EGTOP/2019

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 VI – Feed IV Final Report

The EGTOP adopted this technical report at the plenary meeting of 3 to 5 December 2019.

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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ACKNOWLEDGMENTS

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TABLE OF CONTENTS

EXECUTIVE SUMMARY

The Group made the following conclusions:

Food

Sucrose Esters (E473)
The group cannot make a final recommendation on the use of Sucrose esters as a food additive in Annex VIII A of Regulation (EC) No 889/2008 or to assess the compliance with the objectives, criteria and principles of organic Regulation (EC) No 834/2007.
The addition of Sucrose esters to Annex VIII A of Regulation (EC) No 889/2008 is not recommended, until further information on use on other fruits is received.

Beta-carotene
The use of β-carotene as a colouring in milk based drinks, is not authorised in Regulation (EC) No 1333/2008, therefore, it cannot be assessed as a food colouring in organic foods.
Even if authorised in non-organic food, the addition of β-carotene to organic flavoured milk drinks would not be in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007.

Tricalcium phosphate (E341)
The use of Tricalcium phosphate as a food additive in organic foods is not in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007.
The addition to Annex VIII A of Regulation (EC) No 889/2008 is not recommended.

Xylitol, non-fermentable sugar alcohol (E967)
In the case that Xylitol can be produced according to organic regulation at every stage it should be allowed as a food additive in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007. Therefore, organic Xylitol should be added to Annex VIII A of Regulation (EC) No 889/2008.
However, the group expressed a concern that the process is covered by patent(s) and that this could be a crucial limitation on use of this process. This should be investigated before this process is added to the regulation.

Sorbitan monostearate (E491)
Sorbitan Monostearate is already indirectly included in the Annex VIII of Regulation (EC) No 889/2008, article 27 (1) (b), where it states "preparation of micro-organisms normally used in food processing" are allowed as substances in food processing as these preparations usually include Sorbitan Monostearate.

Iron oxides and hydroxides (E172)
The use of iron oxide as a food additive is not in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007.
The addition to of Iron oxide to Annex VIII A of Regulation (EC) No 889/2008 is not recommended.
The group concluded that laser coding of organic fruit and vegetables without contrast enhancer can be done as there are no current positive or negative lists of labelling processes. Furthermore, it has the potential to reduce packaging materials.

Activated carbon
The use of activated carbon as a food processing aid for food products of animal origin is in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007.
The addition to Annex VIII B of Regulation (EC) No 889/2008 for use for preparation of

foodstuffs of animal origin is recommended.

Sodium alginate (E401)
The use of the Sodium Alginate as an additive to create a skin on animal based sausages is in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007.
The addition to Annex VIII A of Regulation (EC) No 889/2008 with the permission for use for preparation of foodstuff of animal origin is recommended, providing the process of creation of alginate based skins is not covered by limiting patents. Consider also the possibility to limit the conditions for use to be derived from organic certified seaweed.

Calcium chloride (E509)
The use of Calcium chloride as a processing aid to coagulate a Sodium alginate skin on animal based sausages is in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007. The addition to Annex VIII B of Regulation (EC) No 889/2008 with the permission for use with animal based products is recommended, providing the process of creation of alginate based skins is not covered by limiting patents.

Ion Exchange resins (IER) for starch saccharification
The Group concludes that the use of ion exchange to produce highly purified substances such as glucose syrup, maltodextrins etc. is not in line with the objectives, criteria and principles of organic farming as laid down in the organic Regulation (EC) No 834/2007.

Cationic ion exchange resins (IER) for sugar production
The use of ion exchange as a process for decalcification of sugar beet juice is not in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007.
Annex VIII B of Regulation (EC) No 889/2008 cannot be changed to include this process.

Innovative process for whey demineralisation for organic infant formulas
The use of the described processes for demineralisation of whey proteins is not in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007 but it may be considered as an alternative to ion exchange only for production of organic infant formula.
However, the group expressed a concern that the process is covered by patent(s) and that this could be a crucial limitation on use of this process. This should be investigated before this process is added to the regulation.

Steviol Glycosides (E960)
If the issues regarding the patent and the compliance with requirements for E960 can be adequately resolve, the group considers that the use of Steviol glycosides (E960) can be in line with the objectives, criteria and principles of organic regulation 834/2007. Therefore, the addition of Steviol glycoside to Annex VIII A of Regulation 889/2008 can be recommended with the following additional requirements: only from EU certified organic production and only for use in foodstuffs for particular nutritional uses.

Feed

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

Calcium Hydroxide
The addition of Calcium hydroxide to Annex V (1) of Regulation (EC) No 889/2008 as a feed materials of mineral origin for dairy cattle feed is not in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007. The addition to of Calcium hydroxide to Annex V (1) of Regulation (EC) No 889/2008 is not recommended.

1. TERMS OF REFERENCE

In light of the most recent technical and scientific information available to the experts, the Group is requested:
To answer if the use of the below listed substances/techniques are in line with the objectives, criteria and principles as well as the general rules laid down in Council Regulation (EC) No 834/2007 and, hence, can be authorised to be used in organic production under the EU organic legislation:

Food

- Sucrose ester (E473);
- Beta-carotene;
- Tricalcium phosphate (E341 iii);
- Xylitol, non-fermentable sugar alcohol (E967);
- Sorbitan monostearate (E491);
- Iron oxides and hydroxides (E172);
- Activated carbon;
- Sodium alginate (E401);
- Calcium chloride (E509);
- Ion Exchange resins (IER) for starch saccharification;
- Cationic ion exchange resins (IER) for sugar production;
- Innovative process for whey demineralisation for organic infant formulas;
- Steviol Glycosides (E960).

Feed

- Monoammonium phosphate
- Calcium Hydroxide

2. CONSIDERATIONS AND CONCLUSIONS

2.1. Sucrose Esters (E473)

Introduction, scope of this chapter

The assessment of Sucrose esters relates to the request for inclusion of this substance as a food additive in Annex VIII Section A (additives for use in food) for use with organic fruit only. While the dossier is a stand-alone document, it is accompanied by information supporting the use of plasma gas for treatment of fruit.
The dossier was submitted by NL.

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 foods, 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.
EU Organic. Sucrose esters (E473) are not permitted in Regulation (EC) No 889/2008. Ref:

Agronomic use, technological or physiological functionality for the intended use

The use appears to restrict oxygen access to the fruit, reducing grown 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.

Necessity for intended use, known alternatives

The use is not necessary to provide fruit. However, it may reduce wastage, 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.

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 cannot be a food. Further, it is not absolutely clear whether both the Sucrose and the palm oil would be organic or just the sucrose.

Environmental issues, use of resources, recycling.

On the positive side this treatment could significantly reduce spoilage of fruits, reducing wastage, 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.

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

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 could be unlikely to consume organic fruit if labelled with the fact that the surface had been treated with sucrose esters.

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.

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/text-idx?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.pdf

Other relevant issues
None

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. 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.
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.
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.

Conclusions
The group cannot make a final recommendation on the use of Sucrose esters as a food additive in Annex VIII A of Regulation (EC) No 889/2008 or to assess the compliance with the

objectives, criteria and principles of organic Regulation (EC) No 834/2007.
The addition of Sucrose esters to Annex VIII A of Regulation (EC) No 889/2008 is not recommended, until further information on use on other fruits is received.

References
Usable links:

Final reports
https://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports_en

2.2. β-carotene

Introduction, scope of this chapter

This assessment of β-carotene (E160a) relates to the request for inclusion of this substance as a food additive in Annex VIII Section A, of Regulation (EC) No 889/2008 as a colourant for flavoured milk products.
The dossier was submitted by Poland.

Authorisation in general production and in organic production

β-carotene is authorised by Regulation (EU) No 1129/2011of 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 and can be used for the following livestock products:
Ripened cheese (1.7.2) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013)
Processed cheese (1.7.5) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013)
Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions (2.2.2) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013)
Cheese products (excluding products falling in category 16) (1.7.6) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013)
Fats and oils essentially free from water (excluding anhydrous milkfat) (2.1) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013)
Butter and concentrated butter and butter oil and anhydrous milkfat (2.2.1)
It does not appear to be authorised for use in flavoured milk in Regulation (EC) No 1333/2008
It is not permitted as an additive in annex VIII A of Regulation (EC) No 889/2008 for use in organic foods.

Agronomic use, technological or physiological functionality for the intended use

β-Carotene is the most common form of carotene in plants. When used as a food colouring, it has the E-number E160a.

Necessity for intended use, known alternatives

Colourant for flavoured milk products

Origin of raw materials, methods of manufacture

No information available

Environmental issues, use of resources, recycling

No information

Animal welfare issues

Not relevant

Human health issues

In 2012, The EFSA Panel concluded that based on the presently available dataset, no ADIs for mixed carotenes and β-carotene can be established and that the use of (synthetic) β-carotene and mixed β-carotenes obtained from palm fruit oil, carrots and algae as food colour is not of safety concern, provided the intake from this use as a food additive and as food supplement, is not more than the amount likely to be ingested from the regular consumption of the foods in which they occur naturally (5-10 mg/day). This would ascertain that the exposure to βcarotene from these uses would remain below 15 mg/day, the level of supplemental intake of βcarotene for which epidemiological studies did not reveal any increased cancer risk. Furthermore, the Panel could not conclude on the safety in use of mixed carotenes [E 160a (i)]

Food quality and authenticity

No specific information. Nevertheless, in the group' opinion the scope itself conflicts with the authenticity principle.

Traditional use and precedents in organic production
None

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
β-Carotene is listed in USDA National Organic Program as §205.606 Non-organically produced agricultural products allowed as ingredients in or on processed products labelled as "organic."
β-Carotene is not listed in USDA National Organic Program as prohibited additive.
β-Carotene is not listed in IFOAM Norms as a permitted additive in Appendix 4 Table 1. Ref: https://www.ifoam.bio/sites/default/files/ifoam_norms_july_2014_t.pdf

Other relevant issues
None

Reflections of the Group / Balancing of arguments in the light of organic production principles
The use of colourings in milk is not in line with the organic objectives as it hides the true nature of the food.
No information about the origin of the β-carotene used in the milk product was supplied. It is not authorised for use in flavoured milk in Regulation (EC) No 1333/2008.

Conclusions
The use of β-carotene as a colouring in milk based drinks, is not authorised in Regulation (EC) No 1333/2008, therefore, it cannot be assessed as a food colouring in organic foods.
Even if authorised in non-organic food, the addition of β-carotene to organic flavoured milk drinks would not be in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007.

References
EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the re-evaluation of Mixed Carotenes (E 160a (i)) and beta-Carotene (E 160a (ii)) as a food additive. EFSA Journal 2012;10(3):2593. [67 pp.] doi:10.2903/j.efsa.2012.2593. Available online: www.efsa.europa.eu/efsajournal.htm
Kudumovic A., Dervisevic A., 2008, Additives and health consequences. HEALTHMED Volume: 2 Issue: 1 Pages: 55-58 Published: MAR 2008
Final reports
https://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports_en
USDA Organic list
https://www.ecfr.gov/cgi-bin/text-idx?c=ecfrandSID=9874504b6f1025eb0e6b67cadf9d3b40andrgn=div6andview=textandnode=7:3.1.1.9.32.7andidno=7
Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)
http://apps.who.int/food-additives-contaminants-jecfa-database/search.aspx

2.3. Tricalcium phosphate (E341 iii)

Introduction, scope of this chapter

The assessment of Tricalcium phosphate (E341iii) relates to the request for inclusion of this substance as a food additive for foodstuff of animal origin as stabiliser in Annex VIII Section A of Regulation (EC) No 889/2008. The application specially mentioned the use of Tricalcium phosphate in drinks based on raw materials of animal origin (based on milk), iced coffee and flavoured drinks (strawberry, banana, salty caramel).

The dossier was submitted by Poland

Authorisation in general production and in organic production

General production

Tricalcium phosphate is authorised by

Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)

Regulation of Ministry of Health of 22 November 2010 on the permitted additional substances (Dz. U. 2011 nr 91 poz. 525)

Organic production

EU: Regulation (EC) No 889/2008 Annex VIII A: At the moment Tricalcium phosphate E341iii is not allowed in organic production. Only E341i, Monocalcium phosphate is allowed for use as raising agent for self-raising flour.

Agronomic use, technological or physiological functionality for the intended use

Tricalcium phosphate is used as stabiliser and acidity regulator in drinks based on milk.

