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H.3. Organic farming

Expert Group for Technical Advice on Organic Production

EGTOP

Report

On

Organic Food

The EGTOP adopted this technical advice at the 5th plenary meeting
of June 20-21, 2012

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:

www.organic-farming.europa.eu

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Members of the Sub-group are acknowledged for their valuable contribution to this technical advice. The members are:

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With regard to his declared interests, the following member did not participate in the adoption of conclusions on the substance mentioned below:

Alex Beck (Sodium Carbonate).

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All declarations of interest of Permanent Group and Sub-group members are available at the following webpage:

www.organic-farming.europa.eu

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EXECUTIVE SUMMARY

The expert group for technical advice on organic production (EGTOP; thereafter called "the Group") has discussed whether the use of the substances/products/techniques mentioned below is in line with objectives, criteria and principles as well as the general rules laid down in Council Regulation (EC) No 834/2007 and whether they can therefore be authorised in organic production under the EU legislation. The Group concluded the following:

Carnauba wax (E903)

The use of carnauba wax as a food additive (glazing agent) is in line with the objectives criteria and principles of organic farming as laid down in Council Regulation 834/2007. It should therefore be included in Annex VIII A with the following restrictions:

1. As a glazing agent for confectionary only.
2. Only in organic quality

The Group recommends that the authorisation of carnauba wax in Annex VIII B should also be amended to require its use only in organic form.

Beeswax (E 901)

The use of beeswax as a food additive (glazing agent) is in line with the objectives criteria and principles of organic farming as laid down in Council Regulation 834/2007 It should therefore be included in Annex VIII A with the following restrictions:

1. As a glazing agent for confectionary only.
2. From bees managed in accordance to the organic Regulation.

The Group recommends that the authorisation of beeswax in Annex VIII B should also be amended to require use of beeswax only in organic form. Beeswax is available from bees managed in accordance with the organic Regulation.

Thiamin hydrochloride and Diammoniumphosphate

The use of thiamin hydrochloride and diammonium hydrogen phosphate as processing aids is in line with the objectives criteria and principles of organic farming as laid down in the organic regulation. They should therefore be included in Annex VIII B as processing aids. These substances should be permitted for foodstuffs of both plant and animal origin with the specific condition that they are permitted only for use in processing of fruit wines including cider and perry and mead.

Steviol glycosides (E 960)

The use of steviol glycosides (E 960) as food additive is not in line with the objectives criteria and principles of organic farming as laid down in the organic Regulation.

If it would be available in organic quality and meet the needed purity criteria of the food additive regulations, without using ion exchange, the Group concluded that steviol glycosides should be included in Annex VIII A, but only for use in foodstuffs for particular nutritional uses.

Sodium carbonate

The use of sodium carbonate as a processing aid in the production of starch and gluten is in line with the objectives, criteria and principles of organic farming as laid down in the Council Regulation (EC) No 834/2007. It should therefore be included in Annex VIII B.

In addition, the Group concluded that this compound should be allowed without any specific conditions in Annex VIII B.

Wood fibre

Wood fibres as processing aid, specific filter aid, are in line with the aims and principles of the Organic Regulation. Therefore the Group proposes inclusion of wood fibres in Annex VIII B, as filter aid in the foodstuffs production of both plant and animal origin. The entry should include the following restrictions:

1. The source of timber should be restricted to certified, sustainably harvested wood.
2. Wood used must not contain toxic components (post-harvest treatment, naturally occurring toxins or toxins from micro-organisms).

Ion exchange and adsorption resins

The Group concludes that the use of ion exchange and adsorption resins as processing aids to produce carob derived sweetener 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 and the process involved (Articles 6 (c) and 21 (1) of the Organic Regulation, respectively).

Therefore the Group's opinion is that ion exchange and adsorbents resins cannot be added as a processing aid in Annex VIII B for carob derived sweeteners.

Comments and amendments concerning the use of some of the substances listed in Annex VIII A and B to Commission Regulation (EC) No 889/2008.

The Commission asked the Group additional questions concerning amendments to the specific conditions for potassium nitrate (E 252), glycerol (E 422), pectin (E 440), sulphur dioxide (E 220) and potassium metabisulphite (E 224), tartaric acid in Annex VIII A. In addition, on the basis of its knowledge and experience the Group has elaborated some amendments of Annex VIII A and B and also expressed its opinion on processing aids which are generally available in organic form. Details are in chapter 3.9. "Other issues of this report".

