultry feed, is not in line with the objectives, criteria and principles of Council Regulation (EC) No 889/2008.

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2.15. Substance bentonite (feed)

Introduction, scope of this chapter

The assessment of bentonite relates to the request for inclusion of this substance as a feed additive in Annex VI (feed additives used in animal nutrition) of Regulation (EC) No 889/2008.

The dossier was submitted by France.

CAS- number 1302-78-9

E-number E 558

Authorisation in general production and in organic production

Bentonite is authorised by COMMISSION REGULATION (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, Annex 6, point 1. TECHNOLOGICAL ADDITIVES (d) Binders and anti-caking agents.

Bentonite is named in the List of the authorised additives in feedingstuffs (1) published in application of Article 9t (b) of Council Directive 70/524/EEC concerning additives in feedingstuffs (2004/C 50/01) in CHAPTER III: LIST OF OTHER ADDITIVES AUTHORISED FOR AN UNLIMITED PERIOD as Colourants, including pigments 2. Other colourants, as Binders, anti-caking agents and coagulants E 558 Bentonite-montmorillonite for all species or categories of animals at a maximum concentration of 20 000 mg/kg of complete feedingstuff for all feedingstuffs, mixing with additives from the ‘antibiotics', ‘growth promoters', ‘coccidiostats and other medical substances' groups is prohibited, except in the case of: monensin-sodium, narasin, lasalocid-sodium, flavophospholipol, salinomycin sodium and robenidine. Indication on the label of the specific name of the additive.

Bentonite is authorised by COMMISSION REGULATION (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives PART B LIST OF ALL ADDITIVES point 3. Additives other than colours and sweeteners.

Bentonite is also cited in Regulation (EC) No COMMISSION IMPLEMENTING REGULATION (EU) No 1060/2013 of 29 October 2013 concerning the authorisation of bentonite as a feed additive for all animal species

Agronomic use, technological or physiological functionality for the intended use

Bentonites in animal diet act as gut protectants (enterosorbents), which rapidly and preferentially bind aflatoxins from the digestive tract and thus reduce their absorption into the organism. In that manner, adverse effect of aflatoxins on efficiency and liver function is minimised without marked defects in mineral metabolism of the animals (Trckova, 2004)

In the tests of capability of various adsorbents to bind toxins, bentonites showed the best results, followed by kaolin-pectin (Kaopectate). Kaolin alone was less effective. Bentonite supplementation (5%) of the diet given to chickens fed different-type nutrient deficient diets (e.g. deficiency in macroelements, microelements, vitamins and proteins) can enhance the feed intake by the chickens, and the weight gains which may be decreased by these deficiencies (Trckova, 2004)

Vila-Donat et al. (2019) have characterised bentonite clays according to their mycotoxins adsorbent ability. Firstly, 27 bentonite clays from different geographical origins were evaluated, at 0.02% w/v, using an in vitro screening method versus five mycotoxins (aflatoxin B1, AFB1; deoxynivalenol, DON; ochratoxin A, OTA; fumonisin B1, FB1; and, zearalenone, ZEN) by Enzyme-Linked Immunosorbent Assay (ELISA). Subsequently, 7 bentonite clays (6 of which were tri-octahedral bentonites) selected from the preliminary test, and 7 commercial adsorbent products were subjected to an in vitro equilibrium adsorption experiment (at 0.02% w/v) against six concentrations of AFB1 (0.02–4 mg/L), and OTA (0.05–1 mg/L) by using simulated gastrointestinal (GI) juices, and successively analysed by HPLC-FD. Equilibrium isotherm functions were fitted to the data by nonlinear regression analysis. In vitro adsorption equilibrium experiments showed that AFB1 adsorption was very high with all the adsorbents tested. In particular, the seven pre-selected bentonites adsorbed most of the AFB1 present at the lower level tested, while only three of these reached more than 50% of OTA adsorption. Adsorption increased inversely to the toxin concentration and both Langmuir and Freundlich isotherm models fitted well to the data. Generally, the pre-selected bentonites (B1-B7) showed better mycotoxin adsorption than commercial products (C1-C7) at all levels of mycotoxins tested. The 10-fold dose increase of the best tri-octahedral bentonite (B4) rendered a more effective adsorption of OTA, reaching almost 75% of adsorption (at pH 5).

