EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Multilateral relations, quality policy
B.4. Organics

Expert Group for Technical Advice on Organic Production

EGTOP

Final Report On Food (III)

The EGTOP adopted this technical advice at the 10th plenary meeting of 7 to 9 October 2014.

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 2009/427/EC of 3 June 2009, the Commission set up the Expert Group for Technical Advice on Organic Production (EGTOP).

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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The report of the Expert Group presents the views of the independent experts who are members of The Group. They do not necessarily reflect the views of the European Commission. The reports are published by the European Commission in their original language only, at the following webpage:
http://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/index_en.htm

ACKNOWLEDGMENTS

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All declarations of interest of Permanent Group members are available at the following webpage:
www.organic-farming.europa.eu

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The Group made the following conclusions:

Substances

1. The use of **carrageenan** as an additive in all animal based products is not in line with the objectives, criteria and principles of organic regulation due to the authenticity concerns reference Article 6(c) of Regulation 834/2007 regarding misleading the consumer as to the true nature of the product.
Also, because of newest toxicological findings the Group sees the need for a re-evaluation of this additive by EFSA. In line with the precautionary principle, the Group proposes to postpone any decisions on the use of carrageenan until all doubts concerning possible human health effects have been removed.
The Group does not recommend the use of carrageenan in production of organic foodstuffs until these concerns have been addressed.
2. The use of **gellan gum** as a food additive is in line with the objectives, criteria and principles of the organic regulation for addition to Annex VIII, Section A to Regulation 889/2008. Due to concerns over carrageenan there should be an investigation as to whether it can be a replacement for carrageenan in some applications.
3. The Group concluded that for possible production of organic salt (in the proposed organic regulation COM(2014) 180 final) the use of **potassium ferrocyanide** (E536) as an anti-caking agent is not in line with the objectives, criteria and principles of organic farming, due to toxicological concerns (Article 3(c) of Regulation 834/2007) and the availability of alternatives (Article 21.1(i) of Regulation 889/2008). However, it should be clarified that salt with anti-caking agents is currently allowed in organic production in accordance with Article 27(e) of Regulation 889/2008.
4. The listing of **acetic acid/vinegar** in Annex VIII, Section B to Regulation 889/2008 for animal products (fish) is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007 Article 21.1(ii). It should therefore be included in Annex VIII, Section B, with the following restriction(s): For fish processing, only from biotechnological source.
The Group considers that if **organic acetic acid/vinegar** is available in sufficient quality and quantity this should be preferred.
5. The Group considers that the addition of **ammonium sulphate** to Annex VIIIa to Regulation 889/2008 is not necessary due to the availability of other suitable yeast nutrients (Article 21.1(ii) of Regulation 834/2007).
6. The Group considers that addition of **ammonium bisulphite** to Annex VIIIa is not in line with the objectives, criteria and principles of organic farming as laid down in Regulation 834/2007 (Article 21.1(i)) due to the availability of other suitable sources of sulphites.
7. The Group cannot take a firm decision on **chitosan** due to the lack of proof that the substance will enable reduction in the use of sulphur dioxide. The applicants are encouraged to submit further data that proves the claim that sulphur dioxide will be reduced.
8. The Group considers that addition of **chitin-glucan** to Annex VIIIa is not in line with the objectives, criteria and principles of organic farming as laid down in Regulation 834/2007 (Article 21.1(ii)), due to the lack of necessity.
9. The use of **sodium hydroxide** for peeling of salsify is not in line with Regulation 834/2007 Article 4 c regarding restriction of chemically synthesised inputs.
The Group considers that addition of **sodium hydroxide** specifically for the lye peeling of salsify is not consistent with the principles of the regulation (Article 6(c) of Regulation

834/2007) and there are preferable alternatives available (Article 21.1(i) of Regulation 834/2007).
10. The use of **sorbic acid** as food additive is not in line with the objectives, criteria and principles of organic processing. It does not fulfill the requirement of Article 4(c) & 6(b) and 21.1(i) in Regulation 834/2007 regarding limitation of use of chemicals and availability of alternatives. Therefore, it should not be included in Annex VIII, Section A to Regulation 889/2007.
11. The Group is of the opinion that only organic **erythritol** produced in accordance with the EU organic regulation should be added to Annex VIII, Section A to Regulation 889/2008.
12. The Group recommends that only certified organic forms of starch and plant oils should be used as processing aids in yeast production.
Additionally as also mentioned in EGTOP Food I **starches and plant oils** and other processing aids should also be used in certified organic form.
13. The use of **hydrochloric acid** as a processing aid in the production of dextrin from starch is not in line with the objectives, criteria and principles of organic farming as laid down in the Council Regulation (EC) No 834/2007, Article 4, due to the fact that a biological process (enzymatic production) is possible and preferred.
14. The request regarding **fruit acid washes** is asking for the evaluation of a trade product which is not within the competence of EGTOP.

Techniques

15. The Group recommends that **ozone** may be used for sterilisation of equipment, packaging materials etc. However for the moment the Group considers that it should not be permitted for use in applications where there is direct contact with the organic food during food processing.
16. The Group concludes that the use of **ion exchange** and **adsorption resins** as processing aids to produce highly purified substances such as glucose, fructose (decomposed food) (Cases 1 & 2) is not in line with the objectives, criteria and principles of organic farming as laid down in the organic regulation. This is due to the high purification levels, which could mislead the consumer regarding the true nature of the product (Articles 19(3), 6(c)) and the chemical processes involved (Articles 4 and 21(1)).
In the case where minerals are removed in order to fulfill the requirement of the infant formula legislation (Case 3) the use of ion exchange and adsorbent resin techniques is in line with the requirements of the organic regulation. This is 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.
17. The Group is clear that at present there is no restriction in the organic regulation regarding the use of **electroporation** as a means of preserving organic food.
The Group cannot make a decision regarding the future of PEF technology in organic processing until more scientific results are available.
18. The Group is clear that at present there is no restriction in regulation regarding the use of **plasma gas technology** that prevents its use in organic processing.
The Group sees positive possibilities in terms of reduction of chemical input into organic products. However, the Group cannot make a decision regarding the future of plasma gas technology in organic processing until the practical application is clarified, research is undertaken and the results are known. In the Group's opinion, a decision should be taken as soon as these results are available to create certainty in the food industry.

General comment regarding techniques

19. The Group considered a number of **techniques** including electroporation, plasma gas sterilisation etc. Under the organic regulation there is no requirement to set up of a positive list of such approval of such techniques as all food processing methods may be used unless specifically prohibited. However, Articles 6(c) and (d) and 7(c) and (d) make the provision for the prohibition of processes that hide the true nature of food/feed and encourage the use of biological, mechanical and physical methods.
The group underlines that this approach is the opposite of the approach taken in other areas, e.g. for food processing aids, where the "precautionary principle" is followed. The Group sees a need to discuss how the precautionary principle could be applied also to processing methods.

Others

20. The Group had insufficient time available to consider in detail the request from Belgium for removal of **sodium metabisulphite** as a preservative/antioxidant for use with crustaceans from Annex VIII of Regulation 889/2008, as well as the request from Italy to evaluate **mannoproteins** extracted from yeast for tartrate stabilization of wines, so it recommends that these issues are put before EGTOP expert group for Food IV, as high priority.

General comment regarding the dossiers

Finally the EGTOP Expert Group for Food III found that the quality of **dossiers submitted was variable and in many cases poor**. In particular all aspects of the template should be completed with text, rather than just yes/no answers. **Full technical information including references must also be included**. In the future, EGTOP subgroups may reject inadequately completed dossiers.

1. BACKGROUND

In recent years, several Member States have submitted dossiers under the second subparagraph of Article 21(2) of Council Regulation (EC) No 834/2007[1] concerning the possible inclusion, deletion or change of deposition of a number of substances in Annex VIII to Commission Regulation (EC) No 889/2008[2], or more generally, on their compliance with the above-mentioned legislation. Furthermore, several Member States have also requested the evaluation of some techniques used in food production in terms of their usefulness to and compliance with the EU organic farming legislation. Besides, in order not to jeopardize the work on the priorities set by the previous mandate, the EGTOP Report on Organic Food 5/2012 did not assess the use of the following substances: ozone as post-harvest treatment of plant products and acetic acid as processing aid in fish production. Therefore, the Group is requested to prepare a report with technical advice on the matters included in the terms of reference.

2. TERMS OF REFERENCE

[1] Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (O.J. L 189, 20/07/2007, p. 1)

[2] Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (O.J. L 250, 18.09.2008, p. 1)

In the light of the most recent technical and scientific information available to the experts, the Group is requested:

1. 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 farming legislation:

a) Substances:

1. FR dossier (2013): **Carrageenan** as food additive for all products of animal origin
2. BE dossier (2012): **Gellan gum** (E 418) as food additive
3. ES dossier (2013): **Potassium ferrocyanide** (E 536) as food additive, in particular anti-caking agent
4. FR dossier (2011): **Acetic acid** (E 260) as processing aid in the fish production
5. FR dossier (2011): **Ammonium sulphate** (E517) for use or addition in organic products of the wine sector
6. FR dossier (2011): **Ammonium bisulphite** for use or addition in organic products of the wine sector
7. FR dossier (2011): **Chitosan,** for use or addition in organic products of the wine sector
8. FR dossier (2011): C**hitin-glucan,** for use or addition in organic products of the wine sector
9. IT dossier (2014): **Mannoproteins** extracted from yeast for tartrate stabilization of wines
10. BE dossier (2013): **Sodium hydroxide (NaOH)** (E 524) for use as processing aid in the peeling of salsify
11. ES dossier (2014): **Sorbic acid** (E-200) as food additive in the processing of beaten egg-free dough baked goods
12. IT dossier (2014): **Erythritol** as food additive to replace sugar in a wide variety of applications
13. FI dossier (2014): **Organic potato starch** as processing aid for production of organic yeast
14. CZ Dossier (2014): **Hydrochloric acid** for use as a reagent for dextrin production (preparation of foodstuffs of plant origin)
15. UK dossier (2013): **Fruit acid washes** – formulations composed of citric acid, ethanol, sodium alkyl sulphate, grapefruit oil as processing aid for removal of bacterial load from wash water

b) Techniques:

15. NL dossier (2011): **Ozone** as post-harvest treatment of plant products
16. ES dossier (2011) supported by comments from AT (2001, 2012), UK (2008), and IT (2013, 2014): **Ion exchange technology** in organic production (i.e. different applications: e.g. starch syrup de mineralisation and purification, whey demineralisation, juice demineralisation and neutralization, gelatine production, glucose and fructose production from grape or other fruit etc.).
17. IT dossier (2014): **Chromatographic cation exchange** resins for separation of glucose and fructose from rectified concentrated must
18. NL dossier (2013): **Electroporation** as electronic preservation practice of organic food and feed
19. NL dossier (2013): **Plasma gas technique** as electronic preservation practice of organic food and feed

2. To reconfirm if the use of the following substance – BE dossier (2012): **Sodium metabisulphite** (E223) – included in the current list in Annex VIII to Commission Regulation (EC) No 889/2008 is still compliant with organic farming principles. The Group should consider possible alternatives to the substances/techniques in question and/or review the specific conditions for the use of the substances/techniques listed therein including the grouping in animal and/or plant products. Any such proposal(s) should be accompanied by a brief explanation of the reasons.

In preparing the final report, the Group may also assess if food processing methods included in the EU organic farming regulation are in line with the organic farming principles.

3. CONSIDERATIONS AND CONCLUSIONS

3.1. Carrageenan as additive for all animal products

Introduction, scope of this chapter

The following report is based on the request of France for the use of carrageenan (E407) as a food additive for all products of animal origin. Carrageenan is currently allowed for use in organic food as an additive for plant products and for milk products. This dossier specifically requests expansion of the approval to include meat and other animal derived products.

Authorisation in general production and in organic production

Permitted as food additive (Reg. (EC) No 1333/2008). Listed in Group 1 which allows use at *quantum satis* in a wide range of food products.
Carrageenan is authorised as food additive in flavourings in Annex III EC reg. 1333/2008 following the *quantum satis* principle.

Agronomic use, technological or physiological functionality for the intended use

Carrageenan is used according to the principle *quantum satis* in foods as a thickener and gelling agent, and as stabilising and carrier agent. There are three main types of carrageenan based on the number and position of sulphate groups on the galactose/anhydrogalactose chain: kappa-carrageenan, iota-carrageenan and lambda-carrageenan, which contain one, two, and three sulphate groups per disaccharide repeating unit, respectively (Fang et al., 2014).
Use in all animal origin products (withdrawn of the restriction related to milk products). The main applications for carrageenan are in the food industry, frequently, only very small additions are necessary, 0.01-0.05%. For example, kappa-carrageenan (at 0.01-0.04%) added to cottage cheese will prevent separation of whey, and a similar amount added to ice cream also prevents whey separation that may be caused by other gums that were added to the ice cream to control texture and ice crystal growth (McHugh, 2003).
In preparing hams about 0.5% carrageenan is added. Addition of carrageenan to the brine solution used in pumping of hams etc. improves the product because the carrageenan binds free water and interacts with the protein so that the soluble protein is retained.

Necessity for intended use, known alternatives

Other similar plant or seaweed derived polysaccharides such as agar, pectin, alginates etc. may do similar functions, but the affinity of different polysaccharides for different compounds is complex, so it is not clear whether carrageenan has specific uses in animal products that cannot be done by other hydrocolloids.

Origin of raw materials, methods of manufacture

Carrageenans are extracted from seaweed. Most is produced from cultivated seaweed in the Philippines. It is extracted using hot water or dilute alkali so does not require the high quantity and strengths of acids and alkalis needed to produce sodium alginate.

Environmental issues, use of resources, recycling

Cultivation and harvesting of seaweed may create environmental concerns due to habitat damage, over harvesting or pollution associated with the harvesting or cultivation processes, unless produced from organically cultivated or harvested seaweed.
Preparation of carrageenan will be expected to have less environmental effect than sodium alginate due to the lower use of acids and alkalis (EGTOP, 2011).