The Group is of the opinion that a basic set ("basic tool box"; see table VIII A and B) of currently authorised additives should be provided to the organic processing operations without further restrictions in order to facilitate the sector in creating a wide variety of high quality organic foods (Articles 3 (b) and (c)). All the additional or amended conditions suggested by the Group are in line with the relevant EU transversal legislation. Detailed answers and proposals are explained in table 2.

The Group recommends that Ethanol, gelatine, vegetable oils and rice meal should only be used in organic form, even if they are listed in Annex VIII B to Commission Regulation (EC) No 889/2008.

Template for new request of amendments.

The Group also drafted the template for the dossier mentioned in Art. 16(3)(b) of Council Regulation (EC) No 834/2007 in relation to food additives and processing aids.

See Annex I of this document

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 (EC, 2007) (hereafter called the organic Regulation) concerning the possible inclusion of a number of substances in Annex VIII to Commission Regulation (EC) No 889/2008 (Annex VIII) or, more generally, on their compliance with the above-mentioned legislation. In relation to substances and products for use in the production of processed organic food, France made a new request in 2011 concerning Carnauba and beeswax. In addition, France introduced also a request for Steviol glycosides. In the same year, Germany applied for Thiamin hydrochloride and Diammonium hydrogen phosphate for the fermentation of organically produced fruit wines and meads. In 2010, Germany submitted a dossier on Sodium carbonate and Spain on Ion exchange and adsorption resins, while in 2008 Germany presented a dossier on the possible use of Wood fibres. Several requests from private companies and some information received from the Netherlands concerning the use of Ozone, made it necessary to assess the possible use of this substance on fruit and/or vegetables after the harvest. It also became clear that Member States need to be provided with a template to help them prepare a complete technical dossier.

2. TERMS OF REFERENCE

a) In the light of the most recent technical and scientific information available to the experts, the Group is requested to answer the following question; is the use of the following substances/techniques:

1. Carnauba (E 903) wax food additive
2. Beeswax (E901) food additive
3. Steviol glycosides (E 960) food additive
4. Sodium carbonate processing aid
5. Ion exchange and adsorption resins processing aid
6. Wood fibres processing aid
7. Thiamin hydrochloride processing aid (fruit wines and meads)
8. Diammonium hydrogen phosphate processing aid (fruit wines and meads)

in line with the objectives, criteria and principles as well as the general rules laid down in the organic Regulation and can they therefore be authorised in organic production under the EU legislation?

In preparing its final report, the Group may also evaluate if the use of Ozone as post-harvest treatment of plant products, Acetic acid as processing aid on salmons and trout, are in line with the objectives, criteria and principles as well as the general rules laid down in Council Regulation (EC) No 834/2007. In addition, the Group may also suggest amendments to the current list in Annex VIII and consider possible alternatives to the substances in question and/or review the specific conditions for the use of the substances 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.

The Group is also requested to draft the template for the dossier mentioned in the second subparagraph of Article 21 (2) of the organic Regulation in relation to food additives and/or processing aids

3. CONSIDERATIONS AND CONCLUSIONS

3.1 Carnauba wax

Introduction, scope of this report

The request refers to the possible use of carnauba wax as a *food additive* (Annex VIII A to Commission Regulation (EC) No 889/2008 (EC, 2008a) (hereafter called Annex VIII A) in the production of certain organic foodstuffs (confectionary and dietary food supplements). Carnauba wax is currently authorised as *processing aid* (Annex VIII B to Commission Regulation (EC) No 889/2008 (EC, 2008a) (hereafter called Annex VIII B). Other names for carnauba wax are Brazil wax and palm wax.

As suggested in the relevant dossier, the argument for the inclusion of carnauba wax in Annex VIII A is a divergence of interpretations among Member States (MS) concerning the classification of this substance, which is considered as an additive or a processing aid. According to the dossier, some products, which arrive on the French market from other MS and are certified as organic, contain carnauba wax.

Authorization in general agriculture or food processing

Carnauba wax is authorized as food additive (E 903) in Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b), in particular as a glazing agent for confectionary, small products of fine bakery wares coated with chocolate, snacks, nuts and coffee beans, and for surface treatment of certain fruits (fresh citrus fruits, melons, apples, pears, peaches and pineapples). It is also permitted in food supplements and as carrier for colours. The maximum permitted amount of carnauba wax as a glazing agent is restricted to 200 mg/kg for fine bakery ware, snacks, nuts, coffee beans, coffee substitutes, and tablets of food supplements; 500 mg/kg for cocoa and chocolate products as well as other confectionary including breath freshening micro sweets; and 1200 mg/kg for chewing gum. The maximum permitted amount of carnauba wax as surface treatment of fruits is also restricted to 200 mg/kg.