The research results available thus far have indicated that dietary bentonite included into a diet of animals that show varied degrees of diarrhea can cause the symptoms to regress. In the case of calf diarrhea, bentonite improves therapeutic efficacy better than antibiotics and chemotherapeuticals do. A bentonite-supplemented diet for pigs enhances growers’ body conditions and increases weight gains (*Wlazło, 2015)*. Dobrzański et al. (1994) administered bentonite to chicken broilers’ feed for 2 weeks and then observed a substantial reduction in fungal numbers and a decrease in mesophilic bacteria count, up to 70%. Grata et al. (1999) studied the use of urea phosphate for disinfecting poultry liquid manure, and its strong bactericidal properties were observed as early as after 2-week studies. The examples of research on animals indicated that bentonite could improve the efficiency of treatment and relieve the symptoms of various cases of diarrhea (*Wlazło, 2015*). In the studies by Kulok et al. (2005) and Kołacz et al. (2004), halloysite (aluminosilicate clay mineral) was used in fatteners’ diet to decontaminate bacteria, fungi and mycotoxins in feed mixtures as well as reduce ammonia emission; the authors highlighted its high efficiency. The studies by Pasha et al. (2007) also confirmed the strong adsorptive properties of this aluminosilicate towards aflatoxins. These authors indicate a beneficial effect of 0.5% of sodium bentonite used per 100 (mcg/kg) aflatoxins in feed regarding boosting the bird immune system measured by the antibody titers and phagocytosis process rate. Sodium bentonite has proven to be efficient in binding adverse aflatoxins in feed as it can prevent the “depression” of immune response by the elevation of antibody titers against hemagglutinin (HA) as well as improving feed conversion by 23.8% in birds whose diet included a sodium bentonite additive.

Necessity for intended use, known alternatives

No known alternative.

Origin of raw materials, methods of manufacture
Bentonite is an absorbent aluminium phyllosilicate clay consisting mostly of montmorillonite. One of the first findings of bentonite was in the Cretaceous Benton Shale near Rock River, Wyoming.

The different types of bentonite are each named after the respective dominant element, such as potassium (K), sodium (Na), calcium (Ca), and aluminium (Al). Bentonite usually forms from weathering of volcanic ash, most often in the presence of water. However, the term bentonite, as well as a similar clay called tonstein, has been used to describe clay beds of uncertain origin. For industrial purposes, two main classes of bentonite exist: sodium and calcium bentonite. In stratigraphy and tephrochronology, completely devitrified (weathered volcanic glass) ash-fall beds are commonly referred to as K-bentonites when the dominant clay species is illite. In addition to montmorillonite and illite another common clay species that is sometimes dominant is kaolinite. Kaolinite-dominated clays are commonly referred to as tonsteins and are typically associated with coal.

Environmental issues, use of resources, recycling
No information on it.

Animal welfare issues
Bentonites are safe for all animal species when used at a maximum level of 20,000 mg/kg complete feed. (EFSA, 2017).

Human health issues
Bentonites are safe for all the consumers when used at a maximum level of 20,000 mg/kg complete feed. The results of a new genotoxicity study done by EFSA in 2017 reinforced the previous conclusion that smectites are non-genotoxic. Bentonites are not skin irritants but might be mildly irritant to the eye; based on a new study submitted, the additive is not a skin sensitiser. Owing to its silica content, the additive is a hazard by inhalation for the users (EFSA, 2017).

Food quality and authenticity
Not applicable

Traditional use and ***precedents in organic production***
Bentonite clay has outstanding physico-chemical properties which make it useful in a wide range of areas of application such as water treatment, medical, groundwater barrier, farming, and construction to mention just a few. This clay is known to be one of the most versatile and inexpensive treatments available. Some of the many health benefits of bentonite clay are: balancing bacteria in the digestive tract and improving nutrient assimilation.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Bentonite is listed in USDA National Organic Program as §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)).”

Bentonite is not listed in USDA National Organic Program as prohibited additive.