Animal welfare issues

None.

Human health issues

The Group is concerned regarding the health effects of carrageenan, specifically the risk that carrageenans may cause gut inflammation and are associated with precancerous changes in the gut.
The human toxicological position of carrageenan was last evaluated by the EC Scientific Committee on Food in 1992 (EC Scientific Committee on Food, 1996).
Subsequent studies have shown that low molecular weight carrageenans can cause gut inflammation and may be associated with precancerous changes in the gut.
However, commercial carrageenan is purified to remove the low molecular weight polymers. One key question is whether there is breakdown of the high molecular weight product to low molecular weight in the gut. This may occur due either to simple acid hydrolysis or to enzymatic breakdown caused be production of carrageenanase by some gut bacteria. There is significant argument over this issue in current literature.
A study reported ulceration of the intestine of guinea pigs fed high doses of carrageenan, but this was not replicated in a study with rats, which identified no irreversible changes and no histopathology (Tobacman, 2001).
Studies of the carcinogenicity of carrageenan in rats have shown no effect. In addition, the results of assays for the genotoxicity of carrageenan have been negative. A proliferative response of the mucosa of the gastrointestinal tract of rats fed two forms of carrageenan at 2.6 or 5% of the diet has been reported; the response was reversible in the study in which 5% carrageenan was given. (JEFCA, 1999).
There was evidence that carrageenan can affect the immune response of the gastrointestinal tract; however, no validated tests for assessing the nature and potential consequences of such an effect were available (JEFCA, 1999).
No ADI has been set and the high molecular weight product is GRAS (Generally Regarded as Safe) (USDA, 2014).
The EFSA has recently put forward a request for usage levels and or concentration data relating to carrageenan as part of their 2014 draft work programme, Batch 3 (EFSA, 2014).
The previous EGTOP Report on Food II (EGTOP, 2014) included the following. “However, because of the newest toxicological findings the Group sees the need for a re-evaluation of this additive by EFSA. In line with the precautionary principle, the Group proposes to postpone any

decisions on the use of carrageenan until all doubts concerning possible human health effects have been removed. The Group does not recommend the use of carrageenan in organic production until these concerns have been addressed."

Food quality and authenticity

Carrageenan has been used in non organic pates and processed meats to correct texture and sliceability missing from highly processed meat products. The subject of the dossier is so general that this use is not excluded by the application. It is also used to increase viscosity of ice creams, dressings etc. It can therefore be used to hide processing defects.

Traditional use and precedents in organic production

Carrageenan has been used as a gelling agent and clarification agent for many years. It is permitted for use as an additive in organic plant derived and milk based products under Regulation 889/2008.

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

Permitted under §205.605 of the US National Organic Programme. 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 a. Non Synthetics allowed.
Permitted in Japanese Organic Standards (JAS). Table 1. Food additives. Limited for animal products to dairy products only.
Permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive (IFOAM, 2012).

Other relevant issues

Some others hydrocolloids with similar functions are need in processed meat products enable the production to be done by machine and not sliced by hand, but it is not clear whether specific uses of carrageenan in animal products can be done by other hydrocolloids.

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

In view of the concerns over immune and inflammatory response in the intestinal tract and the availability of similar polysaccharides as additives in the organic farming regulations the Group considers that the presence of carrageenan in Annex VIII, Section A to Regulation 889/2008 should be reconsidered. This view is in line with the recommendation on carrageenan made by EGTOP Food II.
The Group sees a potential contradiction to the requirement of Article 3 (c) of EC Reg. 834/2007 that organic products should not harm human health.
There is a potential for carrageenan to be produced in organic quality from organically grown or harvested seaweed. The Group considers that if it is to continue to be permitted, the organic food sector should be encouraged to produce carrageenan in certified organic form from organically harvested or cultured seaweed.

Conclusions

The use of carrageenan as an additive in all animal based products is not line with the objectives, criteria and principles of the organic regulation due to the authenticity concerns reference Article 6(c) of Regulation 834/2007 regarding misleading the consumer as to the true nature of the product.
Also, because of newest toxicological findings the Group sees the need for a re-evaluation of this additive by EFSA. In line with the precautionary principle, The Group proposes to postpone any decisions on the use of carrageenan until all doubts concerning possible human health effects have been removed.
The Group does not recommend the use of carrageenan in production of organic foodstuffs until these concerns have been addressed.

3.2. Gellan gum as food additive

Introduction, scope of this chapter

The following report is based on the request of Belgium for the use of gellan gum (E418) as a food additive in organic food processing.

Authorisation in general production and in organic production

Gellan gum (E418) is authorised as a food additive (E 418) in Regulation (EC) No 1333/2008. It is listed in Group 1 which allows the use at *quantum satis* in a wide range of food products (except jelly mini-cups).

Agronomic use, technological or physiological functionality for the intended use

Gellan gum is used or intended for the use in accordance with the current Good Manufacturing Practice as a thickening or gelling agent. It can produce gel textures in food products ranging from hard and brittle to fluid, and is used as a structure-building, stabilising and suspending agent.
Types of products that typically contain gellan gum include: bakery fillings, confections, dairy products, dessert gels, frostings, icings and glazes, jams and jellies, low-fat spreads, microwavable foods, puddings, sauces, structured foods, toppings and soya milk products.

Necessity for intended use, known alternatives

There is similarity in textural terms (the large hysteresis in setting and melting) between gellan gum and agar, and k-carrageenan. Some similarity is observed in ion-induced gelation commonly associated with formation of alginate gels in the cold by the controlled release of Ca^{2+}. These alternatives are all authorised for organic production.

Origin of raw materials, methods of manufacture

Gellan gum is a high molecular weight polysaccharide gum produced as a fermentation product by a pure culture of Sphingomonas elodea (formally known as *Pseudomonas elodea*). The producing organism is an aerobic, gram-negative bacterium, which has been very well characterised and demonstrated to be non-pathogenic.
Current production is understood to be done using non-genetically modified organisms, but there is a risk that future production may be done using GMOs. It may also be produced from substrates derived from GMOs.

The chemical structure of the polysaccharide has been determined. It has a tetrasaccharide repeat unit consisting of two glucose residues, one glucuronic acid residue, and one rhamnose residue. There are two forms of gellan gum: high- and low-acyl (JECFA, 2014).
The high-acyl form after fermentation is precipitated from solution with isopropyl alcohol, which is then removed. Residual isopropyl alcohol in the gellan gum must not exceed 0.075 percent (USDA, 2010). To manufacture the low-acyl form, an alkali is added and the temperature is raised to remove acetyl groups. A strong acid is then used to lower the pH and the gum is recovered from solution by clarification and precipitation.
The thickness and hardness of the gellan gum is determined by acetyl groups present in the gellan gum obtained from the microbial culture. With acetyl groups present, the gel is soft and elastic. Firmer gels are obtained by removing the acetyl groups to some extent by adding potassium, magnesium, calcium, and/or sodium salts.

Environmental issues, use of resources, recycling

Gellan gum is produced by fermentation. No reports were found of adverse environmental effects caused by the process. There will undoubtedly be a waste liquor from this process, but no publically available information on serious concerns caused by this could be found.

Traditional use and precedents in organic production

No organic agricultural products were identified that could be substituted for gellan gum. However, similar substances listed as non-synthetic non-agricultural (non-organic) substances allowed as ingredients in or on organic processed products (for example in Title 7 of the US Code of Federal Regulations § 205.605(a)) include agar-agar and carrageenan.
Synthetic substances allowed for the same purposes in organic products in the US (according to Title 7 of the Code of Federal Regulations, § 205.605(b)) include alginates, pectin (low-methoxy), and xanthan gum. Like gellan gum, carrageenan, pectin, alginate, and agar are all gelling agents. Other thickeners used in foods include arabic (gum acacia), gum carob, gum karaya, and gum tragacanth. Gums approved by the FDA include arabinogalactan and carrageenan.
Determining which gum to use in an application greatly depends on the type of functionality needed and the application's processing parameters (US NOP, 2006).

Aspects of international harmonisation of organic farming standards

Permitted under §205.605 of the US National Organic Programme, Nonagricultural (nonorganic) allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group (s)). Section a. Non Synthetics allowed.
The US National Organic Program have amended the listing by adding the annotation "high-acyl form only" (US NOP, 2010).
The Canadian General Standards Board listed gellan gum in Permitted Substances Lists for Processing Table 6.3 - Non-organic Ingredients Classified as Food Additive: water, alcohol, acid and base extracts and precipitants that are permitted by this standard only (Canadian General Standards Board, 2006).
NOT permitted as an additive in Japanese JAS Organic Standards.
NOT permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing/post-harvest handling aids as an additive, section b Synthetics allowed (IFOAM, 2012).

Animal welfare issues

None.

Human health issues

Gellan gum does not meet the definition of 'dangerous' as defined in European Directives 67/548/EEC, 1999/45/EC, 2001/58/EC.
Gellan gum is not GRAS. According to the FDA, gellan gum may be safely used as a direct food additive for human consumption as long as its use is in accordance with Title 21, US Code of Federal Regulations § 172.665. Additionally, it is exempt from the threshold of Title 21, US Code of Federal Regulations, § 170.39 for its use as a coating or sizing agent on food contact articles.
No European ADI is specified indicating that this compound is not considered significantly toxic.
There are no known harmful effects on human health after exposure to gellan gum. However, it may have a laxative effect at high intakes. The Joint Expert Committee on Food Additives (JECFA) summarised one clinical trial of consumption of gellan gum as producing no adverse dietary or physiological effects in any of the volunteers. There were no allergenic or other concerns observed. It was noted, however, that gellan gum acted as a fecal bulking agent, increased fecal bile acid, decreased fecal neutral sterols, and decreased serum cholesterol (JEFCA, 1991).
The potential laxative effect at high intakes should be taken into account when used as a food additive.
The EFSA has recently put forward a request for usage levels and or concentration data relating to gellan gum as part of their 2014 draft work programme, Batch 3 (EFSA, 2014).

Traditional use and precedents in organic production

There are other hydrocolloids with similarity in textural terms (agar, kappa-carrageenan). The Group prefers the use of agar due to the concerns with carrageenan expressed in section 4.1 of this report. The uniqueness of gellan gum is the ability to suspend while contributing minimal viscosity via the formation of a uniquely functioning fluid gel solution with a weak gel structure. Gellan gum can be used in production of calcium fortified soy drink, minimising syneresis and calcium sedimentation.

Other relevant issues

None.

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

The wide nature of the application and the many alternative gums available indicate that there are likely to be suitable alternatives to gellan gum already available in Annex VIIIA to Regulation 889/2008 (Article 21.1(i) of Regulation 834/2007).
The Group considers that if it were to be permitted in Annex VIII, Section A to Regulation 889/2008 then it should be accompanied with the specific condition 'high-acyl form only' due to the methods of manufacture (see above).
Gellan gum may be a preferable additive to carrageenan for some applications, due to the health concerns regarding carrageenan mentioned in 4.1 above. It will be necessary to evaluate replacements for carrageenan if the EFSA review removes carrageenan from the list of approved additives.

Conclusions

The use of gellan gum as a food additive is in line with the objectives, criteria and principles of the organic regulation for addition to Annex VIII, Section A to Regulation 889/2008. Due to concerns over carrageenan there should be an investigation as to whether it can be a replacement for carrageenan in some applications.

3.3. Potassium ferrocyanide as food additive, in particular anti-caking agent

Introduction, scope of this chapter

The mandate is based on a request from Spain for using potassium ferrocyanide (E536) as an anti-caking agent in salt (sodium chloride) to be used during roasting and salting of organic nuts. The problem is that salt is hygroscopic and can agglomerate during processing of food.

It needs to be stated that salt is not within the scope of the organic regulation at the moment.
For organic products, Regulation 889/2008 includes the following in Article 27.
"(e) drinking water and salt (with sodium chloride or potassium chloride as basic components) generally used in food processing;" This is generally taken to include salt with normal anti-caking agents, including potassium ferrocyanide, magnesium carbonate & silicates. I.e. all normally used anti-caking agents may be used for salt for use in organic products.

However, in view of the proposed inclusion of salt into the ongoing regulation review the subject of anti-caking agents will need to be included and the Group feels that to discuss potassium ferrocyanide is an important contribution to that process.

Authorisation in general production and in organic production

The ferrocyanides, sodium ferrocyanide (E535), potassium cyanide (E536) and calcium ferrocyanide (E538) are authorised for use as anti-caking agents in salt and its substitutes at a level up to 20 mg/kg (calculated as anhydrous potassium ferrocyanide) individually or in combination (Directive 95/2/EC(1) on food additives other than colours and sweeteners). Sodium ferrocyanide is called "yellow prussiate of soda" in the USA.

Agronomic use, technological or physiological functionality for the intended use

Sodium chloride tends to absorb water at a relative humidity higher than 75%, leading to formation of lumps and blocks of salt. An anti-caking agent is an additive placed in powdered or granulated materials, such as table salt, to prevent the formation of lumps. The anti-clumping effect of ferrocyanides is based on two mechanisms: firstly, the growth of NaCl crystals is altered, and secondly, the tendency to absorb and release water is affected. It is sprayed onto the salt in an aqueous solution.
According to the dossier from Spain, the humidity in their facilities and the humidity involved in the process of salting/roasting of nuts converts salt into "salt stones" that block the conveyors of the salt and the combination of ingredients. Use of potassium ferrocyanide as anti-caking prevents the solidification of salt and allows the flow of salt in all processes (conveyors and mixers).

Necessity for intended use, known alternatives

According to the dossier, “there exists no alternative on the market or at least we have not found it”.
Alternative anti-caking agents available in EU Regulation, to be used for salt instead of ferrocyanides are silicon dioxide (E551) and silicates as calcium silicate (E552), magnesium silicates (E553), sodium/potassium/calcium aluminium silicates (E554, E555, E556) and aluminium silicate (kaolinit) (E559).