Agronomic use, technological or physiological functionality for the intended use

In the production of organic food, carnauba wax is used as a technical processing aid, in particular as releasing agent, in processing of some foodstuffs of plant origin. When used as a releasing agent, some products might be partly coated with carnauba wax.

In the relevant dossier, it is proposed to allow its use also as an additive for glazing of organic confectionary and organic dietary food supplements. Glazing agents can have three functions: to improve the visual aspect of the product surface (glazing), to reduce the process of re-crystallisation, and to avoid that the products stick together (agglomeration).

Application of the wax during glazing of the products is done by means of spraying in a tunnel with a mixture comprising carnauba wax (5%) and plant oil, in particular sunflower oil. Glazing agents are defined by Regulation (EC) No 1333/2008 (EC, 2008b) Annex I 17. "glazing agents" (including lubricants), as substances which, when applied to the external surface of a foodstuff, impart a shiny appearance or provide a protective coating.

Carnauba wax has a specific technological profile. For example the melting point with 82-88°C is much higher than for beeswax with 62-65 °C. Further on Carnauba wax is the hardest plant wax we know. Penetration (ASTM D 1321; 0.1 mm) by 25 Celsius is 2 compared to beeswax 20. It means Carnauba wax is 10 times harder.

Known alternatives

Sugar syrups, dibble oils and beeswax are traditionally also used as glazing agents in food production.

Origin of raw materials, methods of manufacture

Carnauba wax is of plant origin and it is secreted from the leaves and buds of the Brazilian fan palm *Copornicia cerifera*. The carnauba palm occurs mainly in north-eastern Brazil and in smaller areas in southern Brazil, northern Argentina, Paraguay, and Bolivia.

The palm takes about seven years to reach full productivity. The annual yield of wax per palm is 100-150 g. Floral Yellow carnauba wax is obtained from the immature leaves of the *Copornica* palm. After drying the leaves, the wax is shaved off manually or by machine. The purification process involves melting in hot water or steam followed by centrifugation, filtration with additives or solvent extraction (heptane). Additional bleaching with hydrogen peroxide is also carried out. The uses of solvent extraction with heptane, as well the use of the bleaching agent hydrogen peroxide, are not allowed for the production of organic carnauba wax.

Carnauba wax is the most important vegetable wax in regard to applications as well as economy. It is used in the food industry, for cosmetics and pharmaceuticals (coating of tablets), and for technical purposes such as shoe and car polish, as well as in the paper industry. Carnauba wax is very solid, with high melting point (80-88 °C) among the highest of natural waxes. Carnauba wax is a complex mixture of aliphatic monoesters (40%), di-esters of 4-hydroxycinnamic acid (21%), esters of ω-hydroxycarboxylic acids (13%) free alcohols (12%) and other minor components.

Environmental issues, use of resources, recycling

In north-eastern Brazil, where most carnauba wax is produced, *C. cerifera* grows in semi-arid regions. There are no intensively managed plantations, but in poor soils, the palm naturally occurs in high numbers. These stands are harvested regularly ("extractivism"). Based on the limited information available, the Group has no environmental concerns regarding the production of carnauba wax from *C. cerifera*.

Animal welfare issues

No specific concerns

Human health issues

The Joint Food Agriculture Organisation and World Health Organisation (FAO/WHO) experts Committee on Food Additives has allocated an ADI of 0 – 7 mg/kg per kg bodyweight for carnauba wax. This is based on short-time and reproduction toxicological studies as well as special studies on mutagenicity available on carnauba wax. There are no reports on acute toxicity or long-term/carcinogenicity studies, or observations in humans. The Scientific Committee on Food of European Commission has published its Opinion on carnauba wax on 11 July 2001.

The Committee concludes; “Based on the available toxicological data and the exposure estimates of the substance from its permitted uses, the Committee withdraws the temporary status and accepts the use of carnauba wax as a glazing agent up to a maximum use level of 200 mg/kg of food” (European Commission 11 July 2001 “Opinion of the Scientific Committee on Food on carnauba wax” SCF/CS/ADD/MsAd/194 Final).