Bentonite is listed in IFOAM Norms as permitted in APPENDIX 3: CROP PROTECTANTS AND GROWTH REGULATORS, II. MINERAL ORIGIN and APPENDIX 4 – TABLE 1: LIST OF APPROVED ADDITIVES1 AND PROCESSING / POST-HARVEST HANDLING AIDS INS 558 Bentonite, Only for fruit and vegetable products

Other relevant issues
None

Reflections of the Group / Balancing of arguments in the light of organic production principles
The group is aware that this is a request for extension of the current permitted use. It is applicable to all edible animal species.

The group is not aware of alternatives for this specific use. Vegetable carbon may be an alternative, but no dossier is available on this.

As bentonite is already listed as authorized in Annex VI, the group assumes that the applicant wants the substance to be included in Annex V and not VI.

It is likely to improve the health status of the animals and improve the capability of the animals to cope with stress events. Therefore, it may improve animal welfare, without veterinary medical treatment.

The group is aware of a strong need for a substance that will reduce impact of mycotoxins, particularly in poultry feed.

The addition of bentonite must not enable the use of poorer quality feeds with higher levels of mycotoxins or lower nutritional values.

Conclusions
The use of the feed additive bentonite as feed additive is in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007.

The group recommends addition of the feed additive bentonite as a permitted feed additive in Annex V (feed additives used in animal nutrition) to Regulation (EC) No 889/2008

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2.16. Substance Xanthan gum (feed)

Introduction, scope of this chapter

The assessment of Xanthan gum relates to the request for inclusion of this substance as a feed additive in Annex VI (feed additives used in animal nutrition) as Technological feed additives with the sub classification (d) stabilisers and (e) thickeners.

The dossier was submitted by France.

CAS- number 11138-66-2

E-number E415

Authorisation in general production and in organic production

Xanthan gum is listed in the European Union Register of Feed Additives pursuant to Regulation (EC) No 1831/2003 in Annex I List of additives category 1 as Emulsifying and stabilising agents, thickeners and gelling agents.

Xanthan gum is authorised by Commission Regulation (EC) no 889/2008 of 5 September 2008 in Annex VIII section A — Food Additives, including carriers.

Agronomic use, technological or physiological functionality for the intended use

Gum is the common term for hydro colloidal gels-polysaccharides that have an affinity for water and exhibit binding properties with water and other organic/inorganic materials. Traditionally, gums have been derived from a wide variety of plants. Chemically gums are carbohydrate polymers or polysaccharides (however, gelatine is a protein). Polysaccharides are present in all life forms. Dextran, discovered in early 1940s, was the first microbial polysaccharide to be commercialised. The second microbial polysaccharide commercialised was xanthan. Xanthan gum is a natural polysaccharide and an important industrial biopolymer. It was discovered in 1963 (Palaniraj and Jayaraman, 2011).

Xanthan gum is an exopolysaccharide mainly obtained from a plant pathogenic microorganism of the genus *Xanthomonas*, the strain *X. campestris NRRL B-1459* being the mostly used. *Xanthomonas spp*. occur as single straight rods. The cells are Gram-negative, motile, having a single polar flagellum. The microorganism is strictly aerobic, thus oxygen being an essential nutrient both for microorganism growth and for xanthan production [6]. Its production is relatively expensive due to glucose and/or saccharose being used as the sole carbon source. However, there is a possibility of obtaining the carbon source from waste and residues from agriculture in order to reduce the production costs and to encourage the re-use of waste (Lopes et al., 2015; Palaniraj and Jayaraman, 2011).

Xanthan gum is highly soluble in both cold and hot water, and this behaviour is related with the polyelectrolyte nature of the xanthan molecule. Xanthan solutions are highly viscous even at low polymer concentrations. These properties are useful in many industrial applications, especially in the food industry where xanthan is used as a thickener, and to stabilise suspensions and emulsions. The thickening ability of xanthan solutions is related with viscosity; a high viscosity resists flow. Xanthan solutions are pseudoplastic, or shear thinning, and the viscosity decreases with increasing shear rate. The viscosity also depends on temperature (both dissolution and measurement temperatures), the biopolymer concentration, concentration of salts, and pH (García-Ochoa et al., 2000; Lopes et al., 2015).

The major applications of xanthan gum are in food industry as a suspending and thickening agent for fruit pulp and chocolates. United States Food and Drug Administration have approved xanthan on the basis of toxicology tests for use in human food. Many of today's foods require the unique texturisation, viscosity, flavour release, appearance and water-control properties. Xanthan gum improves all these properties and additionally controls the rheology of the final food product (Palaniraj and Jayaraman, 2011).