Necessity for intended use, known alternatives

Tricalcium phosphate is used as stabiliser or acidity regulator. There are several flavoured milk based drinks on the market. As acidity regulator, Sodium citrate (E331) and to stabilise, pectin can be used. There are conventional coffee drinks on the market without any additives. As well organic coffee drinks are on the market not using any stabiliser.

Origin of raw materials, methods of manufacture

Tricalcium phosphate is produced commercially by treating hydroxyapatite with phosphoric acid and slaked lime or heating of a mixture of a calcium pyrophosphate and calcium carbonate. Tricalcium phosphate occurs naturally in several forms as a rock (30 – 40%), in skeletons and teeth of vertebrate animals and in milk.

Environmental issues, use of resources, recycling.

Used as food additives it is a very small amount, it will be metabolised when eating the product.

Animal welfare issues

Not applicable.

Human health issues

EFSA 2019: Re-evaluation of phosphoric acid-phosphate – di-tri- and phoyphosphates (E 338–341, E 343, E 450–452) as food additives and the safety of proposed extension of use:

"The Panel noted that in the estimated exposure scenario based on analytical data exposure estimates exceeded the proposed ADI for infants, toddlers and other children at the mean level, and for infants, toddlers, children and adolescents at the 95th percentile. The Panel also noted that phosphates exposure by food supplements exceeds the proposed ADI. The Panel concluded that the available data did not give rise to safety concerns in infants below 16 weeks of age consuming formula and food for medical purposes."

Considering human health there is no reason not to allow Tricalcium phosphate as additive.

Food quality and authenticity
Not applicable

Traditional use and precedents in organic production
Milk based flavoured drinks are not traditional, therefore there is no traditional use.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Tricalcium phosphate is listed in USDA National Organic Program as Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labelled as "organic" or "made with organic (specified ingredients or food group(s))." Section B: synthetics allowed: Calcium phosphates (monobasic, dibasic, and tribasic).(§205.605)
https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=9874504b6f1025eb0e6b67cadf9d3b40&rgn=div6&view=text&node=7:3.1.1.9.32.7&idno=7#se7.3.205_1605
(834/2007
Tricalcium phosphate is not listed in IFOAM Norms as permitted in Appendix 4 https://www.ifoam.bio/sites/default/files/ifoam_norms_july_2014_t.pdf

Other relevant issues
None

Reflections of the Group / Balancing of arguments in the light of organic production principles
The applicant mentioned the aspect that it is highly relevant for the development of new organic products. The new products address a new trend in consumer preferences. It is true that consumer prefer more and more convenience products including drinks. But, it is possible to produce such drinks without any additives even in conventional products. Therefore, we consider that it is not necessary to use Tricalcium phosphate as a food additive in annex VIII A of Regulation (EC) No 889/2008. Additionally, considering health issues, while there is no reason on health grounds not to allow Tricalcium phosphate, there appears no strong justification to permit it. To do so may hide the true nature of the product (834/2007, art. 6) and be contrary to Art. 6 (b) on the restriction of the use of food additives.

Conclusions
The use of Tricalcium phosphate as a food additive in organic foods is not in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007.
The addition to Annex VIII A of Regulation (EC) No 889/2008 is not recommended.

References
Usable links:
Final reports
https://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports_en

2.4. Xylitol, non-fermentable sugar alcohol (E967)

Introduction, scope of this chapter

The assessment of Xylitol relates to the request for inclusion of this substance as a food additive in Annex VIII Section A of Regulation (EC) No 889/2008 as a sweetener as well as for marketing as a monoproduct. The dossier is accompanied by several documents, relating to the process of Xylitol, but no details of the production are shown.
The dossier was submitted by Germany

Authorisation in general production and in organic production

Xylitol (E967) is authorised by Regulation (EC) No 1333/2008 as sweetener without any restrictions. Xylitol is listed on the EU Register on nutrition and health claims http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=search. It is allowed to use the following claims:

Agronomic use, technological or physiological functionality for the intended use

Xylitol is a substance which is widely known in nature and can be found in various plants, but also in the human body, up to 15 gram is synthesised daily in the liver. Industrially manufactured Xylitol is a natural occurring sweetener with a sweetening power of 100% of Sucrose.
Consumption of foods/drinks containing Xylitol instead of sugar contributes to the maintenance of tooth mineralisation, as well as induces a lower blood glucose levels after their consumption compared to sugar-containing foods/drinks, specifically for the use in Chewing gums.
Chewing gum sweetened with 100% xylitol has been shown to reduce dental plaque. High content/level of dental plaque is a risk factor in the development of caries in children.

Necessity for intended use, known alternatives

As an alternative Erythritol which is available as organic can be used. Erythritol already included in Annex VIII A is not an equivalent substitute for Xylitol, as it only contains approx. 70% of the sweetening power of Sucrose, which leads to problems with the development of recipes. Products made with sugar cannot be produced in the same form with Erythritol. The sweetening power of Xylitol, on the other hand, is almost identical to that of sugar, so that recipes can be converted very easily 1:1. In contrast to Erythritol, no clearly recognisable side taste is present with Xylitol.

Origin of raw materials, methods of manufacture

The dossier contains a flow chart and certificate of existing organic Xylitol. The flow chart shows the production starting with Xylose. Xylose has to be produced first by extracting Xylan from wood or other organic material as corn cobs. The dossier describes two different methods of production.

Method 1

Industrial production begins with Xylan, which is extracted from hardwoods or corncobs. The respective polymers are than hydrolysed into Xylose, which is catalytically hydrogenated into Xylitol. The conversion changes the sugar (Xylose, an aldehyde) into a primary alcohol (Xylitol).

Method 2

Microbial processes, including fermentative and bio-catalytic processes in bacteria, fungi, and yeast cells, benefit from the Xylose-intermediate fermentations in order to produce high amounts of Xylitol. Commonly used yeast cells for effective fermentation and production of Xylitol are *Candida tropicalis* and *Candida guilliermondii*.
For the fermentation process the broth requires Xylose. To produce Xylose – see method 1. A

review paper about processing methods of Xylitol concludes:
"No reports are available in the literature concerning the direct production of Xylitol through saccharification and simultaneous fermentation or enzymatic synthesis from lignocellulosic biomass."
In this publications it is as well written that to obtain a good result genetically engineered organisms should be used/be produced. It needs tailor made organisms.
The following table shows the difference of the process.

Factors of biological and chemical processes for xylitol production

Factor	Biological	Chemical
Carbon source	Xylose from lignocellulose	Pure xylose Xylose from lignocellulose
Catalyst	Yeast/ bacteria/fungi that required xylose reductase and xylitol dehydrogenase enzyme.	Nickel and hydrogenation
Process steps	1. Acid or enzymatic hydrolysis of lignocellulose	1. Acid hydrolysis of lignocellulose
	2. Detoxification of hydrolysate	2. Purification of hydrolysate to obtain pure xylose
	3. Fermentation of hydrolysate to xylitol	3. Hydrogenation of xylose to xylitol
	4. Xylitol purification	4. Xylitol crystallisation
Purification	Complex downstream process because of different microbial by-products	Ion-exchange resins
Cost	Lower energy and mild temperature	High (need two steps of purification process, high energy required, and laborious)

(see Mohamad N.L et al., 2015)

Environmental issues, use of resources, recycling.
If method 1 is used, the environmental issues are different using corncobs or hardwood (bark of birch tree). The first step is to extract Xylan hemicellulose from bark of birch tree or corn cob. Using the bark of birch tree the tree is killed and has to be cut down. It is more environmental friendly to use the corn cob, which is a renewable source. Corn cobs are usually thrown away or used for feed, depending on the maturation phase. Other option is to feed biogas plants or to burn them.
The actual extraction process from hardwood or corncobs is different. The corn cob source uses a natural ion-exchange interaction of hydrogen, hydrochloric acid, and steam. The wastewater from this process is (i.e. used for mushroom farming adjacent to the factory itself, and the pulp is used for fuel). The birch bark source xylitol uses the same process, but uses sulfuric acid in place of hydrochloric acid. This creates a waste product which is not suitable to be reused in

any other manner.
https://xylitol.org/about-xylitol/corn-xylitol-vs-birch-xylitol/

Animal welfare issues
None

Human health issues
Ongoing re-evaluation of food additives – focus on sweeteners at 3 December 2019 and Public consultation https://www.efsa.europa.eu/de/topics/topic/sweeteners
In contrast to sugar, xylitol has positive effects on human health. It promotes dental health because the bacteria that cause tooth decay cannot break down xylitol. Xylitol also causes an unfavourable alkaline environment in the mouth for the bacteria.
In addition, Xylitol is suitable for diabetics of types 1 and 2, since it is almost insulin-independently degraded and the blood sugar level hardly influenced.

Food quality and authenticity
It is listed as food additive, there is food grade quality available.
Traditional use and precedents in organic production
Xylitol has been used since the 2nd World War in Europe (especially in Scandinavia) as a natural sweetener.
Currently Organic Xylitol is produced in China by the company Futaste. The product is certified by CERES.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Xylitol is not listed in USDA National Organic Program as a permitted additive.
Xylitol is not listed in USDA National Organic Program as prohibited additive.
Xylitol is not listed in IFOAM Norms as permitted in Appendix 1 Table 4

Other relevant issues
Xylitol could be produced both as a monoproduct and also as an additive. If the source of the process is organic and if only processing aids listed in Annex VIII, B (889/2008) are used, it is possible to produce organic Xylitol as a monoproduct.
The chemical method (method 1) includes hydrogenation, using catalysts as processing aids, which are not listed in Annex VIII B. The biochemical method seems to use GMO.

Reflections of the Group / Balancing of arguments in the light of organic production principles
If Xylitol could be produced in a manner that it is in line with organic regulation it would be a better alternative to Erythritol due to the sweetening power being the same as Sucrose and the fact that there is no adverse taste.
However, there are a number of concerns with the information supplied, as follows.
The raw material for Xylitol in both methods is Xylose. There is no information in the dossier about methods for production of Xylose.
The dossier doesn’t show the exact description of the production method for organic Xylitol, so insufficient information is present to asses them.
It must be clear that the production of Xylitol should take place according to organic regulation at every stage. This would prevent the possibility that GM micro-organisms or enzymes derived from GM organisms could be used.
The group found documentation other than in the dossier that indicates that GMOs or enzymes from GMOs are used in the fermentation method and that ion exchange and nickel catalysts are used in the chemical method. However, according to the dossier, certified organic Xylitol does exist.

Conclusions
In the case that Xylitol can be produced according to organic regulation at every stage it should be allowed as a food additive in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007. Therefore, organic Xylitol should be added to Annex VIII A of Regulation (EC) No 889/2008.
However, the group expressed a concern that the process is covered by patent(s) and that this could be a crucial limitation on use of this process. This should be investigated before this process is added to the regulation.

References
Usable links:

Final reports
https://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports_en

Mohamad N.L et al., 2015: Xylitol Biological Production: A Review of Recent Studies. Food Reviews International, 31:1, 74-89

2.5. Sorbitan monostearate (E491)

Introduction, scope of this chapter

The assessment of Sorbitan monostearate (E491) relates to the request for inclusion of this substance as a food additive in Annex VIII Section A of Regulation (EC) No 889/2008. Specifically the dossier relates to the use of this additive in manufacture of a preparation of micro-organisms, specifically a strain of baking yeast used to reduce the acrylamide levels in baked goods. (Acryleast ^{TM})

The dossier was submitted by BE.

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

Dried yeast (Acryleast) is a preparation of micro-organisms normally used in food processing as described in article 19, (2) b of Regulation (EC) No 834/2007 and article 27 (1) (b) of Regulation (EC) No 889/2008. Dried preparations of micro-organisms usually include other components and emulsifiers such as Sorbitan monostearate.

The dossier does not mention the possibility of production of organic Acryleast. If this is to be proposed, then Sorbitan monostearate would have to be assessed for addition to Annex VIII A. Therefore the group's opinion is that there is no need to consider addition of Sorbitan Monostearate to Annex VIII A of Regulation (EC) No 889/2008.

Conclusions

Sorbitan Monostearate is already indirectly included in the Annex VIII of Regulation (EC) No 889/2008, article 27 (1) (b), where it states "preparation of micro-organisms normally used in food processing" are allowed as substances in food processing as these preparations usually include Sorbitan Monostearate.