Calcium carbonates (E170), sodium carbonates, (E500), potassium carbonates (E501), ammonium carbonates (E503) and magnesium carbonate (E504) can also be used as anti-caking agent and are allowed as a general additive in production of organic foodstuff of both plant and animal origin. Silicon dioxide (E551) is authorised for use as anti-caking agent of organic herbs and spices (889/2008).

Caking of salt crystals is size dependent and larger crystals (>1mm) do not tend to cake as severely.

Less harmful anti-caking agents already accepted in Annex VIII should be tested or salt added as bigger crystals in organic products to minimise the need for anti-caking agents to be used for production of organic roasted nuts (Article 4(b) of Regulation 834/2007). Again it needs to be stated that currently the use of anti-caking agents in salt added to an organic product is not in the scope of the organic regulation.

Origin of raw materials, methods of manufacture

Potassium ferrocyanide is produced industrially from hydrogen cyanide, ferrous chloride, calcium hydroxide, the combination of which affords calcium ferrocyanide. This solution is then treated with potassium salts to precipitate the mixed calcium-potassium salt, which in turn is treated with potassium carbonate to give the tetrapotassium salt.

Environmental issues, use of resources, recycling

Ferrocyanides are excreted in faeces and urine, mainly unchanged, although most studies on metabolism and kinetics were performed using IV-injection. The level of ferrocyanides used as anti-caking is low and biological effects in the environment may be negligible. Ferrocyanides are also used in salt for road de-icing at levels up to 200 ppm, which is a far more important source of environmental exposure than use in food. Nevertheless some assessment on the environmental fate and impact is missing from the dossier (EC, 2001).

Animal welfare issues

Ferrocyanides are recommended to be used as anti-caking agents in organic feed with a maximum dose rate of 20 mg/kg NaCl in a limited time period (EGTOP, 2011), so there is no reason for animal welfare issues for the use of ferrocyanides in food.

Human health issues

In inorganic chemistry, salts containing the $C{\equiv}N^-$ ion are referred to as cyanides. Many cyanides are highly toxic. Cyanides are found in substantial amounts in certain seeds and fruit stones, e.g., those of apricots, almonds, apples, cherries and peaches, and also in cassava roots. In plants, cyanides are usually bound to sugar molecules in the form of cyanogenic glycosides. When the

plant tissue is crushed, part of the potential hydrogen cyanide is released, and may be responsible for the toxic effect of cyanogenic glycosides.
Ferrocyanides should have low toxicity due to a strong chemical bond between iron and the cyanide group in ferrocyanides.
The acute toxicity of ferrocyanides has been studied (FAO/WHO, 1973).
No long term studies are available. Based on available short term toxicity studies, the estimate of acceptable daily intake (ADI) for man is set to 0-0.025 mg/kg body weight (FAO/WHO, 1973) and this ADI is still in place (EC, 2001), which is relatively low and so this substance does have relevant toxicological concern.

Food quality and authenticity

Organic food is expected to have as few harmful additives as possible and salt used for organic food is expected to be without harmful additives. This seems to be in conflict with the low ADI of potassium ferrocyanides of 0-25 mg/kg body weight and with no information about long term effects.

Traditional use and precedents in organic production

Ferrocyanides are widely used as anti-caking agent in table salt, but it is not specifically allowed in organic food production. Sodium ferrocyanide E 535 is widely used as anti-caking material in salt for organic animal feed (see EGTOP Final Report on Feed) and is now authorised with a maximum dose of 20 mg/kg NaCl (Reg. 889/2008, Annex VI).

Aspects of international harmonisation of organic farming standards

Ferrocyanides as anti-caking agents for salt to be used for organic food in US are not listed in the permitted additives allowed in the US NOP Regulations according to §205.605 "Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labelled as “organic” or “made with organic (specified ingredients or food group(s))”. Traditionally other anti-caking agents than ferrocyanides have been used for salt in US compared to Europe.
Some private national organic standards prohibit or restrict the use of sodium ferrocyanide as anti caking agent (E.g. Demeter, 2014; Bioland, 2014; or Bio Suisse, 2014).

Other relevant issues

None.

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

The Group is concerned about the ADI of ferrocyanides. Organic food is expected to have as few harmful additives as possible, and with ferrocyanides with an ADI of 0.25 mg/kg body weight and with no information about long term effects, there seem to be no reasons for acceptance of potassium ferrocyanide as an anti-caking agent for salt for organic food production as alternatives exist. However, only small quantities of salt are used in food.
The Group understands that salt may be included in future editions of organic regulations in the EU. The subject of anti-caking agents must be considered as part of the production of this part of the new Regulation.

Conclusion

The Group concluded that for possible production of **organic salt** (in the proposed organic regulation COM(2014) 180 final) the use of potassium ferrocyanide (E536) as an anti-caking agent is not in line with the objectives, criteria and principles of organic farming, due to toxicological concerns (Article 3(c) of Regulation 834/2007) and the availability of alternatives (Article 21.1(i) of Regulation 889/2008). However, it should be clarified that salt with anti-caking agents is currently allowed in organic production in accordance with Article 27(e) of Regulation 889/2008.

3.4. Acetic acid as processing aid for fish processing

Introduction, scope of this chapter

The mandate is based on a request from France for using acetic acid as processing aid in the production of organic smoked fish. EGTOP received detailed information presented in a dossier, and this is asking for accepting acetic acid as processing aid for cleaning unprocessed salmon and trout. Other names of acetic acid are glacial acetic acid and ethanoic acid.

Authorisation in general production and in organic production

Acetic acid is a food additive E260 according to Commission Regulation (EU) no. 1130/2011 and is in the list of additives generally authorised in foodstuffs in accordance with the *quantum satis* principle. Acetic acid is therefore authorised as a food additive and processing aid in the production of non organic fish.

Agronomic use, technological or physiological functionality for the intended use

In the fish processing industry, acetic acid is used for cleaning unprocessed salmon and trout in order to improve the quality and safety of the products, especially by reducing the incidence of Listeria species from nearly 20% to about 2% of fish sampled. This is not done through listericidal mechanisms but through chemical mechanisms facilitating the flocculation and elimination of mucus, both from fish and from processing lines and equipment. This is done by cleaning the fish in an aqueous solution of acetic acid having a pH below 2.8 followed by a rinse with drinking water. Acetic acid is used very early in the process and is no longer present after rinsing nor therefore in the finished products. For this reason it can be considered a processing aid.

Necessity for intended use, known alternatives

Chemically produced acetic acid could be replaced by acetic acid produced by fermentation (vinegar) as food vinegar or by vinegar in concentrated form “vinegar essence”. Acetic acid is the main component of vinegars. Vinegar is a liquid consisting mainly of acetic acid (CH_3COOH) and water, and it is produced by the fermentation of ethanol by acetic acid bacteria. Even organic vinegar is available. Normal vinegar has a pH from around 3. Organic quality vinegar based on spirit is available with 12% of acetic acid and a pH from 2.4. Vinegar might not be totally standardised; however, this might not be a problem for a processing aid with a pH far below the pH needed to inactivate Listeria monocytogenes. Organic vinegar is expensive compared to chemically synthesised acetic acid.

Other substances like citric acid (E330) are currently accepted as processing aid for preparation of organic foodstuffs of animal origin in regulation of pH of brine bath in cheese production (Annex VIII, Section B of Regulation 889/2008) but this might be an expensive solution.

Acetic acid/vinegar is used for the surface treatment of fish particularly for production of smoked fish in order to remove mucus and to reduce the incidence of Listeria monocytogenes. There is a need to reduce Listeria levels on the surface of fish for smoking and the use of acetic acid is a vey important part of that process. See also Human health issues above. Acetic acid produced by natural fermentation (vinegar) should be allowed to be used for this application.

Origin of raw materials, methods of manufacture

Acetic acid is a colourless liquid with a pungent vinegar-like odour. Acetic acid is produced on industrial level with biotechnological means or via chemical synthesis. The big majority is produced by chemical synthesis and only 10% of the production is based on biotechnological processes. The chemical synthesis is carried out by different synthesis methods like methanol carbonylation, acetaldehyde oxidation and ethylene oxidation. Most acetic acid is produced by methanol carbonylation, and in this process, methanol and carbon monoxide react to produce acetic acid. The process involves iodomethane as an intermediate. Glacial acetic acid is a trivial name for the concentrated chemical synthesised acetic acid.
The biotechnological production of acetic acid (vinegar) can be based on beer or wine and done with the use of *Acetobacter* ssp. via ethanol by oxidative fermentation. It may also be done by anaerobic fermentation direct from sugar with the help of *Acetobacterium* ssp. These are traditional processes using non GM strains. Vinegar is typically 4-18% acetic acid by mass. It can be used directly as a condiment, and in the pickling of vegetables and other foods. Table vinegar tends to be more diluted (4% to 8% acetic acid), while commercial food pickling employs solutions that are more concentrated.

Environmental issues, use of resources, recycling

Acetic is a weak acid and is mildly corrosive to metals. A large amount of water is necessary in the chemical synthesis of acetic acid. Moreover, to separate the water from the acetic acid product, a large amount of energy is consumed.

Animal welfare issues

Not relevant.

Human health issues

Acetic acid is a normal constituent of foods. The evaluation of JECFA (Joint FAO/WHO Expert Committee on Food Additives) has set out an ADI level as “not specified”, i.e. the toxicity is so low that it is not necessary to set a limit for consumption.
Pure acetic acid is a strong eye, skin, and mucous membrane irritant. Skin contact with glacial acetic acid may result in tissue destruction. Inhalation exposure (8 hours) to acetic acid vapours at 10 ppm could produce some irritation of eyes, nose, and throat; at 100 ppm marked lung irritation and possible damage to lungs, eyes, and skin might result. Latex gloves offer no protection against skin contact, so special resistant gloves, such as those made of nitrile rubber, are worn when handling the compound. Concentrated acetic acid can be ignited with difficulty in the laboratory.

The use of acetic acid to wash fish in processing facilities is primarily to reduce the level of Listeria by washing it away, reducing the risk of human infection, particularly in cold smoked products which are not heated before consumption. Doing so is a relevant contribution for the product safety. This process of removing the mucus with acetic acid is part of the Guide to Good

Hygiene Practice (GGHP) in France for smoked and/or salted and/or marinated fish for the use as a processing aid in the production of smoked fish. The health authorities validated the GGHP on the basis of the absence of acetic acid residues in the finished product.

Food quality and authenticity

In the case where acetic acid is used as a processing aid as described in the production of organic fish, there is no residue on the fish and there is no residual activity in the final product. It has no negative effect on food authenticity. The food quality is improved by reducing the risk of contamination with *Listeria monocytogenes.* In the fish smoking industry acetic acid is used for cleaning unprocessed salmon and trout.

Traditional use and precedents in organic production

Acetic acid as such is not allowed in Regulation (EC) 889/2008 for applications in organic food. Addition of acetic acid is accepted as an additive in production of organic silage if the natural fermentation is not adequate (Regulation (EC) 889/2008, Annex VI). IFOAM Norms and other private standards do not list acetic acid. Organic vinegar has a relevant meaning in the production of organic foods.

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

Codex Alimentarius “Guideline organic farming and food” and the National Organic Program do not list the substance.
Not permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive or post harvest treatment, but this is due to the fact that organic vinegar would be expected to be used (IFOAM, 2012).

Other relevant issues

None.

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

There is a relevant necessity for using acetic acid/vinegar in the production of organic fish for reducing the incidence of Listeria monocygotenes. Theoretically there is the possibility for using organic vinegar for the same purpose. Because of practical reasons and because of the fact that acetic acid in this case is used as a processing aid and because of the fact that the conventional acetic acid can be produced by biotechnological means it is acceptable to allow the use of acetic acid as processing aid for the production of organic fish if organic acetic acid/vinegar is not available in suitable quality and quantity. Due to the fact that acetic acid can even be produced by synthetic means which is strongly contradicting the obligation in Article 4 and Article 21(1) of Regulation (EC) 834/2007 the origin of the accepted acetic acid should be limited of those from biotechnological sources (Not produced by or from GMO as required by Article 9(1) EC Regulation (EC) 834/2007). Similar arguments apply to the current authorisation of citric and ascorbic acids for example.

Conclusion

The listing of acetic acid/vinegar in Annex VIII, Section B to Regulation 889/2008 for animal products (fish) is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007 Article 21.1(ii). It should therefore be included in Annex VIII, Section B, with the following restriction(s): For fish processing, only from biotechnological source.
The Group considers that if organic acetic acid/vinegar is available in sufficient quality and quantity this should be preferred.

3.5. Ammonium sulphate use or addition in organic products of the wine sector

Introduction, scope of this chapter

This report covers the application from France for addition of ammonium sulphate to Annex VIIIa Products and substances authorised for use or addition in organic products of the wine sector referred to in Article 29(c) of Regulation 889/2008.

Authorisation in general production and in organic production

Listed as an additive E517 in Regulation 1129/2011, but not with any specific uses or permitted levels. Permitted as a carrier in Regulation 1130/2011 at *quantum satis*. Permitted as a carrier in food enzymes in part 3 of Regulation 1130/2011 at a level of 100,000mg/l in enzyme preparations, equal to 100mg/l maximum in food except beverages and 50mg/l maximum in beverages.

Agronomic use, technological or physiological functionality for the intended use

Ammonium sulphate provides ammonium ions which yeast can use as a sole nitrogen source allowing yeast to grow and to start fermentation.
Orwine project results tells that some yeast strains can use ammonium sulphate to form sulphur dioxide (SO_2) which will directly bound by acetaldehyde and in this case it has a similar consequence to adding of SO_2), but at a very low level. Most yeast strains didn't use the sulphate and in this case it increases the level of sulphate in the final product.