Xanthan, along with locust bean gum or guar produces a homogeneous gelled product (for blood chunks or semi-moist pet foods). In liquid milk replacers for calves and piglets xanthan gum is used to stabilise the suspension of insoluble substances. Xanthan is often used in combination with locust bean gum and guar gum as stabiliser and binder in the formulation of canned gravy-based pet food (Palaniraj and Jayaraman, 2011).

Industrial xanthan gum products are manufactured to meet formulation criteria such as long-term suspension and emulsion stability in alkaline, acid and salt solution; temperature resistance, and pseudo plasticity. Xanthan has wide applications in the chemical industry. A mixture of xanthan and locust bean gum can be used in deodorant gels (Palaniraj and Jayaraman, 2011).

Necessity for intended use, known alternatives

Currently, lecithins are the only emulsifier for animal feed authorised in organic production. However, their use is restricted to aquaculture. Hence, there is currently no available alternative for feed for livestock species and companion animals. And no feed ingredient can be used as stabiliser and/or thickener for the production of organic feed. Guar gum can be used in organic feed but does not have the same technological properties as xanthan gum.

Xanthan gum has different properties compared to Guar gum (E412) which has a lower viscosity, does not work in extreme pH conditions, high concentrations of trace elements or chlorine. Xanthan gum, unlike guar gum, allow stabilise specific liquid formulations (extreme pH conditions, high concentrations of trace elements, etc.).

Xanthan gum is very resistant to pH variations and is therefore stable in both alkaline and acidic conditions. The thermal stability of xanthan gum is usually superior to most other water-soluble hydrocolloids. Thus, the rheological properties of the final products remain stable, irrespective of being kept in a refrigerator, stored at room temperature, or heated. It tolerates most salts and specifically high levels of monovalent ions. Depending on the type of ions, pH and concentration, the addition of electrolytes can actually increase the viscosity and stability. Xanthan gum also has an excellent stability in the presence of acids and can be dissolved directly into many acidic solutions (García-Ochoa et al., 2000).

High viscosities are achieved even when xanthan gum is present in small concentrations. Even at low concentrations, xanthan gum solutions offer a higher degree of viscosity than other polysaccharides (García-Ochoa et al., 2000)

Origin of raw materials, methods of manufacture

The general structure of xanthan gum consists of a cellulose backbone with trisaccharide side chains (Palaniraj and Jayaraman, 2011). Repeated pentasaccharide units are formed by two molecules of glucose, two molecules of mannose (a carbohydrate), and one molecule of glucuronic acid (an oxidised glucose molecule). The glucose backbone is protected from chemical attack (e.g., from acids, alkalis, or food enzymes) by the large overlapping side chains each consisting of a glucuronic acid unit between two mannose units. When xanthan gum is dissolved in solution, the side chains wrap around the backbone, and it is thought that this contributes to the stability of xanthan gum under adverse conditions such as acidic and high salt environments (Sworn, 2009)

Environmental issues, use of resources, recycling

Xanthan gum is a water-soluble polysaccharide. This substance is naturally secreted by ubiquitous soil bacteria. It is degraded by the bacteria present in nature. The use of this ingredient in animal feed under the recommended conditions of use is therefore not expected to present a risk for the environment.

Animal welfare issues

Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2016) evaluated xanthan gum and declared that no observable adverse effect level (NOAEL) of 750 mg/kg bw per day was established for xanthan gum in neonatal pigs, which are an appropriate animal model for the assessment of the safety of the additive for infants. The margin of exposure based on this NOAEL and the conservative estimate of xanthan gum intake of 220 mg/kg bw per day by infants (high energy requirements for fully formula-fed infants) is 3.4. On the basis of a number of considerations, the Committee concluded that the consumption of xanthan gum in infant formula or formula for special medical purposes intended for infants is of no safety concern at the maximum proposed use level of 1000 mg/L.

Human health issues

The margin of exposure based on the NOAEL established in neonatal pigs and the conservative estimate of xanthan gum intake of 220 mg/kg bw per day by infants (high energy requirements for fully formula-fed infants) is 3.4. On the basis of a number of considerations, the Committee concluded that the consumption of xanthan gum in infant formula or formula for special medical purposes intended for infants is of no safety concern at the maximum proposed use level of 1000 mg/L (JECFA, 2016).