References

Usable links:

Final reports

https://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports_en

2.6. Iron Oxides and Hydroxides (E172)

Introduction, scope of this chapter

The assessment of Iron oxides and hydroxides (E172) relates to the request for inclusion of this substance as an additive in Annex VIII Section A of Regulation (EC) No 889/2008.
The dossier was submitted by ES

Authorisation in general production and in organic production

E172 is authorised as a food additive by Regulation (EC) No 1333/2008. Ref https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1333.
It is authorised as a contrast enhancer specifically by Regulation 510/2013, Ref https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:150:0017:0020:EN:PDF which amends regulation 1333/2008 to allow E172 to be used as a contrast enhancer only for citrus fruit, melon and pomegranates only in association with the laser coding of those fruit. Note that this regulation also permits use of hydroxypropyl methyl cellulose and polysorbates as essential components of the application. These would not be permitted for this use as Regulation (EC) No 889/2008 is written and the current application does not include these compounds. It is therefore not clear whether the process will work without these compounds and therefore whether the dossier is complete.
The following definition of a contrast enhancer is found in (EC) No 1333/2008. 'contrast enhancers' are substances which, when applied to the external surface of fruit or vegetables following depigmentation of predefined parts (e.g. by laser treatment), help to distinguish these parts from the remaining surface by imparting colour following interaction with certain components of the epidermis.
It is therefore assumed that the application is for use as in (EC) No 510/2013 although this is not mentioned anywhere in the dossier.
Regulation (EC) No 889/2008 as amended includes the following in Article 27 (d) as permitted product and substance for use in processing food "colours for stamping meat and eggshells in accordance with, respectively, Article 2(8) and Article 2(9) of European Parliament and Council Directive 94/36/EC."
However, further down, Regulation (EC) No 889/2008 as amended Article 27 . has the following text. "4. For the traditional decorative colouring of the shell of boiled eggs produced with the intention to place them on the market at a given period of the year, the competent authority may authorise for the period referred to above, the use of natural colours and natural coating substances. The authorisation may comprise synthetic forms of iron oxides and iron hydroxides until 31 December 2013. Authorisations shall be notified to the Commission and the Member States." This indicates that this use is no longer permitted.
Therefore, it appears that the use of E172 Iron oxides and hydroxides is now only permitted for stamping meat in organic production.

Agronomic use, technological or physiological functionality for the intended use

Regulation 510/2013 specifically identifies that fruit treated with a laser can be printed with details, such as best before date, brand, or a bar code. In some cases, Iron oxides/hydroxides are required to enhance the colour difference between the laser marked area and the rest of the fruit.

Necessity for intended use, known alternatives

No other alternatives for the specific use as a colour enhancer on the surface of fruit is mentioned or known. This process reduces the need for the alternatives, which may be either packaging or self-adhesive labelling.

Origin of raw materials, methods of manufacture

Iron oxide is a mined mineral. It must be milled and treated in other ways to make it suitable as a colour. Iron hydroxides are dissolved from iron oxides.

Environmental issues, use of resources, recycling.
No significant environmental issues were identified. Use of coding using laser reduce either external packaging or use of adhesive labels. One study identified the possible savings of 10 tons of labels and 5 tons of glue per year for use on avocados in one UK retailer alone. That use does not appear to require Iron oxide as a contrast enhancer. https://www.packagingnews.co.uk/equipment/coding-marking/ms-label-avocados-lasers-save-paper-glue-usage-21-06-2017

Animal welfare issues
None

Human health issues
E172 was re-evaluated by EFSA in 2015. The view of the committee was mixed and not conclusively positive. They identified lack of data on genotoxicity and sub-acute toxicity on some forms of E172. They also identified concerns relating to production of nanoparticles in preparations of these colours and the lack of data on their toxicity. However the legislation for this process relates only to the use for fruits where the skin is not normally eaten.

Food quality and authenticity
No issues identified. While it may cause comment to see brown printing on the surface of a fruit the quality and authenticity is not directly affected, providing the laser is used correctly and does not go through the skin of the fruit.

Traditional use and precedents in organic production
There is no traditional use of laser coding of fruit and no traditional use of E172 as a contrast enhancer, although it has been used as a food colour for many years.
Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Iron oxide is listed in USDA National Organic Program as a source of trace elements, (iron) in agriculture.
Iron oxide is not listed in USDA National Organic Program as permitted additive (7 CFR 205.1-205.690, https://www.ecfr.gov/cgi-bin/text-idx?c=ecfrandSID=9874504b6f1025eb0e6b67cadf9d3b40andrgn=div6andview=textandnode=7:3.1.1.9.32.7andidno=7#se7.3.205_1605
E172 is not listed in IFOAM Norms as permitted additive or processing aid in Appendix 4 https://www.ifoam.bio/sites/default/files/ifoam_norms_july_2014_t.pdf

Other relevant issues
None

Reflections of the Group / Balancing of arguments in the light of organic production principles
The group expressed concerns over toxicity, of Iron oxide particularly relating to nanoparticles. In addition, due to the lack of data, the possible need for other additives and the possible limitation of the use to citrus, melon and pomegranate were sources of concern.
It was not clear whether the use of laser coding of organic fruit and vegetables is included in this application, but the group did consider it.

Conclusions
The use of iron oxide as a food additive is not in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007.
The addition to of Iron oxide to Annex VIII A of Regulation (EC) No 889/2008 is not

recommended.
The group concluded that laser coding of organic fruit and vegetables without contrast enhancer can be done as there are no current positive or negative lists of labelling processes. Furthermore, it has the potential to reduce packaging materials.

References
Usable links:

Lists of Food additives according to 1333/2008
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1333.
Final reports
https://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports_en

2.7. Activated Carbon

Introduction, scope of this chapter

This assessment of Activated Carbon (CAS- number 7440-44-0) relates to the request for inclusion of this substance as processing aid for preparation of foodstuffs of animal origin f in Annex VIII Section B of Regulation (EC) No 899/2008.
The dossier was submitted by Germany.

Authorisation in general production and in organic production

Activated Carbon is authorised as processing aid for preparation of foodstuffs of plant origin Annex VIII B Regulation (EC) No 889/2008

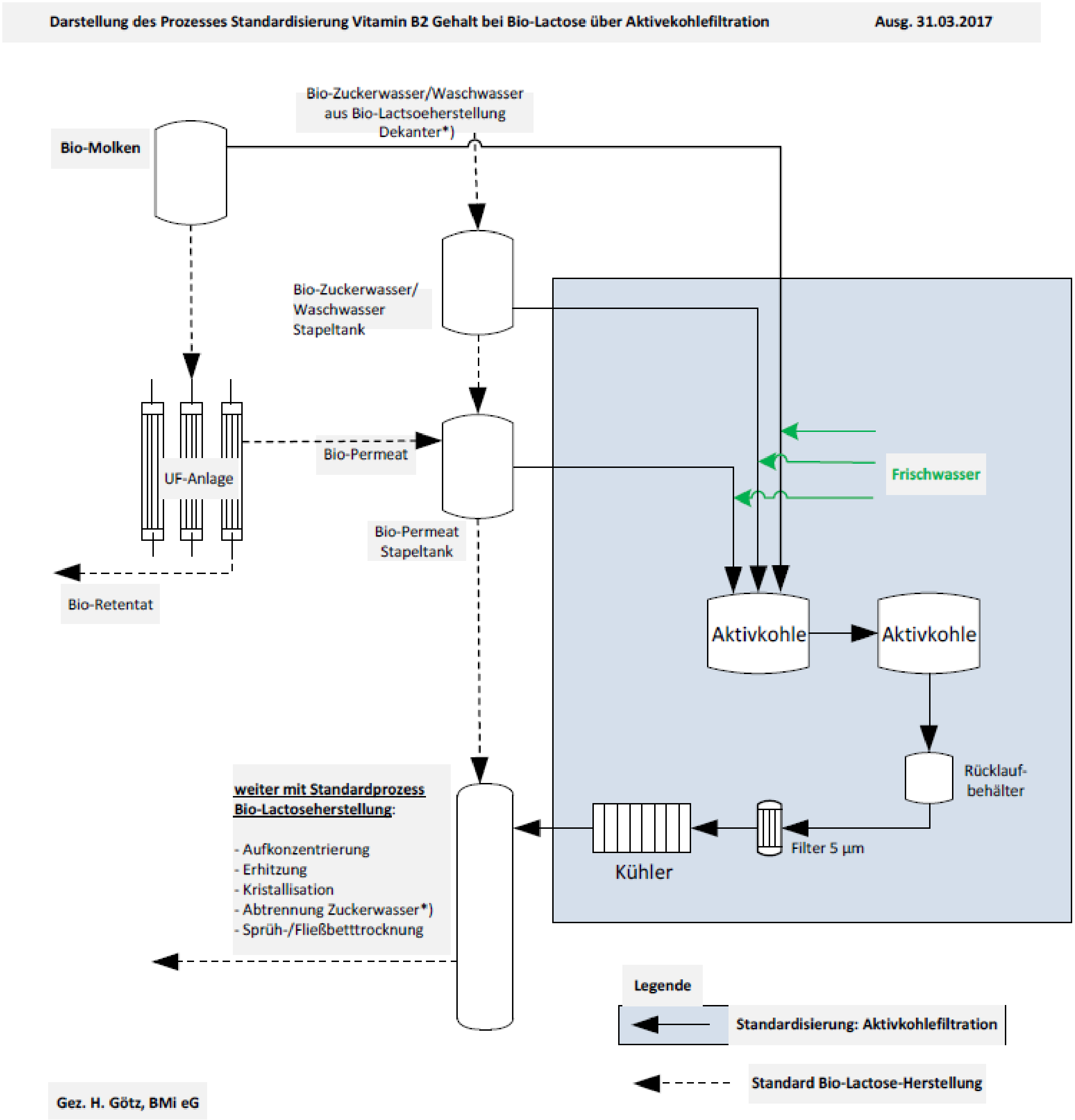
Agronomic use, technological or physiological functionality for the intended use

Activated carbon is used widely to remove organic pollutants from drinking water and wastewater and to remediate water, due to its high surface area (>1000 m2/g). Inexpensive substances with high carbon content and low inorganic content are potential raw materials for activated carbon production. The most frequently used raw materials for manufacturing activated carbon are coal, wood wastes, lignite, pistachio nutshells, corncobs, coconut shells, walnut shells, mango pits, tobacco stems, coffee bean husks, cherry stones, olive pits, and sawdust (Bae et al., 2014).
The adsorptive characteristics of activated carbon depend on the structure of the raw material and its production. Activated carbon can be manufactured by physical or chemical activation. In general, physical activation comprises a carbonisation and activation step. Steam and carbon dioxide are the most common activating reagents in physical activation, significantly influencing the porosity of the activated carbon. Chemical activation in manufacturing activated carbon usually entails a single step, for which zinc chloride, phosphoric acid, or potassium hydroxide can be used as the activating reagent. However, the chemical activation can introduce impurities such as Zn and P, depending on the chemical agent used, and can result in high operating cost due to the addition of chemicals. Therefore, the physical activation can be adapted to make clean activated carbon without incorporation of any mineral impurities and produce essentially microporous carbon (Bae et al., 2014)
The request is about using activated carbon to standardise vitamin B2 content in organic lactose for baby milk.
In the literature, there are no articles describing how to separate or purify vitamin B2 using activated carbon but some explaining how to separate or purify vitamin B12 using activated carbon.
Jia et al (2015) used polyaniline-poly (styrene sulfonate) (PAn-PSS) hydrogels pyrolysed to obtain activated carbons for the adsorption of vitamin B2 molecules. The resulting activated carbon samples maintained the previous network structure of the hydrogels. The optimum carbonisation temperature was 600°C. The activated carbons which were prepared under the optimum condition possessed high mesoporous ratio of above 70%. In addition, these activated carbon samples were nitrogen-enriched due to the PAn-PSS precursor. The adsorption tests indicated that these activated carbons had preferable adsorption ability for vitamin B12 and can reach 1531 mg/g.
Lu et al (2014) and Shen et al (2004) explored valuable technical methods using activated carbon for the purification of vitamin B12

Necessity for intended use, known alternatives

Intended use: Standardisation of Vitamin B2 in organic lactose for baby milks (Infant and Follow-on Formulae according to EU-Reg. 2016/127). Target is to replace Vitamin B2 from biotechnology sources.

Origin of raw materials, methods of manufacture



Environmental issues, use of resources, recycling
No information

Animal welfare issues
Not relevant

Human health issues
Not relevant

Food quality and authenticity
Not relevant

Traditional use and precedents in organic production
Technological function in food, particularly as an adsorption and decolourising agent used in liquid food.

Used in food products in general also as a filter material for purification of all types of liquids. The use of activated carbon to standardise vitamin B2 is not a traditional use and there is no precedent in organic food.