Necessity for intended use, known alternatives

Ammonium phosphate which is already permitted in Annex VIIIa to Regulation 889/2008 will also act as a nitrogen source for yeast, while also adding phosphate ions. The concentration used is almost the same between ammonium sulphate and phosphate for the purpose of feeding yeast.
Ammonium phosphate is basic whereas ammonium sulphate is acid so there is a little advantage to use sulphate in southern Europe (where climate change tends to increase wine pH).
Thiamine is also permitted as a yeast nutrient in Regulation 889/2008 and will act as a sole nitrogen source.
Yeast protein extracts as well as yeast autolysates (both from organic source available) could also be an alternative but not authorised in organic farming. The use of preparations from yeast cell walls (from organic yeast strains) in combination with Thiamine and inactivated yeast, which are authorised in organic wine making regulation can have the same effect for yeast nutrition.

The information in the dossier is not clear why ammonium sulphate is preferable to ammonium phosphate as it discusses levels of potassium ions, but see the comments from Orwine in other relevant issues below.

Origin of raw materials, methods of manufacture

Ammonium sulphate is manufactured from sulphuric acid and ammonia. Both are produced by traditional heavy chemistry techniques (the same way as mineral fertiliser).

Environmental issues, use of resources, recycling

None identified with normal use of ammonium sulphate at the permitted quantities in wine.

Animal welfare issues

None.

Human health issues

No ADI has been set for Ammonium sulphate, which indicates that it is not sufficiently toxic to require a maximum daily intake (EC, 2001a). No concerns identified at the level of normal use in wine, with the exception of the issue of formation of sulphite by some yeasts as discussed by Orwine. Orwine was an EU-funded research project aimed at solving the legislative problems by producing a scientific data set to support the EU commission to develop the legislative framework for organic wine production and processing. See below (Orwine, 2014).

Food quality and authenticity

Ammonium sulphate may be considered as a mineral fertiliser for yeast. Organic wine production should be based on certified organic sources of nitrogen. Therefore it may be considered as not appropriate to use it in production of organic wine.

Traditional use and precedents in organic production

Traditionally used as a yeast nutrient in fermentations, for non organic wine and ciders etc. Not used in EU or US organic wine production.

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

EU organic regulation. Not permitted for any uses at present in Regulation 889/2008 Annex VIII, Section A or B.
US NOP. Not permitted in US National Organic Programme standards, for any use.
Japanese JAS. Not permitted in Japanese JAS standards for any use as a food additive.
IFOAM standards. Permitted in IFOAM organic standards only for wine with the maximum level of 0.3mg/l.

Other relevant issues

According to laboratory experiments in white and rosé wines, it increases the production of SO_2, which is unfavourable in the context of SO_2 limitation. The level of SO_2 produced varies with yeast strain used. Other permitted alternatives, specifically ammonium phosphate and thiamine do not have the same effect (Orwine, 2014).

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

The Group considers that the addition of ammonium sulphate to Annex VIIIa of Regulation 889/2008 is not necessary due to the availability of other suitable yeast nutrients.
Organic wine production should be based on certified organic sources of nitrogen. Therefore it may be considered as not appropriate to use it in production of organic wine.
The pH argument in favour of use of ammonium sulphate rather than ammonium phosphate is not considered a major argument. In particular the fact that ammonium sulphate is another synthetic nutrient is not in line with the objectives, criteria and principles of organic farming as laid down in Regulation 834/2007 (Article 21.1(i)).

Conclusions

The Group considers that the addition of ammonium sulphate to Annex VIIIa of Regulation 889/2008 is not necessary due to the availability of other suitable yeast nutrients (Article 21.1(ii) of Regulation 834/2007).

3.6. Ammonium bisulphite use or addition in organic products of the wine sector

Introduction, scope of this chapter

This report covers the application from France for addition of ammonium bisulphite to Annex VIIIa: Products and substances authorised for use or addition in organic products of the wine sector referred to in Article 29(c) of Regulation 889/2008.

Authorisation in general production and in organic production

Not permitted as a food additive in the EU.
Permitted as an additive in wine under Regulation 606/2009, Line 6 Annex 1A with a maximum dose of 0,2g/l.

Agronomic use, technological or physiological functionality for the intended use

In acidic solution it will break down to provide ammonium ions and sulphite ions. Ammonium ions will be used by the yeast as a nitrogen source. Sulphite ions act as antimicrobial agents and as oxygen scavengers, reducing growth of wild, non desirable yeasts and preventing oxidation of the wines.
The Group noted that ammonium bisulphite is not in the correct place in Annex 1A of Regulation 606/2009. Ammonium bisulphite is not used as a yeast activator despite the fact that it is listed for this use. In fact it can only be used to protect grapes after harvesting, so it is used on grapes and must (but not wine). If used on wine it will have the adverse effect of stopping fermentation (sulphite) if added, even at the very low level of 3g/hl. In this case, it is not possible to feed yeast with ammonium sulphate (for which around 30 g/Hl is needed) without stopping fermentation.

Necessity for intended use, known alternatives

No other compound provides both the nitrogen (to feed the yeast) and sulphite sources (to kill the wild yeast & prevent oxidation). Other compounds such as ammonium phosphate or thiamine, permitted in Regulation 889/2008 for use in wine, will provide the nitrogen needed for yeast growth.
Potassium metabisulphite and Sulphur dioxide (SO_2) are already permitted for use in wine as a source of sulphite ions to reduce non desirable yeast or bacterial growth and to reduce oxidation.

The dossier claims that addition of sulphites as potassium metabisulphite may cause tartaric acid to precipitate as potassium tartrate (which leads to a slight rise of pH), creating a sediment in the wine, whereas the ammonium ions from ammonium bisulphite will all be taken up by the yeast leaving no additional ions.
It is also more stable and less volatile than potassium metabisulphite, making it safer for operators.
Other non permitted products such as lysozyme or potassium sorbate may have similar antimicrobial effect while other antioxidants such as ascorbic acid (permitted in organic products) may have similar antioxidant effects.

It is widely recognised that some use of sulphites is essential in organic wine making at present. The dossier claims advantages for ammonium bisulphite over other sources of sulphites. However, there are other permitted sources of sulphites available, in the organic regulations.

Origin of raw materials, methods of manufacture

Made by reaction of sulphur dioxide (made by burning sulphur) with ammonium hydroxide (made by Haber process).

Environmental issues, use of resources, recycling

None identified.

Animal welfare issues

None identified.

Human health issues

Ammonium bisulphite is a source of sulphur dioxide and sulphites, which are allergens, listed among the top ten allergens that must be labelled. Sulphur dioxide is widely used in the food and drinks industries for its properties as a preservative and antioxidant. Whilst harmless to healthy persons when used in recommended concentrations, it can induce asthma when inhaled or ingested by sensitive subjects, even in low concentration. About one in nine asthmatics gives a history of asthma worsened by drinking 'soft drinks' containing sulphur dioxide. They are comparatively young and their asthma is predominantly extrinsic. The amount of sulphur dioxide in foods is limited by regulation in the UK, by directive in the EEC, and by recommendations to 'good manufacturing practice' in the USA (Freedman, 1980).
It is also thought to adversely affect children contributing to behavioural problems (Henson, 2009).
Levels of sulphites over 10mg/l must be labelled in all foods, with clear reference to the allergenicity.
The general consensus is that they are safe except for children and sensitive individuals (CSPI, 2014).
No ADI for Ammonium bisulphite is published. However, the EFSA indicates ADIs of 0.7mg/kg for similar compounds such as sodium bydrogen sulphite etc which indicates that these additives are moderately toxic. Ammonium bisulphite would be expected to have a similar ADI (EC, 2001a).

Food quality and authenticity

Wines without sulphur dioxide tend to be more susceptible to oxidation and spoilage. However, the most modern techniques for production of wine, such as aseptic techniques and reduction of access to oxygen enable reduction or elimination of these compounds in some regions & products.

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

Sulphites have been used traditionally in wine, initially by burning sulphur in casks.
Ammonium bisulphite is not currently used in organic wine processing.
Potassium metabisulphite and sulphur dioxide are already permitted additives as sources of sulphur dioxide for use in organic wine.

Aspects of international harmonisation of organic farming standards

Not permitted for any other use in EU organic regulations.
Not permitted in USDA NOP standards for any use.
Not permitted in Japanese JAS standards for any use.
Not permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive or post harvest treatment.

Other relevant issues

Rejected by Orwine project for addition to Regulation 889/2008 due to the fact that this product can be used for preservation (source of sulphite) and also as a yeast nutrient (source of nitrogen). It has been negatively evaluated by the experts because of this ambiguity of action. The other point against this product is that it was not widely approved under private standards. It was allowed by Bioland but not by others such as FNIVAB, Demeter France at the time of the Orwine review in 2009.

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

The Group considers that the clear requirements in the organic regulations to restrict additives to those most necessary means that the addition of ammonium bisulphite to the list of permitted additives in Regulation 889/2008 is not desirable.

Conclusions

The Group considers that addition of ammonium bisulphite to Annex VIIIa is not in line with the objectives, criteria and principles of organic farming as laid down in Regulation 834/2007 (Article 21.1(i)) due to the availability of other suitable sources of sulphites.

3.7. Chitosan use or addition in organic products of the wine sector.

Introduction, scope of this chapter

This report concerns the French application for addition of chitosan to the list of permitted additives for wine in Annex VIIIa to Regulation 889/2008, Products and substances authorised for use or addition in organic products of the wine sector referred to in Article 29c of Regulation 889/2008.

Authorisation in general production and in organic production

Permitted as a processing aid for wine in Regulation (EC) 606/2009: Annex1A (as modified by Regulation EU 53/2011). Maximum dose for reduction of Brettanomyces: 10 g/Hl; reduction of heavy metals: 100 g/Hl; reduction of Ochratoxin A: 500 g/Hl. These levels are very high and the effect, particularly in reduction of metals is not as effective as active carbon.
Chitosan has been approved recently as a basic substance for use in plant protection, in accordance with Regulation (EC) 1107/2009.

Agronomic use, technological or physiological functionality for the intended use

The application is for addition of chitosan to wine to precipitate specific yeast species, Brettanomyces, which is a known contaminant of wine, producing off flavours such as phenol esters.
It also precipitates metal ions such as iron, cadmium, lead etc, when added at high concentration. It may also reduce the level of Ochratoxin A in wine.

Necessity for intended use, known alternatives

None known to have the same specific effect of reducing Brettanomyces yeast. Addition of sulphites will reduce growth of non-desirable yeasts, potassium metabisulphite & sulphur dioxide are permitted in EU organic Regulations for this purpose. Other techniques such as high hygienic practises as well as must-pasteurisation will reduce microbial loads, but the permitted temperature of 70°C will not have the same effect.

This application is accompanied by one for Chitin-Glucan, a similar compound also extracted from cells of *Aspergillus niger*. It is not clear what the advantages and differences are between the two, although only chitosan is listed specifically for reduction of Brettanomyces.

The dossier claims that low levels of sulphur dioxide coupled with higher pH of organic wines makes them more susceptible to spoilage by Brettanomyces spp. It is claimed that Chitosan aid will help to reduce that concern.
However detailed data was not presented that proves this point.

Origin of raw materials, methods of manufacture

Manufactured from the remaining cellular material of *Aspergillus niger* after the production of citric acid. The cells are dissolved in acid, washed, precipitated in alkali, dried and washed.
There is a risk that some production of citric acid is done by genetically modified Aspergillus, in which case the chitosan would be derived from a GMO. There is no way to identify whether this by product is derived from GMOs.
Current production of citric acid and the organism producing it may also be done on substrates derived from GMOs.

Environmental issues, use of resources, recycling

Production of citric acid is a polluting process. Several plants around Beijing were closed to improve air quality during the Olympics. Chitosan is a by product of this process.
A significant quantity of acidic and alkaline liquid waste will be produced during the production of the chitosan.
The whole process including filtration etc will have significant energy costs.

Animal welfare issues

None identified.

Human health issues

None identified.

Food quality and authenticity

This is not a traditional additive to wine.

Traditional use and precedents in organic production

Other polymers such as polysaccharides, egg white and isinglass (fish collagen) have been used for clarification of wine by coagulation with yeast and sedimentation. However, none that the Group is aware of have been identified as having specific action against a specific species of yeast.

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

Not permitted for any other use in EU organic regulations.
Not permitted in USDA NOP standards for any use.
Not permitted in Japanese JAS standards for any use.
Not permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive or post harvest treatment (IFOAM, 2012).

Other relevant issues

None.

Reflections of the Group / Balancing of arguments in the light of organic production principles
The Group understands that the main argument is the possibility of Brettanomyces reduction only and as a consequence the reduction in the use of sulphur dioxide for wines in which sulphur dioxide is used. Therefore there will be reduction in the use of the toxic additive sulphur dioxide and use of more physical methods of reduction of infection in line with Article 6(d) of Regulation 834/2007.

For wines produced without sulphur dioxide there will be a reduction in off flavor caused by Brettanomyces, contributing to production of a natural product in line with Article 6(c) of Regulation 834/2007.
If further documentation becomes available that proves that sulphur dioxide levels in wine can be reduced by the use of chitosan then use of this product would be desirable in organic wine.

Conclusions

The Group cannot take a firm decision on Chitosan due to the lack of proof that the substance will enable reduction in the use of sulphur dioxide. The applicants are encouraged to submit further data that proves this that sulphur dioxide will be reduced by the use of chitosan as a processing aid in wine production.

3.8. Chitin-glucan use or addition in organic products of the wine sector

Introduction, scope of this chapter

This report concerns the French application for addition of chitin-glucan to the list of permitted additives for wine in Annex VIIIa of Regulation 889/2008 "Products and substances authorised for use or addition in organic products of the wine sector referred to in Article 29(c) of Regulation 889/2008".

Authorisation in general production and in organic production

Permitted as a processing aid for wine in Regulation (EC) 606/2009: Annex1A (as modified by Regulation EU 53/2011). Maximum dose for reduction of Brettanomyces: 10 g/Hl; reduction of heavy metals: 100 g/Hl; these levels are very high and the effect, particularly in reduction of metals, is not as effective as active carbon.