Food quality and authenticity

Glazing agents can have three different types of functions: to improve the shining appearance of the product surface (glazing), to reduce the process of re-crystallisation (protective coating), as a surface treatment agent in order to avoid that the products will stick together (agglomeration).

The Group opinion is that if carnauba wax is used to improve the shining appearance of the product surface, then it can create a contradiction to the authenticity of food (which would appear to be more fresh because of glazing). However, there are applications in confectionary production where the substance is used as surface treatment to avoid that the products sticks together or to avoid that they become grey due to sugar crystallization on the surface.

Traditional use and precedents in organic production

Carnauba wax is authorised as a technical releasing agent in organic food production (Annex VIII B).

Aspects of international harmonization of organic farming standards

According to the 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" (Codex Alimentarius, 1999 revision 2010), carnauba wax is not included in the list of food additives, but it is included in the list of processing aids as a releasing agent. Carnauba wax may be used as a food ingredient in organic food production in Canada and USA (NOP: Electronic Code of Federal Regulations 2012).

Necessity for intended use

No technical reasons are mentioned in the dossier to support the addition of carnauba wax as a food additive for organic food products. Because of its specific technological characteristics mentioned above there is a necessity for the use as protective coating agent to prevent the products sticking together or to avoid sugar crystallization on the surface.

Other relevant issues

None

Reflections of the Group

The argument in the dossier to authorise the use of carnauba wax as a food additive for organic food production is based on the intention to harmonize the use of this practice at European level, rather than on technically sound reasons. As a matter of fact, no technical reasons are given in the dossier to support the use of carnauba wax as a food additive in organic food production. In addition the group opinion is that the issue concerning consumer information on declaration of processing aids is not specific to carnauba wax, but should be part of a general discussion on whether the consumers should be informed about the occurrence of all technical processing aids.

Carnauba wax can be used in the production of food products as food additive and as processing aid and it can be difficult to distinguish between the two possible uses. In particular, it might be difficult to distinguish between the use as processing aid (releasing agent) and the use as additive because of technical reasons (protective coating and for sensorial reasons (shining appearance)). These different types of additives application must be evaluated separately. However, the amount to be used is limited according to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b), and it is expected that the amount to be used as a technical processing aid is even less.

Organic food is expected to have as little additives as possible (the organic regulation, Article 6b). In addition, carnauba wax has an ADI of 0-7 mg/kg body weight and there is no information about long term effects of this substance. Moreover the substance is accepted in EU as food additive up to a level of 200mg/kg of food. Beeswax, which has not a defined ADI, can be an alternative to carnauba wax in some cases.

Beeswax and carnauba wax are frequently used in combination. Beeswax alone or in combination with plant oils, in organic form, will produce satisfactory products, but the shelf life of the confectionary products may be extended with use of carnauba wax (by reducing re-crystallisation of sugar and keeping the products shiny). The Group is aware that carnauba wax is a cheaper alternative to beeswax for some uses. On the other hand the technical properties of Carnauba wax are quite different from bees wax. Because of the higher melting point carnauba wax is hardening double as fast as bees wax and has better barrier effects because of a higher hardness. Therefore, the amounts used are about half of the needed amount of bees wax. Further on, because of the higher melting point, the Carnauba wax is much more appropriate for soft sweet products in warmer countries, where bees wax will create an oily and fatty appearance. This is in accordance with Article 21 (1) (ii) of the organic Regulation. Further on vegans ask for vegan sweets which cannot be presented by using beeswax.

Carnauba wax is available in organic form.

Conclusions

The use of carnauba wax as a food additive (glazing agent) is in line with the objectives criteria and principles of organic farming as laid down in Council Regulation 834/2007. It should therefore be included in Annex VIII A with the following restrictions:

1. As a glazing agent for confectionary only.
2. Only in organic quality

The Group recommends that the authorisation of carnauba wax in Annex VIII B should also be amended to require its use only in organic form.

3.2 Beeswax

Introduction, scope of this report

The request in the mandate refers to the possible use of beeswax as a *food additive* (Annex VIII A) in the production of certain organic foodstuffs (jelly sweets, cakes etc.). Beeswax is currently listed in Annex VIII B as a *processing aid*. In particular, it is authorised as releasing agent.