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

Activated Carbon is not listed in USDA National Organic Program

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

Activated Carbon is listed in IFOAM Norms as permitted in Appendix 4 – Table 1: list of approved additives1 and processing / post-harvest handling aids.

Other relevant issues

Also named: Prime Granular Activated carbon, Prime Powder Activated Carbon, Acid Washed Activated Carbon, Powdered Acid Washed Activated Carbon

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

Although no scientific evidence of the efficiency of the method to standardise content of vitamin B2 in the final product was provided in the dossier, the group does not see any specific reasons to consider that the specific use is not in line with organic objectives.

The group was aware of no reasons why the permission of using activated carbon to standardise vitamin B2 in lactose could not be extended to other uses with products of animal origin.

Conclusions

The use of activated carbon as a food processing aid for food products of animal origin is in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007.

The addition to Annex VIII B of Regulation (EC) No 889/2008 for use for preparation of foodstuffs of animal origin is recommended.

References

- EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF); Scientific Opinion on the safety evaluation of the active substances, activated carbon, water, iron powder, kaolin calcined, sulphur and sodium chloride for use as active component in food contact materials. EFSA Journal 2012;10(3):2643. [12 pp.] doi:10.2903/j.efsa.2012.2643. Available online: www.efsa.europa.eu/efsajournal
- Wookeun Bae, Jongho Kim and Jinwook Chung (2014) Production of granular activated carbon from food-processing wastes (walnut shells and jujube seeds) and its adsorptive properties, Journal of the Air and Waste Management Association, 64:8, 879-886, DOI:10.1080/10962247.2014.897272
- Y. Jia, J. Jiang, K. Sun. Pyrolysis of polyaniline-poly(styrene sulfonate) hydrogels to prepare activated carbons for the adsorption of vitamin B12, J. Anal. Appl. Pyrolysis, 111 (2015), pp. 247-253, 10.1016/j.jaap.2014.10.023
- Lu, Y., Gong, Q., Lu, F., et al. (2013). Synthesis of porous carbon nanotubes/activated carbon composite spheres and their application for vitamin B12 adsorption. Science and Engineering of Composite Materials, 21(2), pp. 165-171. Retrieved 23 Oct. 2019, from doi:10.1515/secm-2013-0094
- Shen, W., Zheng, J., Qin, Z. et al. Journal of Materials Science (2004) 39: 4693. https://doi.org/10.1023/B:JMSC.0000034173.39514.0e

2.8. Sodium Alginate (E401)

Introduction, scope of this chapter

The assessment of Sodium alginate (E401) relates to the request for inclusion of this substance as a food additive for foodstuffs of animal origin in Annex VIII Section A of Regulation (EC) No 899/2008. The application specifically mentions the use of Sodium alginate to create a "skin" on sausages and similar products. The dossier was submitted by NL.

Note that the dossier was submitted in parallel with one for addition of Calcium chloride. The whole process involves extrusion of the meat followed by re extrusion, with a coating of Sodium alginate. This is then sprayed with a solution of Calcium chloride, to precipitate and fix the coating on the sausage.

Authorisation in general production and in organic production

EU Sodium alginate is a permitted additive in (EC) No 1334/2008. Ref: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1333-20190618andfrom=EN

EU Organic: Sodium alginate is an already allowed additive for the preparation of foodstuffs of plant origin and animal origin, the latter limited to milk-based products (Regulation (EC) No 899/2008, Annex VIII A, Ref: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0889andfrom=EN.

It is authorised in organic production in Regulation 889/2008 Annex VIII A for use with plant based products. It is also authorised in the same regulation for use with foodstuffs of animal origin, but only with the condition "Milk-based products". Therefore, use to coat meat based sausages is currently not permitted.

Agronomic use, technological or physiological functionality for the intended use

The application is for use as a coating for meat based sausages using a co-extrusion process. This process could already be used as a coating for vegetarian sausages as there is no restriction in Annex VIII A relating to application for foodstuff of plant origin.

Necessity for intended use, known alternatives

Organic sausages of animal origin may currently use natural casings as permitted in of Regulation (EC) No 899/2008 Annex IX 3 Animal products. Artificial casings, usually made from cellulose are not permitted for use with organic products. Organic sausages of plant origin may already use Sodium alginate based casings as there is no restriction on the compound's use with foodstuff of plant origin. No other ways of creating an edible skin on sausages are known.

Origin of raw materials, methods of manufacture

Sodium alginate is produced by treating brown seaweeds, especially Laminaria, with Sodium hydroxide or Sodium carbonate. It may be purified using acids such as Hydrochloric acid. It is a soluble polysaccharide

Environmental issues, use of resources, recycling.

The harvesting of wild seaweed can be environmentally damaging. Example Ref https://www.gov.scot/binaries/content/documents/govscot/publications/consultation-paper/2016/11/wild-seaweed-harvesting-strategic-environmental-assessment-environmental-report/documents/00510620-pdf/00510620-pdf/govscot%3Adocument.

Controls are required to ensure that this damage is not increased by use of sodium alginate in organic production. At present organic production of Sodium alginate cannot be conducted as the required chemicals (sodium hydroxide, hydrochloric acid etc.) are not listed for the production of sodium alginate. In the longer term it is hoped that EGTOP could consider the production of organic alginates from certified sustainably harvested seaweed and thereafter a requirement be added to the regulation that only organically certified Sodium alginate should be used as additives in organic production. A requirement that Sodium alginate for use in organic production must be made from organic wild harvested seaweed could help this issue, but would be impossible to police without requiring the Sodium alginate itself to be certified organic.

Animal welfare issues
None

Human health issues
The human health implications of alginic acid and its salts including sodium alginate were assessed by the EFSA and reported in November 2017. "The Panel concluded that there was no need for a numerical ADI for alginic acid and its salts (E 400, E 401, E 402, E 403 and E 404), and that there was no safety concern at the level of the refined exposure assessment for the reported uses of alginic acid and its salts (E 400, E 401, E 402, E403 and E 404) as food additives. The Panel further concluded that exposure of infants and young children to alginic acid and its salts (E 400, E 401, E 402, E 403 and E 404) by the use of these food additives should stay below therapeutic dosages for these population groups at which side-effects could occur." Ref: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.5049

Food quality and authenticity
Alginates are widely used as a viscosifying and gelling/coagulation agent in the food industry, a well-known application for meat products for instance is the production of so-called recombined meat. However, this application specifically mentions that recombined meat production should not be permitted as it hides the true nature of the food. Nowadays, alginates are also commonly used as coating material for fresh, dried and cooked sausages worldwide, both for meat-based and vegetarian and vegan products.

Traditional use and precedents in organic production
Traditionally sausages have been made in natural casings made from intestines of animals. More recently synthetic casings made from collagen, cellulose or plastic have been used for meat based sausages. These are not permitted in organic production. Recently this technology is available to coat sausages, whether meat or non-meat based with Sodium alginate coatings by a co-extrusion process, using Calcium chloride to coagulate the Sodium alginate. This process is novel and not traditional.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Codex Alimentarius: Similar to EU regulation, sodium alginate is allowed for plant and dairy-based products (GL 32-1999, Ref: http://www.fao.org/docrep/pdf/010/a1385e/a1385e00.pdf).
USA: Alginates (not further specified) are allowed as an additive in products labelled as "USDA Organic" in the US National Organic Programme. No distinction is made between plant and animal-based products 7 CFR 205.1-205.690, Ref: https://www.ecfr.gov/cgi-bin/text-idx?c=ecfrandSID=9874504b6f1025eb0e6b67cadf9d3b40andrgn=div6andview=textandnode=7:3.1.1.9.32.7andidno=7#se7.3.205_1605).
Australia: Sodium alginate is listed as "generally unrestricted" for use in organic products (Australia Certified Organic Standard 2017 version 1, http://www.aco.net.au/downloads/ACOS_2017_V1.pdf).
Sodium Alginate is listed in IFOAM Norms (2014) as permitted additive in Appendix 4. Table 1, with no restrictions attached. Ref: https://www.ifoam.bio/sites/default/files/ifoam_norms_july_2014_t.pdf

Other relevant issues
The process requires significant equipment investment, possibly making it out of the reach of small or artisan sausage manufacturers. Ref: https://www.reiser.com/sausage/sausage-alginate-CC215.php.

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

The group expressed a concern that the process may be covered by patent(s). The group is not able to verify clearly whether or not there is/are patent(s) in place on this application. If there are patents in place the group has concern that this could be a crucial limitation on use of this process. This should be investigated before this process is added to the regulation.

Conclusions

The use of the Sodium Alginate as an additive to create a skin on animal based sausages is in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007.
The addition to Annex VIII A of Regulation (EC) No 889/2008 with the permission for use for preparation of foodstuff of animal origin is recommended, providing the process of creation of alginate based skins is not covered by limiting patents. Consider also the possibility to limit the conditions for use to be derived from organic certified seaweed.

References

Usable links:

Lists of Food additives according to 1333/2008
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1333-20190618andfrom=EN

Final reports
https://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports_en

2.9. Calcium Chloride (E509)

Introduction, scope of this chapter

This assessment of Calcium chloride (E509) relates to the request for inclusion of this substance as a processing aid for foodstuffs of animal origin in Annex VIII Section B of Regulation (EC) No 889/2008. The application specifically mentions the use of Calcium chloride with Sodium alginate to create a "skin" on sausages and similar products. This dossier should therefore be considered with the NL dossier on the use of Sodium alginate.

The dossier was submitted by NL.

Authorisation in general production and in organic production

Calcium chloride is authorised as an additive and as a processing aid by Regulation (EC) No 1333/2008, with the specific condition, for milk coagulation as an additive and for plant based products only as a processing aid. Ref: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1333-20190618andfrom=EN

It is authorised as an additive in Annex VIII A of Regulation (EC) No 889/2008 for foodstuffs of animal origin only, with the specific condition “milk coagulation”. It is authorised as a processing aid in Annex VIII B of Regulation (EC) No 889/2008 for processing of foodstuffs of plant origin only, with the specific condition “coagulation agent”. Ref: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R0889-20181112andqid=1556633916926andfrom=EN.

Agronomic use, technological or physiological functionality for the intended use

This application relates specifically to the use of Calcium chloride as a processing aid to coagulate sodium alginate into a skin on the surface of meat based sausages. As it is listed as a coagulation agent for processing food stuff of plant origin it could already be used as a processing aid to coagulation sodium alginate into a skin on the surface of plant based sausages.

Necessity for intended use, known alternatives

No alternatives are listed in the dossier. Clearly Sodium alginate will not coagulate without the addition of divalent ions and calcium chloride is the most appropriate source of soluble calcium ions for this application.

Origin of raw materials, methods of manufacture

Calcium chloride is a mineral and occurs naturally in brine lakes. However, it is normally manufactured by reaction of limestone, Calcium carbonate, with Hydrochloric acid.

Environmental issues, use of resources, recycling.

As a mined mineral there is a risk of environmental issues created by the mining, but the use in food is a tiny fraction of overall use of limestone.

Animal welfare issues

None identified.

Human health issues

The human health implications of Chlorides including Calcium chloride were assessed by the EFSA and reported in 2019. Ref: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5751

It concluded as follows. "In conclusion, chloride is a natural constituent of human, animals and plants and is present in all biological materials, including foodstuffs. Based on the toxicological database available the Panel concluded that the exposure to chloride from hydrochloric acid and its potassium, calcium and magnesium salts (E 507, E 508, E 509, E 511) does not raise a safety concern at the reported use and use levels."

Food quality and authenticity
Organic sausages of animal origin may currently use natural casings as permitted in Annex IX of Regulation (EC) No 889/2008, 3 Animal products. Artificial casings, usually made from cellulose, are not permitted for use with organic products. Organic sausages of plant origin may already use sodium alginate based casings using Calcium chloride as the coagulation agent as there is no restriction on the compound's use with plant based foodstuff.