Agronomic use, technological or physiological functionality for the intended use

The application is for addition of chitin-glucan to wine to precipitate specific yeast species, Brettanomyces, which is a known contaminant of wine, producing off flavours such as phenol esters.
It also precipitates metal ions such as iron, cadmium, lead etc.

Necessity for intended use, known alternatives

None known to have the same specific effect of reducing Brettanomyces yeast. Addition of sulphites will reduce growth of non desirable yeasts, potassium metabisulphite and sulphur dioxide are permitted in EU organic Regulations for this purpose. Other techniques such as pasteurisation will reduce microbial loads.
This application is accompanied by one for Chitosan, a similar compound also extracted from cells of *Aspergillus niger*. It is not clear what the advantages and differences are between the two.

The dossier claims that low levels of sulphur dioxide coupled with higher pH of organic wines makes them more susceptible to spoilage by Brettanomyces spp. This processing aid is intended to help to reduce that concern.

Origin of raw materials, methods of manufacture

Manufactured from the remaining cellular material of *Aspergillus niger* after the production of citric acid.
There is a risk that some production of citric acid is done by genetically modified Aspergillus, in which case the chitin-glucan would be derived from a GMO. There is no way to identify whether this by product is derived from GMOs.
Current production of citric acid and the organism producing it may also be done on substrates derived from GMOs.
The cells are dissolved in sodium hydroxide then heated to 120°C for 30 min to 4h. The filtrate is then washed with demineralised water.

Environmental issues, use of resources, recycling

Production of citric acid is a polluting process. Several plants around Beijing were closed to improve air quality during the Olympics. Chitin-glucan is a by product of this process.
A significant quantity of acidic and alkaline liquid waste will be produced during the production of the chitosan.
The whole process including filtration etc will have significant energy costs.

Animal welfare issues

None identified.

Human health issues

None identified.

Food quality and authenticity

This is not a traditional additive to wine.

Traditional use and precedents in organic production

Other polysaccharides and polymers such as egg white and isinglass have been used for clarification of wine by coagulation with yeast and sedimentation. However, none that the Group is aware of have been identified as having specific action against a specific species of yeast.

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

Not permitted for any other use in EU organic regulations.
Not permitted in USDA NOP standards for any use.
Not permitted in Japanese JAS standards for any use.
Not permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive or post harvest treatment (IFOAM, 2012).

Other relevant issues

None.

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

The Group sees no clear argument for adding chitin-glucan to Regulation 889/2008 for use as an additive in wine. In the Group's opinion, chitosan would be preferable for this purpose (see chapter 3.7).

Conclusions

The Group considers that addition of chitin-glucan to Annex VIIIa is not in line with the objectives, criteria and principles of organic farming as laid down in Regulation 834/2007 (Article 21.1(ii)), due to the lack of necessity.

3.9. Mannoproteins extracted from yeast for tartrate stabilization of wines

The Group had insufficient time available to consider in detail the request from Italy for tartrate stabilization of wines, so it recommends that this issue is put forward through a mandate for Food IV to the EGTOP expert group, as high priority.

3.10. Sodium hydroxide for use as processing aid in the peeling of salsify

Introduction, scope of this chapter

The mandate is based on a request from Belgium on the possible use of sodium hydroxide as a processing aid in peeling of salsify (Annex VIII, Section B to Commission Regulation (EC) No 889/2008) (EC, 2008a).
The Latin name is not mentioned in the request but salsify can be both black salsify or scorzonera, *Scorzonera hispanica* and white salsify, *Trogopogon porrifolius* ('Haferwurzel' in German).

Authorisation in general production and in organic production

Sodium hydroxide is authorised as a food additive (E524) in Regulation (EC) No 1130/2011 amending Annex III to Regulation (EC) no 1333/2008 of the European Parliament and of the Council following the *quantum satis* principle.

Agronomic use, technological or physiological functionality for the intended use

Sodium hydroxide is widely used as a processing aid in chemical peeling of conventional vegetables. Skins can be softened from the underlying tissues by submerging vegetables in hot alkali solution. NaOH may be used at a concentration of about 0.5-3%, at about 93°C for a short time period (0.5-3 min). The vegetables with loosened skins are then conveyed under high velocity jets of water which wash away the skins and residual lye. According to the dossier, neutralisation of NaOH after lye peeling of salsify is not needed as the washing and boiling process is enough to restore original pH in salsify.
Sodium hydroxide (NaOH) is also used as acidity regulator for application in food and during processing of food (lye, caustic soda). It increases the pH of foodstuff.

Necessity for intended use, known alternatives

Peeling of vegetables with steam is an alternative to peeling with lye (sodium hydroxide). However, according to the request, peeling of salsify with steam does not seem to be sufficient as some remains of the peel stay on the product even when the salsify is brushed. After transporting, those remaining pieces of peel produce milky substances which are left in the glass bowls in which the salsify is sold to the consumer. Manual peeling of the remaining peel after steam peeling should be an alternative but it is a more expensive process.

Mechanical peeling of salsify as supplement to steam peeling should be possible to avoid lye peeling.

Origin of raw materials, methods of manufacture

Sodium and hydroxide ions are ubiquitous in nature. However, pure sodium hydroxide is produced from sodium chloride by electrolysis. The electrolysis is done in different ways, i.e. membrane, amalgam or diaphragm technology.

Environmental issues, use of resources, recycling

The electrolytic conversion of sodium chloride to sodium hydroxide and chlorine is potentially one of the most damaging processes used due to the production of reactive chlorine molecules that are used in the production of toxic materials, either deliberately or as by-products of other processes.
However, this risk is managed if correctly produced and handled according to EU environmental legislation.

Lye peeling of vegetables salsify results in considerable amounts of alkaline waste water, which has to be neutralised (USDA ARS, 2014). The possibility of recycling of lye is not mentioned.

Animal welfare issues

No specific concerns.

Human health issues

No ADI level has been specified which means that the level of intake normally encountered as a food additive is unlikely to cause toxicity to humans (EC, 2001a). The concentrated liquid and the sold forms however, are very caustic and must be handled with care and with suitable protective clothing etc.

Food quality and authenticity

The food quality should not be changed by lye peeling as the lye is neutralised by water after peeling. The visual quality is improved by good peeling.

Traditional use and precedents in organic production

Sodium hydroxide is used as a food additive in the organic production of pretzel, pretzel sticks and pretzel rolls (Laugengebäck) to get the typical brown colour at the surface, and it is allowed as a processing aid in processing of organic sugar(s) and rape seed oil in Regulation 889/2008 Annex VIII, Section A and B.
The EGTOP Food Group II suggested that neutralisation of oils by the mean of NaOH was in line with the objectives and principles of organic Regulation. The Group proposed to delete in Annex VIII, Section B for NaOH the specific condition "Oil production from rape seed (Brassica spp)" and replace it by "Oil production".

Sodium hydroxide is also authorised for disinfection. In Annex VII, it is listed as 'caustic soda'.

Other relevant issues

None.

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

According to US National Organic Programme List of permitted and non-permitted substances for organic food (§205.606 of the US), lye peeling of organic fruits and vegetables is prohibited.

The FAO Codex Alimentarius Commission "Guidelines for the production, processing, labelling and marketing of organically produced foods Annex 2: Permitted substances for the production of organic foods" allows sodium hydroxide as a processing aid in sugar production.

According to Japanese JAS Organic Standards, sodium hydroxide is permitted as an additive and post-harvest treatment with the condition: For sugar processing and for the surface treatment of traditional bakery products only.

Permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive. For sugar processing and for the surface treatment of traditional bakery products only (IFOAM, 2012).

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

The Group wonders why pieces of peeling should give rise to the white substances as the roots are rich in a milky sap, so it is expected that the sap can give rise to the mentioned substances. The Group is aware of the difficulty of handling salsify due to the rapid enzymatic oxidation of the sap.
The use for peeling of vegetables is very different to the proposed use for reduction of carcinogens during the refining of oils, which was discussed by EGTOP Food II.
The use of chemical methods to peel organic fruit and vegetables in general is not consistent with the expectations of the Group (Article 6(c) of Regulation 834/2007) and there are preferable alternatives available (Article 21.1(i) of Regulation 834/2007). It is also not in line with Article 4(c) of Regulation 834/2007 regarding use of chemical methods. Further the Group is concerned that approval for this specific use will encourage applications for other uses for peeling of organic fruit and vegetables.

Conclusion

The use of sodium hydroxide for peeling of salsify is not in line with Regulation 834/2007 Article 4(c) regarding restriction of chemically synthesised inputs.
The Group considers that addition of sodium hydroxide specifically for the lye peeling of salsify is not consistent with the principles of the regulation (6(c) of Regulation 834/2007) and there are preferable alternatives available (Article 21.1(i) of Regulation 834/2007).

3.11. Sorbic acid for beaten egg-free dough baked goods

Introduction, scope of this chapter

The following report is based on the request of Spain for the use of sorbic acid in organic food processing. Sorbic acid (E200) was requested to be used as food additive in the processing of beaten egg-free dough baked goods to obtain a shelf life of 10 weeks. The dossier asks for the application of sorbic acid in these products as preservative. The main topics are objectively described based on an accurate literature research. In a second step, the decision on the use of sorbic acid is made on the basis of these facts.

Authorisation in general production and in organic production

Sorbic acid is generally allowed as a food preservative in the European Union. According to (EU) No 1129/2011, sorbic acid is allowed to be added to a wide range of foods including fermented milk products, processed fruits and vegetables, alcoholic beverages, bakery products and others.

Agronomic use, technological or physiological functionality for the intended use

Sorbic acid is a flavorless food additive which is used to extend the shelf-life of foods. It inhibits microbial growth, thus preventing food products from spoilage and the growth of pathogens. It is especially effective against yeasts, molds, and certain bacteria (Franzke, 1996). The mode of action includes the inhibition of several microbial enzymes and therefore interferes with the microbe's metabolic pathways. Sorbic acid shows optimal antimicrobial activity below pH 4.75, where it is present in its more active undissociated form.
In 1994, the EFSA evaluated sorbic acid and its sodium (E201), potassium (E202), and calcium (E203) salts. The EFSA expert panel concluded that these compounds are neither toxic, nor mutagenic or carcenogenic. In certain population subgroups high dosages caused weak hypersensitivity reactions (urticaria). However, sorbic acid and its salts were concluded to be safe for the consumer. Currently, there is a re-evaluation under way for food additives including E200-E203, with an upcoming deadline in 2015.

Origin of raw materials, methods of manufacture

Sorbic acid is naturally present in the berries of the mountain ash tree, from where it used to be isolated originally. Nowadays, sorbic acid is synthetically manufactured by the polymerisation reaction of ketone and crotonaldehyde and further processing (Verbraucherinitiative, 2014).

Necessity for intended use, known alternatives

There are possible alternatives for sorbic acid as preservation agent of bakery products. Other methods like packaging in modified atmosphere; nitrogen and/or carbon dioxide are available. Nevertheless such methods will presumably not deliver 10 weeks of shelf life. Both modified atmosphere gasses are listed as processing aids in the commission Regulation (EC) No 889/2008 (Annex VIII, section B). For some bakery products other methods, like spraying a thin layer of ethanol, laying in ethanol or reducing the pH value in the dough are available. Further, the keeping time could be reduced or preservation by freezing could be discussed.

In general, the use of new preservatives can only be allowed in accordance to Article 21 1) of ECC 834/2007 if they are really necessary and no alternatives are available. The bakery products could be sold as fresh goods (with shorter shelf life), which would be in line with the principles of organic production. Moreover, there are acceptable alternatives instead of sorbic acid, as mentioned above.

Food quality and authenticity

Food additives and especially preservatives should be avoided unless they are absolutely necessary (Art 21.1(ii) of Regulation (EC) 834/2007). The use of preservatives is able to prolong the shelf live of a product relevantly. In the proposed case the shelf life of the fresh product is extended to 10 weeks. Important attributes of organic foods are their freshness and naturalness. Therefore the use of preservatives is strongly restricted to a minimum in the organic regulation.

The application of a preservative risks regularly misleading the consumer on the true age and nature of the product.

Traditional use and precedents in organic production

There is no traditional use or precedent known in organic food production.

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

The use of sorbic acid is not accepted in Codex Alimentarius Organic labeling standards, is not accepted in the NOP and not listed in IFOAM Basic Standards.

Human health issues

The ADI of sorbic acid is 25mg/kg, which indicates that the compound has a low but significant toxicity.

Other relevant issues

None.

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

Important attributes of organic foods are their freshness and naturalness. The use of preservatives aims to prolong shelf life of the product. The application of a preservative risks misleading the consumer as to the true age and nature of the product. Further it is clear in Articles 4(c) and 6(b) of Regulation 834/2007 that chemical substances should be strongly restricted. Therefore the use of preservatives needs to be restricted to a minimum in organic production. Physical methods such as freezing or previously approved substances such as nitrogen and carbon dioxide should be preferred to the addition of new additives (Article 21.1(i) of Regulation 834/2007).

Conclusions

The use of sorbic acid as food additive is not in line with the objectives, criteria and principles of organic processing. It does not fulfill the requirement of Article 4(c) and 6(b) and 21.1(i) in Regulation 834/2007 regarding limitation of use of chemicals and availability of alternatives. Therefore, it should not be included in Annex VIII, Section A to Regulation 889/2007.

3.12. Erythritol

Introduction, scope of this chapter

The following report is based on the request of Italy for the use of conventional erythritol (E968) as a food additive in organic food processing as a low calorie sweetener for the obese and for diabetics.
The focus of the report lies on the production process of erythritol. In addition, its function and possible health issues are highlighted. The subsequent decision is based on this information.

Authorisation in general production and in organic production

Erythritol (E 968) is listed as a sweetener in the Commission Regulation (EC) No 1129/2011. It is generally allowed to be used in foods with the exception of drinks (EC) No 2006/52.
Erythritol 1,2,3,4-butanetetrol (ERT) is a natural C4 polyol (sugar alcohol).
INS number 968
CAS Number: 149-32-6
EINECS Number: 205-737-3
(FAO, 2014).