Based on the reported use levels, a re□ned exposure of up to 64 mg/kg bw per day in children for the general population, 38 mg/kg bw per day for children consumers only of food supplements at the high level exposure and 115 mg/kg bw per day for infants consuming foods for specia l medical purposes and special formulae (FSMPs), were estim ated. Based on the reported use levels, a re□ned exposure of up to 64 mg/kg bw per day in children for the general population, 38 mg/kg bw per day for children consumers only of food supplements at the high level exposure and 115 mg/kg bw per day for infants consuming foods for specia l medical purposes and special formulae (FSMPs), were estim ated. Based on the reported use levels, a re□ned exposure of up to 64 mg/kg bw per day in children for the general population, 38 mg/kg bw per day for children consumers only of food supplements at the high level exposure and 115 mg/kg bw per day for infants consuming foods for specia l medical purposes and special formulae (FSMPs), were estim ated. Based on the reported use levels, EFSA (2017) estimated a refined exposure of up to 64 mg/kg bw per day in children for the general population, 38 mg/kg bw per day for children consumers only of food supplements at the high-level exposure and 115 mg/kg bw per day for infants consuming foods for special medical purposes and special formulae (FSMPs). No adverse effects were reported at the highest doses tested in chronic and carcinogenicity studies and there is no concern with respect to the genotoxicity. Repeated oral intake by adults of xanthan gum up to 214 mg/kg bw per day for ten days was well tolerated, but some individuals experienced abdominal discomfort, an undesirable but not adverse effect. The Panel concluded that there is no need for a numerical ADI for xanthan gum (E 415), and that there is no safety concern for the general population at the refined exposure assessment of xanthan gum (E 415) as food additive. Considering the outcome of clinical studies and post-marketing surveillance, the Panel concluded that there is no safety concern from the use of xanthan gum (E 415) in FSMPs for infants and young children at concentrations reported by the food industry. The current re-evaluation of xanthan gum (E 415) as a food additive is not considered to be applicable for infants under the age of 12 weeks (Mortensen et al., 2017)

Food quality and authenticity
Food grade xanthan gum is used in feed.

Traditional use and precedents in organic production
Xanthan gum is used for the formulation of liquid animal feed supplements with minerals, vitamins, proteins, fats and others components that are stable over time. These specialties cannot be used without stabilisers such as xanthan gum. It also helps to ensure all ingredients are easily mixed, pumped and poured for free-flowing products in hot and cold weather. The use of xanthan gum will allow the offering of efficient nutritional products in organic farming such as calcium gels for cows, trace elements paste for young animals (all species). In these products, the contributions of minerals will be better adapted to the physiological phase (growth, production, reproduction, etc.). In addition to the better efficiency of the products, the handling for breeders is easier and dosing during administration is more precise. It is also used to ensure the stabilisation of premixture of silage additives when dispersed in water for application onto fresh forage, before ensiling. Without xanthan gum, silage feed additives such as microorganisms do not remain well dispersed into the water tank and flocculate at the bottom of the tank. In consequence, the even distribution into silage is affected.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Xanthan gum is listed in USDA National Organic Program as §205.605 Non-agricultural (nonorganic) substances allowed as ingredients in or on processed products labelled as “organic” or “made with organic (specified ingredients or food group(s)).” point (b) Synthetics allowed.

Xanthan gum is listed in IFOAM Norms as permitted in APPENDIX 4 – Table 1: List Of Approved Additives1 And Processing /Post-Harvest Handling Aids as additive

Other relevant issues
None

Reflections of the Group / Balancing of arguments in the light of organic production principles
Xanthan gum is already authorised by the European regulation for the production of organic food as an additive (Annex VIII to Regulation (EC) No 889/2008. It is present in Annex I to Regulation (EC) No 1831/2003 as Emulsifying and stabilising agents, thickeners and gelling agents.

The properties of Xanthan gum are well described and seems to improve the stability of the product.

The group is clear that Xanthan gum produced by GM organisms or from GM substrates would not be permitted.

Conclusions
The use of Xanthan gum as a feed additive, is in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007.

The addition of Xanthan Gum to Annex VI to Regulation (EC) No 889/2008 is recommended.

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