Traditional use and precedents in organic production
While Calcium chloride is widely used traditionally as an additive and processing aid in organic production, as a coagulation agent this particular use is novel and not traditional.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Codex Alimentarius: Calcium chloride can be used in different food categories from plant and animal origin, amongst which processed meat and edible casings Ref: GL 32-1999, http://www.fao.org/docrep/pdf/010/a1385e/a1385e00.pdf.
USA: NOP. Calcium chloride is allowed as an ingredient in organic products, with no restrictions. 7 CFR 205.1-205.690 Ref: https://www.ecfr.gov/cgi-bin/text-idx?c=ecfrandSID=9874504b6f1025eb0e6b67cadf9d3b40andrgn=div6andview=textandnode=7:3.1.1.9.32.7andidno=7#se7.3.205_1605).
Australia: Calcium chloride is allowed both as an ingredient and a processing aid in the production of organic milk, fruit and vegetables, soybean and fat products Ref: Australia Certified Organic Standard 2017 version 1, http://www.aco.net.au/downloads/ACOS_2017_V1.pdf.
Calcium Chloride is listed in IFOAM Norms (2014) as permitted additive in Appendix 4. Table 1, with no restrictions attached. Ref: https://www.ifoam.bio/sites/default/files/ifoam_norms_july_2014_t.pdf

Other relevant issues
This application is specifically to add Calcium chloride as a coagulation agent for meat products so that it may be used in the creation of sodium alginate skins on meat based sausages. While no adverse effects can be seen by permitting it for all uses as a processing aid for animal based foodstuffs, this addition should not be approved if the group decides that the parallel application for addition of sodium alginate cannot be approved, and vice versa. As mentioned in the Sodium alginate report, this process may be covered by patents. Certainly it requires significant equipment investment, making it out of the reach of small or artisan sausage manufacturers.

Reflections of the Group / Balancing of arguments in the light of organic production principles
The group expressed a concern that the process may be covered by patent(s). The group is not able to verify clearly whether or not there is/are patent(s) in place on this application. If there are patents in place the group has concern that this could be a crucial limitation on use of this process. This should be investigated before this process is added to the regulation.

Conclusions
The use of Calcium chloride as a processing aid to coagulate a Sodium alginate skin on animal based sausages is in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007. The addition to Annex VIII B of Regulation (EC) No 889/2008 with the permission for use with animal based products is recommended, providing the process of creation of alginate based skins is not covered by limiting patents.

References
Usable links:

Final reports
https://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports_en

2.10. Ion exchange resins (IER) for starch saccharification

Introduction, scope of this chapter

This dossier relates to the request for inclusion of Ion Exchange Resin for starch saccharification as a food processing aid in Annex VIII Section B of Regulation (EC) No 889/2008

The aim of the process is to produce a microbiologically stable and sensorially pure organic starch saccharification products such as organic glucose syrups, organic maltodextrins, organic dextrose and degraded organic starches. The dossier was submitted by Austria.

Ion exchange technology has already been assessed several times through EGTOP mandate (Food report I and III, wine report)

Authorisation in general production and in organic production

Ion-exchange and adsorption technology are widely used in processing of food and for water treatment in the EU (EC Reg. 1935/2004 amended by EC Reg. 596/2009).

The next organic regulation EC 2018/848 confirms organic wine regulation EC 203/2012 i.e. that cationic exchange is forbidden to ensure the tartaric stabilisation of organic wine, but in the meantime, the use of ion exchange resins for the must rectification has not been reviewed and then are still authorised as such for this specific purpose in organic wine production.

In some EU countries ion exchange is considered as a processing aid and so is not permitted in organic processing, as it is not a permitted processing aid in Annex VIII, B of Regulation (EC) No 889/2008 (Egtop food report III)

Agronomic use, technological or physiological functionality for the intended use

The intended use of ion exchange resins for sugar beet juice processing is to ensure a high level of purification of the juice by removing calcium carbonate residues.

Sugar production from sugar beet is a complex process made of several steps linked together very tightly. It means that a little change at one step of the process can have a big impact on the downstream process. The dossier here deals with a very narrow step of the process already in place in several sugar factory dedicated to produce sugar in a conventional way for near a century. It seems anyway relevant to try to understand if some other production pathway could be assessed in a more systemic point of view.

Necessity for intended use, known alternatives

According to Lloyd (1984), the hydrolysate can be clarified by filtration using a filter aid such as diatomaceous earth or crushed perlite. In some systems, activated, powdered carbon that has had prior use in other refining stages is applied to effect some decolourisation and make more efficient use of the decolourising carbon used in the next step.

Although carbon refining is adequate for purification of most conventional corn syrups, some applications require syrups that are ash-free, have essentially no taste other than sweetness, and are more colour stable than can be produced by carbon treatment alone.

In such cases, the carbon refined liquor is ion-exchange deionised. Such treatment removes substantially all remaining soluble nitrogenous compounds, including amino acids and peptides that contribute colour body formation via the Maillard reaction with reducing sugars. In addition, heavy metals and weakly acidic organic constituents that can affect syrup colour development on storage are removed. A typical ion-exchange deionisation system consists of six fixed-bed columns (three pairs of cation and anion exchange resin columns, two pairs of which are in service and one which is out of service for regeneration).

Ion exchange is essential in the production of certain types of sweeteners, such as high fructose syrups (Hobbs, 2009)

Origin of raw materials, methods of manufacture

The leading synthetic ion exchange resin manufacturers within Europe explain that ion

exchange resins have a polymer structure bonded to ionic groups. The nature of the ion exchange resin is greatly influenced by the network structure of its polymer matrix. For most ion exchange resins, the matrix consists of copolymers made of:
−styrene and divinylbenzene;
−methacrylate and divinylbenzene (acrylate and divinylbenzene);
−methylmethacrylate and divinylbenzene (methylacrylate and divinylbenzene).
IER can be divided into:
1.Cationic, main ionic groups:
a. Strongly acidic:-SO3- (sulfonic group)
b. Weakly acidic:-COO- (carboxylic group)
2.Anionic
a. Strongly basic:-NR3+
b. Weakly basic: -NH2; -NHR; -NR2
3.Special Ion Specific Active Groups -e.g. chelating (ref. SOIA)
In this dossier, the applicant does not introduce the type of ion exchange resin or adsorbent medium needed. It can be found in the patent list and literature that cationic and anionic ion exchange resin seems to be both used techniques for starch saccharification products refining (Lloyd, 1984: Hobbs, 2009) As an example, the cation exchangers can contain sulfonic, phosphonic, phosphorous, arsenic and like acid groups. Sulfonated phenol-aldehyde condensation products are another form of suitable cation exchange resin which can be used in the process of the invention -expired US patent US4330625A-)(Lloyd, 1984)
See also EGTOP food report I

Environmental issues, use of resources, recycling.
See EGTOP food report I

Animal welfare issues
See EGTOP food report I

Human health issues
See EGTOP food report I
As food contact material, IER are regulated at EU and national level anyway some substances from resin can be released in the treated material (Sidewell, 2006) but should not have health effect according to European Council committee of experts on materials coming into contact with food.

Food quality and authenticity
In EGTOP Food report III, it can be read that “Selected constituents can be removed very specifically, or a single constituent within the food can be selectively purified from the rest of the original food. This means that it is possible to remove, for example, some specific minerals from a product or to purify a raw material from all other constituents so that finally one substance remains. It must be mentioned clearly that the character of the original raw material is totally lost.”
In the case of starch saccharification the ultimate purpose of the production is to produce pure starch saccharification products where the raw material is no longer identifiable.

Traditional use and precedents in organic production
The use of ion exchange resin in organic processing is restricted to specific requirement like baby food production where a strict regulation controls nutritional composition.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Ion exchange resins are not listed in IFOAM Norms as permitted in Appendix 4. IFOAM EU recommends authorisation of the use of ion exchange only if there are no alternative techniques

available or if a general regulation requires some specific purity criteria as for instance in baby food production (IFOAM reaction on food report 2015).
In Swiss regulation (bourgeon), ion exchange is allowed for bleaching of starch, cereal syrups, and sugar derived from starch as well as active carbon filter.
A memorandum to the national organic standards board from USDA have been published earlier this year on this very topic and it clearly states that ion-exchange filtration is allowed in organic processing. However, non-agricultural substances used in the ion-exchange process must be on the National List of Allowed and Prohibited Substances (National List). This includes, but is not limited to, resins, membranes, and recharging materials.

Other relevant issues
None

Reflections of the Group / Balancing of arguments in the light of organic production principles
This technique is a chemical one and as such should not be allowed in organic processing, however, for pure starch saccharification product it seems that no alternative method is suitable so far for this use.
The status of ion exchange is unclear, as it is a food process, rather than a processing aid. However, previous EGTOP Food I and EGTOP Food III has taken the view that the addition of ions via ion exchange is not in line with the objectives, criteria & principles or organic Regulations 834/2007. The following is text from Food III….
"The Group opinion is that the use of ion exchange and adsorption resins as processing aids to produce glucose and fructose based on starch should not be allowed in organic production for the purpose as presented in the dossiers because of the high purification levels (decomposition of the food), which this process implies and which could mislead the consumer on the true nature of originating organic raw material (product) (Art 6 c and 19 3)), as well as because of the chemical processes involved. In particular, ion exchange does not fulfil the requirements for mechanical, physical and microbiological processes, as mentioned in Article 21 (1) and Article (4) of the organic regulation.
In the case where minerals are removed in order to fulfil the requirement of the infant formula legislation the use of ion exchange and adsorbent resin techniques is in line with the requirements of the organic regulation. Because of the specific status of those products in organic Regulation (Article 6(b) and 19.2(b)) and the target of the application is the selective removal of substances, such as minerals and not an overall decomposition."
This group shares these views. The dossier asks for a change to annex VIII. This is not possible as ion exchange is not considered as a processing aid in the regulation.

Conclusions
The Group concludes that the use of ion exchange to produce highly purified substances such as glucose syrup, maltodextrins etc. is not in line with the objectives, criteria and principles of organic farming as laid down in the organic Regulation (EC) No 834/2007.

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2.11. Cationic ion exchange resins (IER) for sugar production

Introduction, scope of this chapter

The assessment of ion exchange resin technique relates to the request for inclusion of this process as a food processing aid in Annex VIII Section B of Regulation (EC) No 889/2008.
The aim of the process is to remove calcium carbonate (decalcification or softening) from sugar beet juice before evaporation in order to avoid scaling of evaporators.
The dossier was submitted by France.
Ion exchange technology have already been assessed several times through EGTOP (Food report I and III, wine report)

Authorisation in general production and in organic production

Ion-exchange and adsorption technology are widely used in processing of food and for water treatment in the EU (EC Reg. 1935/2004 amended by EC Reg. 596/2009).
The next organic regulation EC 2018/848 confirms organic wine regulation EC 203/2012 ie that cationic exchange is forbidden to ensure the tartaric stabilisation of organic wine, but in the meantime, the use of ion exchange resins for the must rectification have not been reviewed and then are still authorised as such for this specific purpose in organic wine production.
In some EU countries ion exchange is considered as a processing aid and so is not permitted, as it is not a permitted processing aid in Annex VIII, Section B of Regulation (EC) No 889/2008 (EGTOP food report III)

Agronomic use, technological or physiological functionality for the intended use

The intended use of IER for sugar beet juice processing is to ensure a high level of purification of the juice by removing calcium carbonate residues.
Sugar production from sugar beet is a complex process made of several steps linked together very tightly. It means that a little change at one step of the process can have a big impact on the downstream process. The dossier here deals with a very narrow step of the process already in place in several sugar factory dedicated to produce sugar in a conventional way for near a century. It seems anyway relevant to try to understand if some other production pathway could be assessed in a more systemic point of view.

Necessity for intended use, known alternatives

Sugar production from sugar beet is made of many step for some of which technical alternatives are known.
The first raw juice is made by diffusion after having shred the washed beet. Raw juice is then purified from non-sugar substances to give a thin juice which is softened to avoid scaling evaporators.
Calco-carbonic purification or carbonatation is an epuration step which permit to discard non sugar molecules from the raw juice. Organic molecule are discarded with calcium carbonate formed during this step by adjunction of lime (milk of lime) and CO_2 but this step must be followed by a decalcification to remove Ca^{++} still present in the juice. Vaccari et al (2005) are firmly convinced that, in a more or less distant future, the technology of sugar production has to become more simplified, more environmentally compatible via less energy and water consumption and, in particular, the use of lime is to be avoided. They recommend using microfiltration to avoid calco-carbonic depuration. Moreover, calcium carbonate fouling is more common in factories that use the carbonatation for clarification due to the increased amount of CO_3^{--} ions in solution and calcium carbonate fouling generally occurs earlier in the evaporator set (East, 2015).
It is possible to purify juice without adding decalcification/softening step but in this case frequent use of chemical descaling agent is needed (most often HCl) or the size and/or number

of heat exchanger/evaporators have to be raised. The same problem happen in the cane sugar factory as Pollio wrote in 1978: the formation of scales on heat exchange surfaces has been a serious problem in cane sugar production. Under the best of conditions, frequent shutdowns with expensive labour and chemical costs have been experienced. The repeated use of chemicals to dissolve scale followed by reheating of the equipment results in high mechanical maintenance and costly equipment repair. Added to these items is the serious energy shortage, which makes efficient heat exchange and heat utilisation very important.
Vaccari (2005) propose an alternative solution which is to concentrate raw juice directly at low temperature with backward-feed multiple effect concentrators. Bruhns (2010) confirms that by combining crystallization with membrane filtration, which guarantees microbiological sterility and elimination of insoluble matter, it should be possible to produce white sugar without lime purification and avoiding high temperature sterilisation.