Agronomic use, technological or physiological functionality for the intended use

Erythritol is a naturally occurring sweetener with a sweetening power of 60-80 % of sucrose. Additionally, it has many other functional properties *e.g.* as flavour enhancer, carrier, stabiliser, and thickener. Erythritol is a zero calorie sugar alcohol which does not influence the human insulin metabolism.
Erythritol is naturally present in low concentrations in some fruits (eg. grapes and melons) (Calorie Control Council, 2014) and fermented products. The industrial production process, however, includes a fermentation step followed by several purification steps.

Necessity for intended use, known alternatives

There are no calorie free sweeteners available for organic products. There are many sweeteners allowed in organic food production such as sucrose, fructose, glucose, honey, agave, maple syrup etc. However, these sweeteners are caloric, influence the insulin metabolism and promote dental caries. Steviol-glycosides could have served as an additional alternative, but EGTOP food mandate I concluded that steviol glycoside was considered not to be in line with organic regulations.

The Group does not see a need for a low calorie sweetener for diabetics or the obese but there may be a need in the market. If there is a market need for sweeter products which do not contain additional calories erythritol would be a possible source. In general, there is no necessity for the use of an artificial sweetener, because this function can be fulfilled through the addition of sucrose, fructose or honey and other organic sweeteners.

Human heath issues

There are no severe health concerns about the consumption of erythritol.
So far, only one case of anaphylactic shock which could be linked to erythritol consumption has been reported in Japan.
However, as with many other sugar alcohols its consumption may have laxative effects (Oku & Okazaki, 1996). According to an EFSA report in 2003 (European Food Safety Authority EFSA 2003), the digestive tolerance of erythritol lies between 0.5 and 1.0 g/kg body weight per day as NOAEL (No-observed-adverse effect) for laxative effects. ADI level is not specified, which indicates that there is no toxicological risk. It is considered as GRAS (Generally Recognised As Safe) by the US FDA. Erythritol is not appropriate for the consumption by children, because of the laxative effects.
It is a zero calorie sweetener and could be used in organic low-sugar diets or zero calorie products for example in case of obesity. However, there could be side-effect for healthy people: data suggest that co-ingestion of equimolar concentrations of fructose and erythritol increased carbohydrate malabsorption (Kim et al., 2011).
There are some indications that, when a sweet product is ingested, the body expects glucose levels to rise in the blood. When sweet tasting low/no calorie products are ingested, which do not

result in raised blood glucose, they can confuse this response which can lead to excess consumption (Swithers et al., 2008).
Previously it was believed that the use of sweeteners like erythritol had positive health effects for people with diabetic diseases. This has since been disproved and their use for this purpose should therefore not be recommended (Stapperfend & Scherbaum, 2001).The marketing of low calorie products for diabetics containing products such as erythritol was previously protected. This specific regulation for diabetic products has since been withdrawn (EC Directive 39/2009/EG).

The use of erythritol and xylitol was associated with a statistically significant increase in the plaque and saliva levels of *Streptococcus mutants* responsible for dental cavities (Mäkinen et al., 2005).

Erythritol acts as an antioxidant in vivo and may help protect against hyperglycemia-induced vascular damage.

Food quality and authenticity

With the existing organic sweeteners, the production of sweet products with fewer calories is not possible. However, erythritol doesn't fulfil the requirements of the Regulation Article 6(b): Organic products should have less food additives and be natural. The production process to get pure erythritol does not seem to lead to a natural product. After the fermentation by microorganisms, there are many purification steps following. These harsh processing steps can be seen as a change of the product's authenticity, which would not be in line with the principles of organic food production (Article 6(d)). Nevertheless the applicant demonstrated that organic erythritol is available.

Origin of raw materials, methods of manufacture

The request contains a process flow diagram. The details are not mentioned.
For example the FDA describes processes of manufacturing erythritol (FDA 2011). The first step is the fermentation of glucose using a pure culture of *Y. lipolytica* strain 1431. Following fermentation, the culture is filtered (ultrafiltration) to remove microbial cells. The filtrate is then concentrated, cooled, and erythritol crystals are removed by centrifugation. These crystals are redissolved and activated carbon is added; the resulting solution is then demineralised using an ion-exchange resin. Afterwards, the solution is concentrated and the erythritol recrystallised. The resulting erythritol crystals are then separated by centrifugation. The crystals are dried and screened to achieve the appropriate pArticle size for the finished product.
The purity reported is > 99%, Many articles suggest that GM organisms are much more efficient than previously used conventional organisms.

Animal welfare issues

None.

Environmental issues, use of resources, recycling

None.

Traditional use and precedents in organic production

There is no traditional use or precedent known in organic production.

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

Recently, the NOP allowed an organic erythritol production process similar to those included in the Italian dosser.

Other relevant issues

None.

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

The Group opinion is that there is not a general need for sweetened low calorie organic products, but there may be a need for specific nutritional purposes especially for diets in cases of obesity. In general, The Group considers that erythritol (E968) does not fulfil the requirement in Article 21(1) of Regulation 834/2007 regarding availability of alternatives.
The dossier includes information that organic erythritol certified to NOP standards is available. In that case it needs to be mentioned that to our knowledge the purification step is based on ion exchange. See chapter 3.16 of this report and the report on Steviol glycosides in the report of EGTOP Food 1. Both reports confirm EGTOP's view which is that ion exchange only has a potential role in organic food processing, when used to achieve a legal product limit, e.g. for sodium in baby foods.
A possible use of erythritol e.g. for low calorie organic soft drinks could conflict with the principle mentioned in Art 6 (c) of Regulation 834/2007 regarding the true nature of the product.

Conclusions

The Group is of the opinion that only organic erythritol produced in accordance with the EU organic regulation should be added to Annex VIII, Section A to Regulation 889/2008.

3.13. Organic starch & plant oils for organic yeast production

Introduction, scope of this chapter

Finland brought forward the proposal that only organic potato starch should be used as processing aid in the processing of organic yeast (Annex VIII, Section C of Regulation 889/2008). The dossier argues that in the past only organic starch was used for this purpose and that organic starch is available in sufficient quantity and quality.
EGTOP is not able to check the market availability of organic potato starch.
As stated by EGTOP several times before, (e.g. EGTOP Food I) even processing aids should be used in organic quality when available in sufficient quantity and necessary quality. To the knowledge of the Group different starch varieties are available in organic form on the market place in large quantities.

In Annex VIII, Section C to Regulation 889/2008, potato starch and plant oils are mentioned as processing aids. In the Group's opinion organic plant oils are also available in different qualities and large quantities and both should therefore be used as processing aids in the production of organic yeast.

Conclusion

The Group recommends that only certified organic forms of starch and plant oils should be used as processing aids in yeast production.

Additionally, as also mentioned in EGTOP Food I, starches and plant oils and other processing aids should also be used in certified organic form.

3.14. Hydrochloric acid for use as a reagent for dextrin production (preparation of foodstuffs of plant origin)

Introduction, scope of this chapter

The mandate is based on a request from Czech Republic for addition of hydrochloric acid as a reagent for dextrin production in the Regulation (EC) no 889/2008 Annex VIII, Section B (technical processing aid – preparation of foodstuffs of plant origin).
Hydrochloric acid was known to European alchemists as spirits of salt or acidum salis (salt acid). Both names are still used, especially in non-English languages, such as German: Salzsäure.

Authorisation in general production and in organic production

Hydrochloric acid (HCl) is accepted as a food additive "E507" according to Commission Regulations (EU) no. 1130/2011 and (EU) No 1129/2011 (applicable from 01/06/2013), and is in the list of Group 1 additives generally authorised in foodstuffs (including starches) to be used in accordance with the *quantum satis* principle. In addition hydrochloric acid is authorised to be used only for pH adjustment in accordance with the *quantum satis* principle for:
1) Processed cereal based foods and baby foods as defined by Directive 2006/125/EC (13.1.3);
2) Other foods for young children (13.1.4);
3) Dietary foods for infants for special medical purposes and special formulae for infants (13.1.5.1).

Agronomic use, technological or physiological functionality for the intended use

Hydrochloric acid is a strong inorganic acid and is an effective chemical to be used for pH adjustment in preparation of several foods. It is also used for the acid hydrolysis of starch to produce sugars and short chain polysaccharides.

Necessity for intended use, known alternatives

Weaker acids such as acetic acid, lactic acid and citric acid can be used for adjustment of pH, but they might influence the products as larger amounts of acids are needed for the pH adjustment.
Enzymic processes may be used to produce dextrins. The dossier is not clear on the reasons why this process is not suitable for the production of organic dextrins.

Hydrochloric acid is intended to be used as a processing aid in the processing of organic dextrin from potato starch. The acids splits the glycoside bonds in the starch so smaller molecules are formed. Citric acid and sulphuric acid are now authorised as processing aids for preparation of organic foodstuffs of plant origin, and they have been tested for the purpose of dextrin formation from starch; however they are not good for this purpose. Dextrins may also be produced by enzymatic treatment of starch. Enzymatic methods should be used preferably and the applicant should make it clear why if this method is not applicable.

Origin of raw materials, methods of manufacture

Hydrochloric acid is ubiquitous in nature; for example, it occurs in the human stomach. Hydrochloric acid is a clear colourless or slightly yellowish liquid with a pungent odour. Hydrochloric acid is prepared by dissolving hydrogen chloride in water. Hydrogen chloride can be generated in many ways, and thus several precursors to hydrochloric acid exist. Hydrochloric acid is produced in solutions up to 38% HCl (concentrated grade). Higher concentrations up to just over 40% are chemically possible, but the evaporation rate is then so high that storage and handling need extra precautions, such as pressure and low temperature. Bulk industrial-grade is therefore 30% to 34%, optimised for effective transport and limited product loss by HCl vapors.

Environmental issues, use of resources, recycling

Waste water with high concentration of hydrochloric acid must be neutralised with bases before putting to the waste system, resulting in a saline solution being discharged.

Animal welfare issues

No specific concern.

Human health issues

Gastric acid is one of the main secretions of the stomach of human and animals, and it consists mainly of hydrochloric acid and acidifies the stomach content to a pH of 1 to 2. The stomach itself is protected from the strong acid by the secretion of a thick mucus layer, and by secretin induced buffering with sodium bicarbonate.
There is no ADI specified, which means that at levels found in food it is unlikely to be toxic.
Concentrated hydrochloric acid forms acidic mists. Both the mist and the solution have a corrosive effect on human tissue, with the potential to damage respiratory organs, eyes, skin, and intestines irreversibly. Prolonged exposure to low concentrations of gaseous hydrochloric acid leads to erosion of teeth; exposure to acid mist produces bleeding nose and gums with ulceration of oral and nasal mucosa and tender facial skin (FAO/WHO, 1966).
Personal protective equipment such as rubber or PVC gloves, protective eye goggles, and chemical-resistant clothing and shoes are used to minimize risks when handling hydrochloric acid.

Food quality and authenticity

No human health issues are related to the use of hydrochloric acid in food in general as the acid is neutralised in the food. This ingredient can be used in food without other limitations than the level must not exceed current good manufacturing practice (FAO/WHO, 1966).

Traditional use and precedents in organic production

Hydrochloric acid is authorised as a processing aid for preparation of organic foodstuff of animal origin, specified as use for gelatine production, and for the regulation of the pH of the brine bath in the processing of cheeses Gouda, Edam, Massdammer, Boerenkaas, Friese and Leidse Nagelkaas.

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

According to USDA organic, hydrochloric acids is not authorised as a processing aid for preparation of organic food.

Not Permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive or processing aid.

Other relevant issues

None.

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

In general enzymic methods, using enzymes produced by non GM organisms, is preferred to chemical methods such as use of hydrochloric acid. Enzymatic methods should be used preferably (Article 21.1 of Regulation 834/2007) and the applicant should make it clear why if this method is not applicable. The need for hydrochloric acid for preparation of organic dextrin is not proven.

Conclusion

The use of hydrochloric acid as a processing aid in the production of dextrin from starch is not in line with the objectives, criteria and principles of organic farming as laid down in the Council Regulation (EC) No 834/2007, Article 21.1, due to the fact that a biological process (enzymatic production) is possible and preferred.

3.15. Fruit acid washes based formulations composed of citric acid, ethanol, sodium alkyl sulphate, grapefruit oil as processing aid for removal of bacterial load from wash water

A dossier on the use of fruit acid washes was brought forward by UK. The fruit acid wash formulation composed of citric acid, ethanol, sodium alkyl sulfate, and grapefruit oil was intended for use as processing aid to reduce bacterial load in wash water.
This request is asking for the evaluation of a trade product which is not within the competence of EGTOP.

3.16. Ozone as post-harvest treatment of plant products

Introduction, scope of this chapter

The Group considers that the proposed application in the dossier presented by NL is as a disinfectant or as a plant protection product for use as a post harvest treatment.

- As a disinfectant for organic animal housing it is not within the scope of the EGTOP group on food and should be discussed by another sub-group (Article 14.1(f) of Regulation 834/2007).

- The application may be seen as an application for a disinfectant in primary plant production (Article 12.1(j) of 834/2007).

- Alternatively as a disinfectant for handling facilities in processing units it is not within the scope of the organic regulation.

- If for use to react with ethylene to prevent over ripening or to treat fungi on the surface of fruit and vegetables this may be seen as use as a plant protection product. In this case, the legal status under plant protection legislation should be clarified and, if appropriate, it should be discussed by EGTOP plant protection.

The EGTOP SG Food concluded that the request as forwarded by NL is partly not within the scope of organic regulation and not in the scope of the food mandate. Never the less the Group decided to deliver some thoughts on the ozone topic in order to facilitate future debates.

The following text was produced by the Group in preparation for the discussion and may be of use to other groups in discussing these uses of ozone.