Origin of raw materials, methods of manufacture

The resin itself is produced in majority from petrochemical molecules listed in the technical document 1 of the policy statement concerning ion exchange and adsorbent resins in the processing of foodstuffs version 3 – 28.01.2009 .
The leading synthetic ion exchange resin manufacturers within Europe explain that ion exchange resins have a polymer structure bonded to ionic groups. The nature of the ion exchange resin is greatly influenced by the network structure of its polymer matrix. For most ion exchange resins, the matrix consists of copolymers made of:
−styrene and divinylbenzene;
−methacrylate and divinylbenzene (acrylate and divinylbenzene);
−methylmethacrylate and divinylbenzene (methylacrylate and divinylbenzene).
IER can be divided into:
1.Cationic, main ionic groups:
    a.Strongly acidic:-SO3- (sulfonic group)
    b.Weakly acidic:-COO- (carboxylic group)
2.Anionic
    a.Strongly basic:-NR3+
    b.Weakly basic: -NH2; -NHR; -NR2
3.Special Ion Specific Active Groups -e.g. chelating (ref. SOIA)
In this dossier, applicant introduce 2 types of cationic exchange resins: Strong acid cation (SAC) and weak acid cation (WAC) ion exchange resins. The first one use NaOH as regenerant which can be upcycled in the Akzo/Nra process although the latter one use H_2SO4 as regenerant which can also be recycled in the process but lead to a decrease of pH of the juice which have a negative yield and colouring effect.
For water treatment, weak acid resin i.e. with carboxylic functional group are used for decarbonatation because their selectivity is better for polyvalent cation than strong acid resin i.e. with sulfonic functional group and then need less acid for their regeneration (stoichiometric reaction) (Lignes directrices pour l'évaluation des échangeurs d'ions utilisés pour le traitement d'eau destinée à la consommation humaine, 2009).
In the NRS (New Regeneration System) process also called Akzo, SAR (strong acid resin) have an advantage over the weak ones in that the regeneration eluate can be recycle upstream in the process and so require only a little amount of caustic soda and do not incur the risk of Sucrose inversion and enable removal of all cations (Luqman, 2012)
See also food report I

Environmental issues, use of resources, recycling.

This technology allows resins regeneration i.e. the same resins can be used several times after having been regenerated. In this case the regeneration is made with NaOH which can be then

recycled upstream in the process (akzo/nrs). So from an environmental point of view, it is better to reuse NaOH in this very process to limit waste effluent than rejecting HCl charged wastewater.
Cheesman (2004) explain that most impacts of sugar processing on biodiversity are secondary effects from environmental pollution, such as the discharge of effluent into waterways and concerning energy consumption, the effective management of the evaporators is very important in determining the energy efficiency of the whole processing operation.
See Food report I

Animal welfare issues
See Food report I

Human health issues
See Food report I
As food contact material, IER are regulated at EU and national level anyway some substances from resin can be released in the treated material (Sidewell, 2006) but should not have health effect according to the European Council Committee of Experts on Materials coming into contact with food.

Food quality and authenticity
Food report III, stated that *"Selected constituents can be removed very specifically, or a single constituent within the food can be selectively purified from the rest of the original food. This means that it is possible to remove, for example, some specific minerals from a product or to purify a raw material from all other constituents so that finally one substance remains […] It must be mentioned clearly that the character of the original raw material is totally lost."* In the case of solid crystal sugar from sugar beet, this is actually the purpose of this purification step to discard most of the non-wanted substances to reach the purity level as stated by EU regulation (Council Directive 2001/111/EC). Moreover, sugar beets are not considered as food for human consumption in its raw state.

Traditional use and precedents in organic production
The use of ion exchange resin in organic processing is restricted to specific requirement like baby food production where a strict regulation rules nutritional composition.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Ion exchange resins are not listed in IFOAM Norms as permitted in Appendix 4. IFOAM EU recommends authorisation of the use of ion exchange only if there are no alternative techniques available or if a general regulation requires some specific purity criteria as for instance in baby food production (IFOAM reaction on food report 2015).
A memorandum to the national organic standards board from USDA have been published earlier this year on this very topic and it clearly states that ion-exchange filtration is allowed in organic processing. However, non-agricultural substances used in the ion-exchange process must be on the National List of Allowed and Prohibited Substances (National List). This includes, but is not limited to, resins, membranes, and recharging materials.

Other relevant issues
In the bibliography of the dossier the French national food safety authority ANSES deliver firstly unfavourable opinion about RESINEX KW-8 for the renewal of market authorisation of this resin for water treatment purpose (saisines 2017-SA-0219) and then give the agreement after receiving complementary data (Comité d'experts spécialisé «Eaux» Procès-verbal de la réunion du 4 Septembre 2018) and the other reference deals with anion exchange resin which are not in the scope of this request.
By the way, in France, IER have to pass Anses evaluation for marketing authorisation. Anses

opinion on the Lewatit S1568 which is cited in the SAC NRS process of the dossier have been firstly unfavourable for renewal (Avis de l'Anses, Saisine n° 2017-SA-0241) but then have been authorised by authority after complimentary data (Comité d'experts spécialisé «Eaux»Procès-verbal de la réunion du 2 octobre 2018; Liste des résines échangeuses de cations agréées, 2018).

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

This technique is a chemical one and as such should not be allowed in organic processing. However, on the environmental side, this is the best available techniques for the sugar production process already in place in conventional plant. It is possible to make sugar otherwise but it means more in depth changes in the full process. It appears that the process using ion exchange is only necessary if sugar beet juice is to be stored. Continuous processing may be conducted without ion exchange.

The group considers that Ion exchange is a food process and not a processing aid.

Furthermore, previous EGTOP Food I and EGTOP Food III has taken the view that the addition of ions, via ion exchange, is not in line with the objectives, criteria & principles of organic Regulations (EC) No 834/2007 (Articles 19(3), and 6 (c)) and the chemical processes involved. (Articles 4 and 21 (1)).

The dossier asks for a change to Annex VIII B. This is not possible as ion exchange is not a processing aid.

Conclusions

The use of ion exchange as a process for decalcification of sugar beet juice is not in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007.

Annex VIII B of Regulation (EC) No 889/2008 cannot be changed to include this process.

References

See references in 2.10.

2.12. Innovative process for whey demineralisation for organic infant formulas

Introduction, scope of this chapter

This dossier relates to the request for change of disposition for whey demineralisation for organic infant formulas.

By the way, there is no such disposition in the current regulation.

The aim of the process is to produce demineralised whey without the use of ion exchange resin which complies with in force regulation (EU) No 609/2013 of the European Parliament and of the Council and Commission Delegated Regulation (EU) 2017/1091 also known as baby food law. The dossier was submitted by France.

Ion exchange technology has already been assessed several times through EGTOP mandate (Food report I and III, wine report)

Authorisation in general production and in organic production

The process includes membrane filtration and electrodialysis (ED), none of these techniques are forbidden in EU organic processing.

Organic wine regulations forbid the use of electrodialysis for tartaric stabilisation for wine and restrict the use of membrane filtration to membrane above 0,2 µm (EC regulation 606/2009).

Approved in horizontal legislation for non-organic production.

Agronomic use, technological or physiological functionality for the intended use

The process is based on a series of filtration steps of milk including ultrafiltration, (UF) then nanofiltration (NF) and ED.

Necessity for intended use, known alternatives

Microfiltration using a membrane of 0,1 µm pores give a new category of whey with serum protein in their native state (Gésan-Guiziou, 2014)

Nanofiltration allows simultaneously concentration and partial demineralisation of whey.

Demineralisation can be achieved by ED, ion exchange resin or nanofiltration.

This whole process avoids ion exchange resin for demineralisation. It also gives an alternative way to produce whey without making cheese.

Origin of raw materials, methods of manufacture

Nanofiltration membranes are defined as having a pore size in the order of nanometers (nm) (1×10^{-9} m). As a comparison, the atomic radius of a sodium ion and a chlorine ion is about 0.97 nm (0.97×10^{-9} m) and 1.8 nm (1.8×10^{-9} m), respectively. This demonstrates that nanofiltration membranes are near the range to remove rather small ions.

However, the term nanofiltration is really a misnomer. As the nanofiltration membranes are charged, the removal mechanism is not purely filtration as with ultrafiltration membranes, but also osmotic. This makes them a true hybrid, bridging ultrafiltration and reverse osmosis membranes in the range of membrane treatment options.

In general, the primary factors that affect the performance of the membranes include the membrane material (charge of the membrane), concentration polarisation at the membrane face (build-up of concentration at the membrane face), and fouling of the membrane to name a few. As such, pore size alone does not predict the removal of constituents. (Roth, 2009)

Membrane material could be made of organic material or mineral ones or a mix of both. The basic organic materials are cellulose, polyamides or polysulphone, acid polyacrytic, polyacrylonitrile, polymers fluorinated (PVDF, PTFE...), absorbent polyfine (Nitto), polypropylene (Hoechst, Celancese, Memtec, Enka), polyfulone and polyethylene.

The mineral materials used are composite of entirely principle mineral (ceramic matter, sintered metal, glass), of alumina, oxide zirconium titanium and oxide (zirconia). Their arrival made it possible to work under extreme conditions of temperature and chemical aggression, which opened new ways in separation by membrane (CARDOT C., 2002)

Materials	Type of application			
	MF	UF	NF	RO
Cellulose acetate, polyamide	√	√	√	√
Regenerated cellulose, copolymer containing vinyl chloride, polysulphone (PSU), vinylidene polyfluoride (PVDF)	√	√		
Acrylic polyacid + oxidize zirconium, polyamide		√		√
Cellulose nitrate, gelatine, vinyl polychloride (PVC), polycarbonate, polyimide, polytetrafluoroethylene (PTFE)	√			
Mix diacétate and cellulose triacetate, mix cellulose esters, polyacrylonitrile (PAN), polybenzimidazole (PBI), mix polyelectrolytes, polyethylene/imine + toluene disocyanate		√		
Polypiperazinze amide			√	

Electrodialysis membranes are produced in the form of foils composed of fine polymer particles with ion exchange groups anchored by polymer matrix. Impermeable to water under pressure, membranes are reinforced with synthetic fiber which improves the mechanical properties of the membrane (AWWA, 1995). The two types of ion exchange membranes used in electrodialysis are:

- Cation transfer membranes which are electrically conductive membranes that allow only positively charged ions to pass through. Commercial cation membranes generally consists of crosslinked polystyrene that has been sulfonated to produce $–SO_3H$ groups attached to the polymer, in water this group ionizes producing a mobile counter ion (H^+) and a fixed charge ($-SO3^-$).
- Anion transfer membranes, which are electrically conductive membranes that allow only negatively, charged ions to pass through. Usually, the membrane matrix has fixed positive charges from quaternary ammonium groups ($-NR_3^+ OH^-$) which repel positive ions (Valero et al, 2011).

See also Food report I

Environmental issues, use of resources, recycling.

The environmental issues are the use of membrane cleaning agent (type and frequency), energy use for pressure and the discard or recycle of membranes.

Environmental impacts of the operational aspects of the membrane filtration process are far more important than the environmental impacts associated with the membrane manufacturing aspects (Tangsubkul, 2006).

In water treatment plants, NF membrane lifetime has been established at 10 years (Bonton et al., 2012)

It is not easy to find a synthetic conclusion over environmental impact of membrane filtration but it seems that the most important impact is due to energy used in production phase (Ribera, 2014).

See Food report I.

Animal welfare issues

There is no impact on animal welfare.

Human health issues

As said by the applicant, protein from milk are better preserved with this technique: protein denaturation rate of 3.5% compared to more than 30% for demineralised whey on ion exchange resins. This fact is confirmed by Gésan-Guiziou, (2014) unless the milk has not been chemically treated.

Food quality and authenticity
The proteins produced by this process are in a more natural state i.e. whey composition is closer to the raw milk used (pH and remaining components).

Traditional use and precedents in organic production
The use of this whole process could lead to the discard of the former restricted IER technique for specific requirement (demineralisation) like baby food product where a strict regulation rules mineral content.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
The processes under consideration are not currently regulated in organic production in the EU or in other states. They are not mentioned in IFOAM norms.

Other relevant issues
The process is protected by patent number WO2016207579.

Reflections of the Group / Balancing of arguments in the light of organic production principles
The use of electrodialysis and nanofiltration to produce demineralised whey for infant formula is an alternative to the use of ion exchange for that purpose.
However, it is used to produce a different product, as the electrodialysis process uses milk rather than whey as basic raw materials, but both are demineralised.
Previous EGTOP Food I and EGTOP Food III took the view that the addition of ions, via ion exchange, is not in line with the objectives, criteria & principles of organic Regulations 834/2007 (Articles 19(3), and 6 (c)) and the chemical processes involved. (Articles 4 and 21 (1)). However, EGTOP Food III also included the following text. "In the case where minerals are removed in order to fulfil the requirement of the infant formula legislation the use of ion exchange and adsorbent resin techniques is in line with the requirements of the organic regulation. Because of the specific status of those products in organic Regulation (Article 6(b) and 19.2(b)) and the target of the application is the selective removal of substances, such as minerals and not an overall decomposition. This process adds and removes ions in a similar, but not identical manner. Therefore, the group could recommend use of this process for production of demineralised products for infant formula, but not for production of other organic products.

Conclusions
The use of the described processes for demineralisation of whey proteins is not in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007 but it may be considered as an alternative to ion exchange only for production of organic infant formula.
However, the group expressed a concern that the process is covered by patent(s) and that this could be a crucial limitation on use of this process. This should be investigated before this process is added to the regulation.

References

See reference in 2.10. and the following:

Gésan-Guiziou, 2014, Integrated Membrane Operations: In the Food Production,

Customization and Multistage Nanofiltration Applications for Potable Water, Treatment, and Reuse, Roth 2009, doi: 10.1016/b978-0-8155-1578-4.50017-2

HUSSON-MAREUX et J.A. FABY., 1995 - Les procédés à membrane pour le traitement d'eau potable et l'épuration. Document Technique Fndae 14

CARDOT Claude. 2002 - Techniques membranaires. .. IN : Les traitements de l'eau: procédés physico-chimiques et biologiques. Cours et problèmes résolus. Paris, Ellipse Edition. Chapitre V, p. 71 à 87

AWWA (1995). AWWA M38. Electrodialysis and Electrodialysis Reversal, American Water Works Association, Denver, CO.

Fernando Valero, Angel Barceló and Ramón Arbós (2011). Electrodialysis Technology - Theory and Applications, Desalination, Trends and Technologies, Michael Schorr (Ed.), ISBN: 978-953-307-311-8, InTech,Available from: http://www.intechopen.com/books/desalination-trends-and-technologies/electrodialysis-technology-theory-and-application

Tangsubkul, N., Parameshwaran, K., Lundie, S., Fane, A. G., and Waite, T. D. (2006). *Environmental life cycle assessment of the microfiltration process. Journal of Membrane Science, 284(1-2), 214–226.* doi:10.1016/j.memsci.2006.07.047

Ribera, G., Clarens, F., Martínez-Lladó, X., Jubany, I., V.Martí, and Rovira, M. (2014). Life cycle and human health risk assessments as tools for decision making in the design and implementation of nanofiltration in drinking water treatment plants. Science of The Total Environment, 466-467, 377–386. doi:10.1016/j.scitotenv.2013.06.085

2.13 Steviol Glycosides (E960)

Introduction, scope of this chapter

The assessment of Steviol glycosides E960 relates to the request for inclusion of this substance as a food additive in Annex VIII Section A (additives for use in food) of Regulation (EC) No 889/2008. The dossier was submitted by FR.

Authorisation in general production and in organic production

Regulation 1131/2011 (available at: http://eur-ex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0205 : 0211: en: PDF "authorises at the Community level Steviol glycosides , extracted from the leaves of the plant *Stevia rebaudiana* Bertoni, as a sweetener (additive E960) and a food additive (conventional)." Therefore, Steviol glycosides (E960) are authorised as a food additive (sweetener) by Regulation (EC) No 1333/2008 in a wide range of foods. Ref: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1333-20190618andfrom=EN.

The leaves of Stevia rebaudiana, have recently been removed from the Novel Food regulation, which allows the stevia plant to be certified organic for human consumption.

The leaves or extracts may also be used in flavourings.

Steviol glycoside (E960) is not currently authorised as a food additive (sweetener) in EU organic food according to Regulation (EC) No 889/2008

Agronomic use, technological or physiological functionality for the intended use

Steviol glycosides are a Non-Nutritive Sweetener. The present application aims to include steviol glycosides (95% purity) from an organic certified extraction and purification process in the list of permitted additives for use in organic food.

Necessity for intended use, known alternatives

One non sugar sweetener, Erythritol is permitted in organic production in Annex VIIIA of regulation 889/2008. It must be used when derived from organic production without using ion exchange technology. Steviol glycosides have an advantage over Erythritol in that they are significantly more sweet than Sucrose (250 to 300 times), whereas Erythritol has a lower sweetness, so recipe changes are required for replacement of Sucrose with Erythritol.

Previous EGTOP, Food III ref (https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/farming/documents/egtop-final-report-food-iii_en.pdf) discussed the addition of Steviol gylcosides to Annex VIIIA of regulation 889/2008. Conclusion was as follows: "The use of Steviol glycosides (E 960) as food additive is not in line with the objectives criteria and principles of organic farming as laid down in the organic Regulation. If it would be available in organic quality and meet the needed purity criteria of the food additive regulations, without using ion exchange, the Group concluded that Steviol glycosides should be included in Annex VIII A, but only for use in foodstuffs for particular nutritional uses."

Origin of raw materials, methods of manufacture

The dossier indicates a detailed process for extraction of Steviol glycosides from stevia leaf using hot water and the subsequent purification using successive filtration including molecular-sieving. This removes the need for ion exchange which was a major reason for rejection of the application considered by EGTOP Food III for addition of Steviol glycoside (E960) as an additive to Annex VIIIA of regulation EC 889/2008

Environmental issues, use of resources, recycling.

None identified.

Animal welfare issues

None

Human health issues

In 2010, EFSA published its first opinion on the safety of steviol glycosides for human consumption, following the advice of JECFA. In 2011, EFSA published a second opinion confirming the safety of steviol glycosides and the initial ADI of 4 mg / kg body weight Ref: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2010.1537. They were reassessed in 2015, with no change in ADI or change to the safety assessment following extension to use. Ref: https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.4146

Food quality and authenticity

The use of sweeteners instead of sugar has implications for food quality and authenticity. It was for this reason that the following text was added to the assessment of steviol glycosides in EGTOP Food III. "If it would be available in organic quality and meet the needed purity criteria of the food additive regulations, without using ion exchange, the Group concluded that steviol glycosides should be included in Annex VIII A, but only for use in foodstuffs for particular nutritional uses."

Traditional use and precedents in organic production

While South American tribes have used the leaves of the Stevia rebaudiana plant as a sweetener for many centuries the use in European foods cannot be regarded as traditional. However, EGTOP Food III set a precedent for allowing the use of organic sweeteners in organic food, with the recommendation to add Erythritol (E968) to Annex VIIIA of regulation 889/2008.

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

Steviol Glycoside is not listed in USDA National Organic Program as a permitted additive. However, as there is no prohibition of use of ion exchange within the US NOP regulations it is assumed that organic Steviol glycoside, however produced, would be allowed in US certified organic products.
Steviol glycoside is not listed in USDA National Organic Program as prohibited additive.
Steviol glycoside is not listed in IFOAM Norms as permitted in Appendix 1, Table 4
The dossier reports that organic steviol glycoside is also produced in China, presumably using ion exchange.

Other relevant issues

The dossier indicates that the process by which organic Steviol glycoside could be produced in compliance with the EU organic regulations is governed by a patent.
The dossier includes the following text. "The present application relates to a process of extraction and purification different from the one evaluated by the European Commission under the code E960 not usable in AB". It is, therefore, not entirely clear that Steviol glycosides produced by the molecular sieving process complies fully with the requirements for E960 in conventional legislation.

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

The group noted that the process is covered by a patent. The group has concern that this could be a crucial limitation on use of this process. This should be investigated before this process is added to the regulation.
Similarly, the group has concern that the process, as described in the dossier, may not be approved as a method of producing Steviol glycoside E960 according to regulation 1333/2008. This again must be clarified before adding the product of this process to Annex VIIIA of regulation 889/2008.
Furthermore the group shared the concerns expressed by EGTOP Food III regarding general use of sweeteners to replace sugar.

Conclusions

If the first two issues above regarding the patent and the compliance with requirements for E960 can be adequately resolve the group considers that the use of Steviol glycosides (E960) can be in line with the objectives, criteria and principles of organic regulation 834/2007. Therefore, the addition of Steviol glycoside to Annex VIII A of Regulation 889/2008 can be recommended with the following additional requirements. Only from EU certified organic production and only for use in foodstuffs for particular nutritional uses.

References

Usable links:
https://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports_en
Regulation 1131/2011.
http://eur-ex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0205 : 0211: en: PDF
Regulation (EC) No 1333/2008.
Ref: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1333-20190618andfrom=EN
EGTOP, Food III ref (https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/farming/documents/egtop-final-report-food-iii_en.pdf)
EFSA opinion 2011. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2010.1537.
EFSA opinion 2015. https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.4146

2.14. Monoammonium Phosphate

Introduction, scope of this chapter

The assessment of Monoammonium phosphate relates to the request for inclusion of this substance as a feed additive in Annex VI of the organic Regulation (EC) No 889/2008 as a source of phosphorous for aquaculture species. It states that the Monoammonium phosphate is better digestible than the allowed mono calcium phosphate. The dossier was submitted from NL.

Authorisation in general production and in organic production

Monoammonium phosphate is authorised in the Feed catalogue (Reg. EU 68/2013 amended by Reg. EU 2017/1017) entry number: 11.3.17

The correct name of the compound is Ammonium dihydrogen orthophosphate (CAS 7722-76-5).

Agronomic use, technological or physiological functionality for the intended use

The substance is also used as fertiliser, but it is not allowed for this purpose in the organic regulation.

Necessity for intended use, known alternatives

Monoammonium phosphate is a feed material (Feed catalogue: Reg. EU 68/2013 amended by Reg. EU 2017/1017 part C: 11.3.17) and is used as a source of highly digestible phosphorus for the production of feeds for fish and shrimp. Within Europe, salmon feeds are almost exclusively produced with monoammonium phosphates. Also, the use of monoammonium phosphate in other fish species like trout, seabass, seabream, carp is a daily practice.

The use of other phosphates could be possible, like Monocalcium phosphate (MCP; EU 2017/1017 part C: 11.3.3), which is listed in Annex V of Reg. (EC) No 889/2008. However, MCP contains a lower total phosphorous level and a much lower level of digestible phosphorus. Therefore, the inclusion rate of MCP would need to be much higher, and also the loss of phosphorus into the environment via the faeces is much higher, because of the lower phosphorus digestibility.

Origin of raw materials, methods of manufacture

Monoammonium phosphate is produced by reacting purified feed grade phosphoric acid, obtained from natural rock phosphate, with ammonia. After prilling, drying and sieving the resulting product is a feed grade monoammonium phosphate, (mineral feed phosphate).

Environmental issues, use of resources, recycling.

Monoammonium phosphate is a source of highly concentrated phosphorus but above all a source of highly digestible phosphorus in fish feeds. The use of monoammonium limits the phosphorus levels in the feeds, thereby decreasing the output of phosphorus via the faeces into the environment

Animal welfare issues

Monoammonium phosphate is a source of highly digestible phosphorus. The use of monoammonium phosphate is also a safe guard to supply sufficiently the phosphorus requirements of fish, thereby, decreasing the occurrence of spinal malformations, or other bone deformations. Phosphorus as such plays also an important role in other metabolic functions, like: energy utilisation and transfer, protein synthesis, maintenance of osmotic pressure and acid base balance.

Human health issues

Use of monoammonium phosphate has no known effects on human health.

Food quality and authenticity
Use of monoammonium phosphate has no known effects on food quality and authenticity.