Ozone is a form of oxygen with three atoms of oxygen which are linked to each other. Sometimes it is called "activated oxygen". Ozone is the second strongest disinfectant and the strongest oxidant among disinfecting agents. Ozone is a powerful oxidant but it will decay rapidly, because it is unstable with a relatively short half life. In water the half life is shorter than in air and is strongly dependent on temperature, pH, UV-light and organic matter. Half life is at 20°C in water ca. 20min and in air ca. 3 days. As the pH value increases the formation of OH radicals increases in water. A method used by Kjer and Ahlert is to combine ozone gas with water through a nozzle. In this case the reaction time against microorganisms is very short (and even for spores such as Bacillus the contact times are much less than are needed for high temperature) and for such a short time it is possible to increase the temperature for an even better reaction. This technique can be used, for example, for disinfection and sterilisation of packaging material.

Authorisation in general production and in organic production

Not restricted for use in conventional foods production plants.
Ozone is currently one of the disinfectants currently being tested as a substitute for formalin for disinfection of poultry houses. This use is not yet authorised.
Currently used as a disinfecting treatment in containers and fruit cold stores. The air around the fruit is treated creating a specific ozone level, consuming ethylene reducing ripening and disinfecting the fruit, preventing fungal spoilage.
Authorised in the Netherlands for cleaning and disinfection of aquaculture equipment & facilities in the absence of aquaculture animals.

Origin of raw materials, methods of manufacture

Ozone is always generated on site by an ozone generator. This is necessary because of the short half life of ozone, but means that there must always be complex equipment at the point of use. Therefore it is a complex system for disinfection and it needs a lot of experience compared with the use of chlorine for example.

Two main methods are used, one with UV-light and the other by corona-discharge. Under normal circumstances corona-discharge is used. UV-light is used for small amounts of ozone. The use of pure oxygen (95% of oxygen gives higher amounts of ozone than with air (21% oxygen) with a factor from 1,7 to 2,5 at constant power.
An ozone generation unit will consist of the oxygen source, a filter, gas dryer, the ozone generator, the contact unit and a method of destruction of excess ozone. Further, it is extremely corrosive and all contact materials must be stainless steel.

In production areas a common method is to use a double substance nozzle to produce a fog out of a mixture of gas and water, to treat the area, followed by treatment with UV radiation to break down the ozone creating a safe, sterile environment.

For small producers the installation of an ozone system is difficult because of the costs and the complexity.

The corona-discharge ruptures the stable oxygen molecule into two oxygen radicals and these radicals can combine with another oxygen molecule to produce ozone. During this process there is an excessive production of heat which has to be cooled down. The whole process should be run between 5 – 20°C. The oxygen source has to be dried before coming into the ozone generator, e.g. by molecular sieves. After the use of the ozone the remaining gas has to be destroyed by catalysts or UV light. The fact that ozone is produced solely at the point of use so there are no transport problems. Other advantages of ozone are that it is very effective compared with other disinfections like chlorine and it needs only a short contact time. Further, it decomposes rapidly and almost no harmful residues will be left. It provides complete destruction of the microorganisms so there is no recovery as may occur with UV-light or chlorine disinfection. Finally it leaves no remaining tastes or colours.

However during studies for the QLIF project it was proven that, with regard to ecological aspects, ozone is a good alternative to the existing disinfectants, such as chlorine, in the organic field (Kretschmar, 2009).

It should be noted that normally ozone reacts predominantly with vegetative organisms and is less effective with sporeforming bacteria.

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

Authorised in US NOP standards without restriction in post harvest treatment (205.605). In the pre-harvest phase ozone is authorised in gaseous form only for disinfecting water pipes. This application is currently being re assessed.

Environmental issues, use of resources, recycling

The costs for ozone systems are high, due partly to the fact that the generation process needs high amounts of electric energy. A big part of this energy is used in cooling of the process.
However, no chemical residues are left after treatment with ozone.

Human health issues

Ozone reacts in the respiratory tract and causes irritations of mucous membranes and often a headache. Higher concentrations (more than 50ppm) or longer exposure times (more than 30 min) may be dangerous. The MAC (Maximum alveolar concentration) value for long term periods has to be less than 0.06ppm ozone and for short time the value can rise to 0.3 ppm. Ozone has a very strong smell and the MAC values can be noticed easily. The border value above which humans can detect ozone is about 0.02ppm.
It is extremely irritating for workers and the gas has to be destroyed completely after use, for example by the use of UV light.

Food quality and authenticity

In some cases it may promote food quality by providing suitably sterile environments to ensure stable safe food.

Traditional use and precedents in organic production

No traditional use and no precedents in organic production exist. Drinking water is frequently used, and this may sometimes be treated with ozone.

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

Ozone is useful for the disinfection and sterilisation of packaging materials instead of peroxides, because it works very fast especially at higher temperatures. It can also be used for the disinfection, sterilisation of apparatus such as filling systems which are in contact with sterile food, providing care is taken to avoid materials that may be corroded by ozone.

In the opinion of the Group and because of the high oxidative potential ozone should not come into direct contact with organic food.

Conclusions

The Group recommends that ozone may be used for sterilisation of equipment, packaging materials etc. However for the moment the Group considers that it should not be permitted for use in applications where there is direct contact with the organic food during food processing.

3.17. Ion exchange technology in organic production (i.e. different applications)

Introduction, scope of this chapter

With the first food mandate EGTOP discussed the use of ion-exchange and adsorption technology for production of a “natural fruit sweetener” based on carob with a high purification level based on a Spanish request from 2011. Basic information for the evaluation of such products can be found there. For this mandate the topic of ion-exchange and adsorption technology was listed with reference to further possible applications of ion-exchange and adsorption technology for the use in starch syrup demineralisation and purification, whey demineralisation, juice demineralisation and neutralisation, gelatin production etc. Dossiers were available for a number of these applications, e.g. the production of rectified concentrated must or other juice. For other types of application (e.g. starch scarification or whey and milk demineralisation) request was provided by member states in the form of incomplete dossiers.
The first EGTOP food report took a position regarding the carob based sweetener. By discussion of this topic and by reflecting on the broad variety in terms of possible application and impacts of this technology for food it is clear that the evaluation must be based on specific application and cannot be done in general in order to address the aims and principle of organic regulation.
This report therefore will therefore focus on three cases:

- The demineralisation and neutralisation of fruit juice concentrates including the special case of rectified concentrated must;
- The use of those technologies in the context of starch scarification;
- The use of those technologies for the preparation of ingredients (whey and starch based products) for the production of baby foods.

For the use of those technologies in gelatin production no information was provided by member states. A check of EGTOP members with industry producing organic gelatin delivers the

information that these technologies are not used and are not necessary for the production of organic gelatin. Therefore this topic is not addressed in this report.
It needs to be mentioned that the main source for the evaluation of methods are the requirements given in Article 19(3) of EC Reg. 834/2007.

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 (Regulation (EC) 1935/2004). The new organic wine regulation (Regulation (EC) 203/2012) forbids the use of cation exchangers to ensure the tartaric stabilisation, but authorises the use of ion exchange resins for the must preparation in Article 4(b) for a transition period, with the additional comment: "The use of ion exchange shall be re-examined by the Commission before 1 August 2015 with a view to phase out or to further restrict those practices."

In France and other 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 889/2008.

Agronomic use, technological or physiological functionality for the intended use

These technologies are “reversible chemical reactions between a solid and an aqueous solution that allows the interchange of ions”.
Ion exchange is based on the principle that a solid mass with immobilised charges can attract the mobile ions of the opposite charge in a fluid medium and exchange them with other ions, preferably H+ or OH-. Two types of resins are in use, cation and anion exchange resins. This is predominantly a chemical process.
Adsorption technology is a similar method where, with the help of specific functional groups on the resins, specific molecules (constituents) from the liquid can be attracted and bound onto the resin and therefore specific substances are removed from the fluid media (product). Typical applications are demineralisation, decolouring, removal of contaminates, organic acids and proteins. They comprise chromatographic separation technologies, and molecular filters. Adsorption resins do not normally change the molecules in the product but have a very specific influence on the chemical composition of the product by removing a number of natural constituents of a liquid food, but there are applications where the technology works like a catalyst by influencing the molecular structure of the constituents. For example, the technology can be used for the conversion of glucose to fructose. This is predominantly a physical process.

Case 1: Fruit concentrates purification

Fruit concentrates are normally concentrated then purified using ion exchange. “Chromatographic separation of glucose and fructose for rectified concentrated must, to produce pure grape fructose and grape dextrose in syrup and crystalline forms” (Italian Dossier 2013). This process is carried out by the separation of natural glucose and fructose available in grape juice (1:1). The end product is highly purified fructose and glucose. The Italian dossier points out that the remaining “impurities” at a level of less than 2% cannot be considered a “component” and have no nutritional significance. The process applied to grape juice is comparable to the application for other types of fruit juice.

Case 2: Starch saccarification

The dossier presented by Austria 2001 and amended by a later statement (no date) point out "Ion exchangers are required in order to remove most of the neutralising salts introduced during the hydrolysis process, some at a very high concentration." Austria would like to see "a general decision on the use of ion exchange resins for the production of carbohydrate rich syrups or carbohydrates from different raw materials as starch and fruits."

Case 3: Baby food

The dossier brought forward by Austria 2001 was based on the statement "A corresponding demineralisation process is the only way to ensure the product quality required … by producers of infant formulae, as required under Directive 91/321/EEC". It was demonstrated that the mineral content of infant formula requirement in Directive 91/321/EEC can only be fulfilled by the use of ion exchangers. The dossier points out that sodium will be reduced from 1540 mg/kg to 9 mg/kg and potassium (197 mg/kg) and magnesium (69 mg/kg) to 0. The argument for the technology is built upon the need for low sodium concentrates for infant food in accordance with relevant regulations.
This is underlined in a document from the company Agrana from 2004. Company BMI has handed a document to the Bavarian authorities in 2002 explaining the need of ion exchangers for the demineralisation of whey used for baby food with the same arguments brought forward by Austria. This request was completed by a document provided by French 2014 authorities pointing out the need for demineralisation with help of ion exchange for milk powder used for baby food.

Necessity for intended use, known alternatives

Annex VIII, Section B to Regulation 889/2008 includes a number of substances which can partially perform ion-exchange and adsorption functions, for example silicon dioxide, bentonite, kaolin, active carbon or perlite. However, these substances are less effective and selective for the purification of liquid food products. In particular, some effects cannot be achieved with these substances such as the highly selective removal of sodium ions from whey for use in infant formulas or the extremely high purification level of sugars and it is certainly not possible to separate fructose and glucose.

Case 1: Fruit concentrates purification

To produce highly purified sweeteners from fruit raw materials and achieve a clear separation of fructose and glucose from the original raw material as pointed out by the dossier, with the requested purification level and a complete separation of fructose and glucose is only possible with the help of ion exchange and adsorbent resins.
Filter substances already listed in Annex VIII of Regulation 889/2008 (as mentioned above) can only partly remove constitutes and are less effective. In accordance with Regulation (EC) 606/2009, for the preparation of wine grape must concentrate, rectified grape must concentrate (based on ion exchange and adsorbent resins) and in some wine growing zones sugar (saccharose) can be added.

Case 2: Starch scarification

To produce highly purified sweeteners from starch with the requested purification level is only possible with the help of ion exchange and adsorbent resins.
The Group recognises that organic starch scarification products are today on the EU market produced with and without the use of ion exchange and adsorbent resins. These products are

different in their composition and other characteristics, but both qualities are marketed in a relevant scale. However filter substance already listed in Annex VIII to Regulation 889/2008 (as mentioned above) can only partly remove constitutes and are less effective.

Case 3: Baby food

EC Reg. 141/2006 defines absolute levels for the presence of minerals and other micronutrients in infant food. However, when ion exchange and adsorbent resins are used for the preparation of organic raw materials like starch or whey for infant food, we face a different situation. In this case it is the objective to remove some specific constituents selectively and not to decompose the overall product. Other methods are available but they are less selective and causing additional nutrient losses. This highly selective removal can only be carried out by the use of ion exchange and adsorbent resins. Further, it needs to be mentioned that specific regulatory background here mostly relevant in regard to an upper limit of sodium (Max. 14mg/100kJ) and other minerals present (Annex I 10.1 to Regulation (EC) 141/2006) in the final product needs to be respected.

Production of highly purified glucose or fructose from fruit or starch raw materials with the requested purification level and the separation of fructose and glucose is only possible with the help of ion exchange and adsorbent resins.
The Group recognises that organic starch scarification products are today on the EU market produced with and without the use of ion exchange and adsorbent resins (Sipal, 2014). These products are different in their composition and other characteristics, but both qualities are marketed in a relevant scale.
However, when ion exchange and adsorbent resins are used for the preparation of organic raw materials like starch, milk or whey for infant food, we face a different situation. Because of Council Regulation (EC) No 141/2006 the end product must fulfill specific dietary requirements.
Therefore, in this case minerals are removed only in order to fulfill the requirement of the infant formula legislation. This requirement can today only be fulfilled efficiently by the use of ion exchange and adsorbents resins.

Origin of raw materials, methods of manufacture

See Food report I.

Environmental issues, use of resources, recycling

See Food report I.

Animal welfare issues

See Food report I.

Human health issues

See Food report I.

Food quality and authenticity

Ion exchange and adsorbent technologies influence the food on a molecular level. 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. Another application is to completely remove pesticides present in the raw material (Sunresin, 2014).