Traditional use and precedents in organic production
Fish need some phosphorus, but it can be obtained from other sources, such as fishmeal. Also Monocalcium phosphate, which is allowed by the Regulation (EC) No 889/2008, can be used. However, Monoammonium phosphate is used instead in conventional aquaculture because it is a source of highly digestible phosphorus. It limits the phosphorus levels in the feeds, thereby decreasing the output of phosphorus via the faeces into the environment.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Monoammonium phosphate is not listed in USDA National Organic Program as appendix 205.603.
Monoammonium phosphate is not listed in USDA National Organic Program as prohibited additive 205.604
Monoammonium phosphate is not listed in IFOAM Norms as permitted in Organic Aquaculture Feed. Ref: https://www.ifoam.bio/sites/default/files/ifoam_norms_july_2014_t.pdf" https://www.ifoam.bio/sites/default/files/ifoam_norms_july_2014_t.pdf

Other relevant issues
Fishmeal contains enough phosphate, therefore, where fishmeal is fed there is no need to add ammonium phosphate in feed. However, due to the worldwide situation of overfishing, there is a clear awareness of the unsustainability of the current consume of fish meal. This is why the EU common fishery policy has lay down specific rules for achieving a sustainable yield of the fishery, and also the aquaculture sector is keen to reduce its dependence on fishmeal.

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

From one hand, the problem with Monoammonium phosphate is that it is produced chemically and also a source of synthetic, non-protein nitrogen. On the other hand, Monoammonium phosphate is a source of highly digestible phosphorus, thereby decreasing the output of phosphorus via the faeces into the environment.

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

References

Usable links:

Lists of Feed additives according to 1831/2003
https://ec.europa.eu/food/safety/animal-feed/feed-additives/eu-register_en

Final reports
https://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports_en

2.15. Calcium Hydroxide

Introduction, scope of this chapter
The assessment of Calcium hydroxide (1305-62-0; E526) relates to the request for inclusion of this substance as a feed material in Regulation (EC) No 889/2008, Annex V Feed materials as referred to in Article 22(d), Article 24(2) and Article 25m(1)
The dossier was submitted by Netherlands.

Authorisation in general production and in organic production
Calcium hydroxide is listed as a feed material (11.1.7) under Section 11: Minerals and products derived thereof, of Commission Regulation (EU) 2017/1017 of 15 June 2017 amending Regulation (EU) No 68/2013 on the Catalogue of Feed Materials.
Calcium hydroxide is authorised by 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 and can be use as in the following categories:

- Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC (13.1.3) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013) only processed cereal based foods and baby foods, only for pH adjustment
- Dietary foods for infants for special medical purposes and special formulae for infants (13.1.5.1) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013) only for pH adjustment

Calcium hydroxide is authorised by Regulation (EU) 2016/691 of 4 May 2016 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of food additives in edible caseinates and can be use as in the following category(ies): Edible caseinates (1.9) (legislation: (EU) No 2016/0691, applicable as from 25/05/2016)
Calcium hydroxide is 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 II: Pesticides — Products referred to in Article 5(1), 3. Substances other than those mentioned in Sections 1 and 2 When used as fungicide, only in fruit trees, including nurseries, to control *Nectria galligena*.
- Annex VII: Products for cleaning and disinfection and specially subchapter 2.1 products used for cleaning and disinfection of equipment and facilities in the absence of aquaculture animals.
- Section B — Processing aids and other products, which may be used for processing of ingredients of agricultural origin from organic production in preparation of foodstuffs of plant origin.

Agronomic use, technological or physiological functionality for the intended use
In early lactation, dairy cows have large requirements for energy. The addition of fat sources, such as Ca salts of long-chain fatty acids (Ca-LCFA), to the diet of high producing dairy cows may improve their energy status. Increasing the intake of long-chain fatty acids (LCFA) by addition of fat to the diet should improve the metabolic efficiency of energy utilisation for milk production. Preformed fatty acids of dietary origin can be incorporated directly into milk fat, reducing the energy cost for synthesising fatty acids incorporated into milk, thereby sparing energy for other productive functions in the mammary gland. Several scientists indicated that efficiency of milk production was maximised when LCFA constituted 16 to 20% of the total metabolisable energy (ME) intake. Maximal efficiency of milk production is achieved when diets for lactating dairy cows contain about 7 to 8% total fat or 5% supplemental fat (Schauff

and Clark, 1992).

Supplementing the diet of dairy cows with fat permits greater energy consumption, especially during early lactation when dry matter intake is limited by rumen capacity. Dietary fat may also optimise efficiency of energy utilisation, as the fatty acids can be incorporated directly into milk fat in the mammary gland. Replacing grain in high energy diets with fat can improve the forage to concentrate ratios, thus shifting ruminal fermentation toward more acetic acid production and maintaining milk fat percent. However, large quantities of fat in the ration of high producing dairy cows depress ruminal fermentation of cellulose. Calcium salts of long-chain fatty acids (CSFA) are insoluble at normal rumen pH and are thus inert toward fermentative digestion in vitro. In the abomasum they are converted by acid to Free Fatty Acids and Ca ions. The fatty acids are then absorbed from the small intestine. Feeding of Ca salts efficaciously protects ruminal microbes from the adverse effects of fat (Schneider et al., 1988)

Necessity for intended use, known alternatives
Currently, there are no authorised products that could be used in the place of the calcium hydroxide in the production of calcium salts of palm fatty acids as an organic animal feed material. Calcium hydroxide is necessary to facilitate the fusion process to produce the calcium salts of palm fatty acids feed material.

Origin of raw materials, methods of manufacture
Calcium hydroxide is widely available in the European Union from industry suppliers. It can have origins from the geographic region of Europe, or be supplied from other international mineral sources. The calcium hydroxide available for use in Europe is of a high quality standard and can be purchased with a $Ca(OH)_2$ > 98% purity rating. It is available to be purchased in wholesale and retail quantities from European companies, and described as suitable for use in the construction industry, paper manufacturing, chemical industry, and for the production of food and feed products.
The origins of calcium hydroxide are from mineral rich rock deposits. Such deposits can be found in Europe or abroad, the origin of calcium hydroxide can be specified during the purchase of the material. The calcium carbonate material (limestone $CaCO_3$) is crushed and then burnt in rotary or shaft kiln where it breaks down into calcium oxide. The calcium oxide is then slacked with water to produce calcium hydroxide. The non-hydrated parts are then separated from the hydrated parts by an air classifiers, and filtered into different grades of particle sizes of calcium hydroxide.
One of the raw materials used for the production of the calcium salts of palm fatty acids feed material (palm fatty acid distillate, PFAD) is a by-product from the food industry, the distillate is created during the production of refined palm oil for use in various food products.

Environmental issues, use of resources, recycling
There are no relevant EU evaluations available on the substance for feed use (EFSA 2013 is related to PPP).

Animal welfare issues
There are no relevant EU evaluations available on the substance for feed use.

Human health issues
None identified

Food quality and authenticity
None

Traditional use and precedents in organic production
Calcium salts are widely used as fat supplements for dairy rations. They help disturbances in ruminal digestion and are easy to incorporate into concentrates (Elmeddah et al., 1994).

The use of these substance as animal feed belongs to animal husbandry practice that is not in line with the basic principles of organic production.

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

Calcium hydroxide is not listed in USDA National Organic Program. Ref: https://www.ecfr.gov/cgi-bin/text-idx?c=ecfrandSID=9874504b6f1025eb0e6b67cadf9d3b40andrgn=div6andview=textandnode=7:3.1.1.9.32.7andidno=7#se7.3.205_1605

Calcium hydroxide is not listed in USDA National Organic Program as prohibited additive. Ref: https://www.ecfr.gov/cgi-bin/text-idx?c=ecfrandSID=9874504b6f1025eb0e6b67cadf9d3b40andrgn=div6andview=textandnode=7:3.1.1.9.32.7andidno=7#se7.3.205_1605

Calcium hydroxide is listed in IFOAM Norms as permitted in

- Appendix 3: CROP PROTECTANTS AND GROWTH REGULATORS II. MINERAL ORIGIN, For application on aerial plant parts only
- APPENDIX 4 – TABLE 1: LIST OF APPROVED ADDITIVES1 AND PROCESSING / POST-HARVEST HANDLING AIDS as Food additive for maize tortilla flour, Processing aid for sugar
- APPENDIX 4 – TABLE 2: INDICATIVE LIST OF EQUIPMENT CLEANSERS AND EQUIPMENT DISINFECTANTS

APPENDIX 5: SUBSTANCES FOR PEST AND DISEASE CONTROL AND DISINFECTION IN LIVESTOCK HOUSING AND EQUIPMENT. Ref: Ref: https://www.ifoam.bio/sites/default/files/ifoam_norms_july_2014_t.pdf

Other relevant issues

Some articles in the scientific literature explained the utility of feed implementation with Calcium salts of unsaturated fatty acids for the milk production of the cows

The formation of Ca salts has previously been shown to partially protect unsaturated fatty acids from rumen biohydrogenation. Theurer et al. (2009) evaluated feed intake, milk production, and milk composition of cows fed Ca salts of palm fatty acids (CS) compared with those fed Ca salts of palm fatty acids with an increased content of PUFA (CS+PUFA). Concentrations of conjugated linoleic acid increased when cows consumed CS+PUFA, indicating that some biohydrogenation did occur. The CS+PUFA supplement supplied more linoleic acid to the small intestine for milk fat synthesis (Theurer et al., 2009).

Lipid supply decreased the proportion of short- and medium-chain fatty acids (6-14 carbons) in both trials and both periods, increased C16:0 in both trials during weeks 1-6 only, and did not modify C18:0 and increased C18:1 during the 2 periods in trial 1 and during weeks 7-12 in trial 2. No difference in proportion of these fatty acids was observed between diets SL and FL1 (Elmeddah et al., 1994).

Gandra et al. (2014) carried out a study to evaluate the effects of using different lipid sources in diets for dairy cows during the transition period and early lactation on productive performance and physiological parameters in Holstein cows. The cows were fed with the following diets: 1) control; 2) Refined soybean oil; 3) Calcium salts of unsaturated fatty acids (Megalac-E). The lipid sources soybean oil and calcium salts not directly influence the plasmatic physiological parameters of dairy cows in the period transition. But, fat supplementation in the transition period resulted in a better metabolic status and productive performance, mainly improving energy balance post-partum (Gandra et al., 2014)

Schauff and Clark (1992) investigated the effects of feeding Ca salts of long-chain fatty acids. Calcium salts of long-chain fatty acids increased milk fat percentage and production of fat and Full cream milk (FCM) when fed as 3 or 6% of the dietary organic matter but decreased yields

of milk fat and Full cream milk (FCM) when fed as 9%. Calcium salts of fatty acids can be fed to provide up to 6% of the dietary organic matter (OM) without deleterious effects on ruminal fermentation and digestibility of most nutrients (Schauff and Clark, 1992).
Schneider et al. (1988) determined digestibility and production responses to feeding Ca salts of fatty acids in lactating cows. No after effects of feeding Ca salts were observed. Body weight changes and rumen Volatile Fatty Acids were similar, whereas dry matter intake was 0.9 kg less and plasma Volatile Fatty Acids decreased with feeding Ca salts. It is concluded that inclusion of Ca salts of fatty acids in early lactation enhances production of milk and Full cream milk (FCM) (Schneider et al., 1988).

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

The group considered that the addition of Calcium salts of fatty acids to dairy diets is predominantly to increase milk yields The principles of organic animal husbandry look at animal welfare, and environmental issues and that's why the EU regulation includes the compulsory high use of roughage and fodder. This use therefore has to be considered an unsustainable intensification of dairy production that do not belong to organic production. The group also expressed concern over possible effects on milk quality, increasing yield at the expense of milk protein levels.

Conclusions

The addition of Calcium hydroxide to Annex V (1) of Regulation (EC) No 889/2008 as a feed materials of mineral origin for dairy cattle feed is not in line with the objectives, criteria and principles of organic Regulation (EC) No 834/2007. The addition to of Calcium hydroxide to Annex V (1) of Regulation (EC) No 889/2008 is not recommended.

References

European Food Safety Authority, 2013; Outcome of the consultation with Member States and EFSA on the basic substance application for calcium hydroxide and the conclusions drawn by EFSA on the specific points raised. EFSA supporting publication 2013:EN-488. 41 pp. https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2009.1143r

Elmeddah, Y., Doreau, M., Rouel, J., Chilliard, Y., 1994. Effects of calcium salt supplementation on dairy cow performances in early lactation. Influence of the nature of concentrates. Ann. Zootech. 43, 341–353. https://doi.org/10.1051/animres:19940404

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