Case 1 and 2 Fruit concentrates purification /Starch saccarification

To produce highly purified sweeteners from fruit raw materials and a clear separation of fructose and glucose from the original raw material as pointed out by the dossiers with the high purification level is only possible with the help of ion exchange and adsorbent resins. It is true that the ordinal character of the constituents of the original raw material is normally not changed. It must be mentioned clearly that the character of the original raw material is totally lost. The target of the processes used and proposed in the dossiers is the complete decomposition of the original food. The Group's view is that this must be seen as clearly in contravention of to Article 6(c) and 19(3) of Organic Regulation 834/2007, where the true nature of the product is addressed.
From the request concerning production of sweeteners based on fruit juice and products containing starch it is clear to the Group that the end product is completely different from the original natural raw material. Both technologies change deeply the original character of the food at molecular level. The refining process seeks to remove "impurities" from the food. In this case, naturally occurring minerals, vitamins, protein, colour and flavour are the "impurities" (decomposition). The nutritional quality (nutrients density) of the product is very low because in fact all nutrients except glucose or fructose are removed, which is not in line with Article 3 (b) of Organic Regulation 834/2007.
The Group argues that in this case, when the product has totally lost its natural characteristics due to the high purification level, there is also a risk of misleading the consumer on the true nature of the product. The consumer will never identify the sweetener with the source fruits or starch. This is not in line with Articles 6(c) and 19(3) of the Organic Regulation 834/2007. Therefore both applications can have a tremendous influence on the natural composition of the food by changing deeply the original character at molecular level. Depending on the type of application, the end products can have totally different properties from the "true nature of the product" (Article 19(3) of Regulation 834/2007) and can be possibly misleading to the consumer (Article 6(c) of Regulation 834/2007).

Case 3 baby food

In the case where ion exchange and adsorbent resins are used for the preparation of organic raw materials for infant food, we are facing a different situation, because according to the EC Directive 141/2006 (EC, 2006) the end product has to fulfil specific dietary requirements. EC Reg. 141/2006 sets absolute levels for the presence of minerals and other micronutrients in infant food. At present this requirement can only be fulfilled efficiently by the use of ion exchange and adsorbents resins. In this case the target is not the complete "purification"; the target is the selective removal of some constituents, to achieve the legal specification in the baby food Regulations.

Traditional use and precedents in organic production

These techniques have been commercially available for almost 30 years. It is important to mention that EGTOP has in this case not to evaluate a possible new application of a technology not used in organic processing before. Because of legal uncertainty, ion exchange and adsorbent resins are currently accepted in some MS for processing of organic products. Ion-exchange technologies and adsorption technology have been used in organic processing in some EU countries for 20 years. Organic products produced with ingredients based on these technologies have been on the shelf in all EU counties for two decades (Sipal, 2014).

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

See Food report I.

Other relevant issues

See Food report I.

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

Ion exchange and adsorbent resins have been used for processing of organic foods for many years in some MS while in others their use is not allowed. The Group notices that this situation leads to commercial conflicts. In the case of amendment of the organc regulation in regard to ion exchange and adsorbent resins, the change made in the regulatory framework should be phased in by establishing an appropriate phase out time for existing products and production equipment.
Ion exchange and adsorbent technologies use a broad variety of different resins and functional groups. The possible applications of these technologies are wide ranging. They influence specifically the chemical composition of the foods at a molecular level and some applications of these technologies have a tremendous influence on the overall composition. Furthermore they have the potential to mislead the consumer on the true nature of the product, which contradicts Article 6 (c) and 19(3) of the organic regulation (EC 834/2007).
Therefore, the Group is of the opinion that ion exchange and adsorbent resins must always be evaluated in accordance with the specific planed usage (technological application) and cannot be evaluated appropriately in general. The applications must be carefully evaluated on the basis of technical dossiers.

Case 1 Starch saccarification

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 fulfill the requirements for mechanical, physical and microbiological processes, as mentioned in Article 21 (1) and Article (4) of the organic regulation.

Case 2 Fruit concentrates purification

The target of this application of ion exchange and adsorption resins is quite the same as for the starch saccarification. The same reasoning applies.

Case 3 Baby food

When ion exchange and adsorbent resins are used for the preparation of organic raw materials like starch, milk or whey for infant food, we face a different situation. In this case the objective of the process is not the total decomposition of the product; the objective is the focused elimination of specific constituents. Because of Council Regulation (EC) No 141/2006 (EC, 2006) the end product has to fulfill specific dietary requirements. The organic regulation is established in Article 6 b) and 19 (2) b) of Regulation 834/2007 the requirements to handle organic food for special dietary purposes as infant food in a different ways to normal foods. Therefore, in the case where minerals are removed in order to fulfil the requirement of the infant formula legislation the use of ion exchange and adsorbents techniques is in line with the requirements of the organic regulation.

Conclusions

The Group concludes that the use of ion exchange and adsorption resins as processing aids to produce highly purified substances such as glucose, fructose (decomposed food) (Cases 1 & 2) is not in line with the objectives, criteria and principles of organic farming as laid down in the organic regulation. This is due to the high purification levels, which could mislead the consumer regarding the true nature of the product (Articles 19(3), 6 (c) and the chemical processes involved (Articles 4 and 21(1)).
In the case where minerals are removed in order to fulfill the requirement of the infant formula legislation (Case 3) 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.

3.18. Electroporation as electronic preservation practice of organic food and feed

Introduction, scope of this chapter

The Netherlands brought forward the question whether electroporation can be used for organic processing and has delivered some background text.
It needs to be mentioned that the main source for the evaluation of processing methods are the requirements given in Articles 6(c) and 19(3) of ECC Reg. 834/2007.
These articles are the basis for a possible exclusion of processing methods. In the system of organic regulation processing methods are allowed when not actively excluded.

Authorisation in general production and in organic production

Processing methods are regularly not a subject to an authorisation process.

Agronomic use, technological or physiological functionality for the intended use

Electroporation is a non-thermal technology for the pasteurisation of food especially for fluids like juices. This technique allows a highly effective inactivation of microorganisms in a short time under low processing temperatures. Electroporation permeabalises cellular tissues and can replace time and energy consuming conventional techniques.

Intermittent application of short duration pulses of high electric field to a product (food) (Pulsed Electric Field, PEF) which is placed between two electrodes. For cell disintegration (plant or animal cells) 0.5 – 4KV/cm are used and for the microbial in activation there is a need of 10-40KV/cm. The use of an external electric field induces structural changes and a rapid breakdown of cell membranes. This technique has been used for more than 30 years in plant and microbial genetics to infuse foreign DNA through the pores of the membrane. In food technology PEF can be used with a higher intensity for an irreversible pore formation.

The process is dependent on the strength of the electric field, time of treatment (pulses), the frequency, the specific, product and the temperature. The conductivity, the pH value and the composition of the product influences also the process. For the inactivation of microorganisms the type of organisms, the cell shape and size and the growth phase will influence the results.

- Microbiology:

There are several different publications on the inactivation of microorganisms. Vegetative cells are sensitive to PEF, spores are much more resistant. Small cells (bacteria) are less influenced than larger cells (yeasts). For a better inactivation a combination with other technologies gives synergistic effects. The transformation of foreign DNA during the processing with PEF seems to be improbable. The same is valid for plant and animal cells because of their minor viability.

- Chemistry:

Chemical reactions are possible if the process is not handled in a correct way. The causes are reactive substances from the decomposition of water. Toxic material from the electrodes have to be avoided which could pollute the food with heavy metals.
Enzymes are much more difficult to handle during the pasteurisation with PEF, e.g. the activity of lipoxigenase, polyphenoloxidase, pectinmethylesterase and peroxidases are not reduced under low temperatures and they can work further in the food.

Necessity for intended use, known alternatives

Heat pasteurisation is used for many products, but can cause loss of nutrients and changes of flavour. Other methods such as high pressure pasteurisation can have the same effects as the use of Electroporation.

Human health issues

There is a relatively low influence to the food during the processing with PEF. The possibility of stress induced formation of secondary metabolites and the induction of pathogenic related proteins in plant material is given. There are only few publications about the allergenic potential as a result of processing with PEF.

Food quality and authenticity

The application of PEF is an effective inactivation of micro-organisms without a heat load. The positive contribution of PEF is the possibility to replace technologies like thermal pasteurisation which has more negative effects. This can be seen as positive effects on the “naturalness” of the product.
Another application of PEF is cell disintegration replacing thermal methods or enzyme based technologies. It needs to be mentioned that the result can be increased compared to the other methods mentioned.

Traditional use and precedents in organic production

None.

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

No information.

Other relevant issues

The term electroporation is used for any process whereby a pulsed electrical field is used to create porous cell membranes. In addition to the application under consideration in this report a similar process is used to make cells permeable to genetic material as a means of creating a genetically modified organism (New England Biolabs, 2014). However it is not essential that genetic transfer occurs during electroporation and the technique under consideration for food use does not in any way constitute genetic engineering.

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

The technique of electroporation is interesting for the pasteurisation of fluids, but up to now there are too many questions on safety. The development of plants just starts. The regulations are not exactly formulated and the comparison with conventional pasteurisation methods has to be done in a range of products and conditions in order to assess chemical reactions, microbiology efficacy and allergenic potential in real food situations).
In general the organic regulation gives a priority toward physical methods instead of chemical processes (Art 6(d) ECC reg. 834/2007).
In the future this technique may be useful also in organic processing but up to now we need more information and experience.
The Group is aware that on EU level a big research project is active for evaluation of advantages and disadvantages of PEF technology used in food processing (EP4Bio^{2}Med, 2014). Therefore EGTOP has the opinion that it is too early to take a decision on this topic.

Conclusion

The Group is clear that at present there is no restriction in regulation regarding the use of Electroporation as a means of preserving organic food.
The Group cannot make a decision regarding the future of PEF technology in organic processing until more scientific results are available.

3.19. Plasma gas technique as electronic preservation practice of organic food and feed

Introduction, scope of this chapter

The Netherlands brought forward the question whether plasma gas technique can be used for organic processing and has delivered some background text.
In the system of organic regulation processing methods are allowed when not actively excluded. The main source for the evaluation of processing methods are the requirements given in Article 6(c) and 19(3) of Regulation 834/2007.
Plasma is a gas with free electrons, ions, neutral particles and reactive radicals. The non-thermic-plasma (cold plasma) is generated e.g. in a dielectric barrier charge (DBD). This form of plasmagas can be used direct with food.

Authorisation in general production and in organic production

Processing methods are not subject to an authorisation process.

Agronomic use, technological or physiological functionality for the intended use

Processes with plasmagas are used in different fields of industry, e.g. medical technology. The use of cold plasmagas (20° - 40°C) reduces the contamination of surfaces from microorganisms. This technique is applied in laboratory or pilot plant scale with food especially to prolong the shelf life of fruits. The inactivation of microorganisms under cold conditions allows the processing of heat sensitive foods. There is only little experience with this technique as an alternative to the use of chemicals as an antimicrobial process and there are only relative few scientific publications regarding food.

During the application of plasma gas free radicals are created, in a similar way to hydrogen peroxide, UV-light, ozone etc. It is these free radicals which kill micro-organisms by disrupting macromolecules such as DNA. Some types of microorganisms on the food surface are reduced with plasmagas rapidly in a few minutes (3 – 5 Log reduction); sporeforming bacteria are much more resistant. (DFG, 2012). Up to now there are only a few publications relating to food use under controlled conditions (size, pH, surface of the food.).
Effects are dependent on the technology (production of the plasma, geometry, current, pressure, gas mixture, volume and temperature) and the plasma itself.

Necessity for intended use, known alternatives

For organic products the use of water or organic acids may be used.
The used alternatives in conventional food processing are the application of substances like organic acids or in wash water or the application of ozone, preservatives etc.

Human health issues

For the health evaluation of plasma gas application currently there is not enough scientific information available. This is relevant for possible generation of toxic and allergenic substances. The actual application of plasma gas is not standardised and the more concrete possible application in product groups are not clarified or practically tested. This information is needed for a more concrete evaluation of possible negative health effects.

Food quality and authenticity

The decontamination of foods surfaces allows longer storage times and reduces microbiological risk. Other methods to extend shelf life are based on chemicals and have the same effects. But there is a clear preference for physical methods such as plasma gas (EC 834/2007, Art. 6(d) instead of the application of chemical agents.

Traditional use and precedents in organic production

None.

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

None.

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

The use of plasma in food technology has advantages to be used in the organic food production because of the low temperature, the specific surface decontamination of food and because of its potential to prolong the food's shelf life.
The actual application of plasma gas is not standardised and the more concrete possible application in product groups are not clarified and practically tested. But this information is the basis for a more detailed evaluation of this technology.
In general organic regulation gives a priority toward physical methods instead of chemical processes (Art 6(d) EC Reg. 834/2007).
At the moment this technology can not be recommended because of the limited experience of the technique on food and there is a need for further investigations.
The reduction of microorganisms has to be measured under practical conditions and the possible toxicological effects need to be studied.

Conclusion

The Group is clear that at present there is no restriction in regulation regarding the use of plasma gas technology that prevents its use in organic processing.
The Group sees positive possibilities in terms of reduction of chemical input into organic products. However, the Group cannot make a decision regarding the future of plasma gas technology in organic processing until the practical application is clarified, research is undertaken and the results are known. In the Group's opinion, a decision should be taken as soon as these results are available to create certainty in the food industry.

3.20. General comment on food processing techniques used in organic processing

The Group considered a number of techniques including electroporation, plasma gas sterilisation etc. Under the organic regulation there is no requirement to set up of a positive list of such approval of such techniques as all food processing methods may be used unless specifically prohibited. However, Articles 6(c) and (d) and 7(c) and (d) make the provision for the prohibition of processes that hide the true nature of food/feed and encourage the use of biological, mechanical and physical methods. In accordance with those requirements, techniques are prohibited for the processing of organic foods.
The group underlines that this approach is the opposite of the approach taken in other areas, e.g. for food processing aids, where the "precautionary principle" is followed. The Group sees a need to discuss how the precautionary principle could be applied also to processing methods.

3.21. Use of sodium metabisulphite (E223) with crustaceans

The Group had insufficient time available to consider in detail the request from Belgium for removal of sodium metabisulphite as a preservative/antioxidant for use with crustaceans from Annex VIII of Regulation 889/2008, so it recommends that this issue is put before EGTOP expert group for Food, IV, as high priority.

4. REFERENCES

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