The argument for the inclusion of beeswax in Annex VIII A to Commission Regulation (EC) No 889/2008 is that there is a divergence of interpretation among Member States (MS) concerning the classification of this substance, which is considered as an additive or a processing aid. In particular, according to the report some products containing beeswax, which are certified as organic, arrive on the French market from other MS. Other names for beeswax are: comb wax, bee capping, *cera flava* (yellow beeswax), *cera alba* (white beeswax or bleached beeswax).

Authorization in general agriculture or food processing

Beeswax is authorized as food additive (E 901) in the European Union, in particular it is permitted as a glazing agent following the *quantum satis*¹ principle on confectionary (excluding chocolate), small products of fine bakery wares coated with chocolate, snacks, nuts and coffee beans as well as for surface treatment of certain fruits (fresh citrus fruits, melons, apples, pears, peaches and pineapples). It is also permitted in food supplements and as carrier for colours.

Agronomic use, technological or physiological functionality for the intended use

In organic food production, beeswax is used as a technical processing aid, in particular as releasing agent for the preparation of foodstuffs of plant origin. The use proposed in the dossier is as a food additive glazing agent, for glazing of organic confectionary and organic dietary food supplements.

Known alternatives

Sugar syrup, plant oils, carnauba wax may be used to replace beeswax, or they may be used together with it.

Origin of raw materials, methods of manufacture

Beeswax is of animal origin. According to EU specifications (EC, 1996), beeswax is produced by the domestic worker bee *Apis mellifera* L. In other parts of the world, beeswax may also be produced by *A. cerana* and *A. florae*, as well as other honeybee species. According to the dossier, beeswax from France, Madagascar, Morocco, Tunisia, Angola, Brazil, Mali, or the West Indies contains many impurities, which are removed by the processes described below.

Beeswax for food and pharmaceutical uses is obtained by melting the honeycombs of bees after removal of honey by draining and filtering or centrifuging. The combs are melted in boiling water or steam. Impurities can be extracted from the melted beeswax by pressure filtration and/or use of active carbon/or diatomaceous earth. The yellow cleaned wax is called “*cera flava*”. It can be bleached by peroxides, sunlight or bleaching earth (hydro silicates) to produce white beeswax “*cera alba*”.

Beeswax is a complex mixture of saturated and unsaturated linear and complex monoesters (57%), free fatty acids (18%), hydrocarbons (16%), free fatty alcohols (0.6%), and other minor substances produced by the worker honeybee (values for wax from *A. mellifera*). The most abundant compounds of beeswax, the fatty acid monoesters, are composed of saturated alkyl palmitates (C38-C52) and unsaturated alkyl esters of oleic acid (C46-C54).

¹ The *quantum satis* principle allows the use of an additive in the application according to good manufacturing practice, at a level not higher than necessary to achieve the intended purpose.

The predominant hydrocarbons of beeswax are odd chain *n*-alkanes (C23-C31) as heptacosane (C27), nonacosane (C29), hentriacontane (C31) pentacosane (C25) and tricosane (C23). The most common alkenes are odd chain alkenes (C27-C39) with a *cis* double bond at position C10.

Environmental issues, use of resources, recycling

Beekeeping provides essential pollination services for many crops and wild plants. Production of beeswax has no negative impact on the environment. Residues of unused beeswax may be recycled after sterilization in an autoclave.

Animal welfare issues

The harvest of beeswax has a positive effect on the bee colony. Some bee workers are specialised only to build the wax combs, and the bee society seems to be more harmonic when those workers can be active by producing new wax combs. A regular renewal of the wax is also important to avoid diseases from old combs.

Human health issues

Beeswax is an accepted food additive (E 901) in the European Union with no upper level of the amount (*quantum satis*) to be used. Biochemical and toxicological studies on beeswax are lacking, and the existing data are insufficient to establish an ADI. However, the main constituents of beeswax do not appear to be absorbed from the gastrointestinal tract to any significant extent, and a European Food Safety Authority (EFSA) panel has concluded that the use of beeswax as an additive for food uses is not of safety concern (EFSA, 615, 2007). In the USA, beeswax (yellow and white) is affirmed as GRAS².

The joint FAO/WHO Expert Committee on Food Additives concluded that the current uses of beeswax would not result in dietary exposure that raised concern about safety, especially in view of the long history of use of beeswax and the absence of toxicity of the main components. The committee could not reach a conclusion about the potential allergenicity of beeswax as the available information was very limited (FAO, 2005; WHO, 2006a).

Food quality and authenticity

Glazing agents can have three different types of functions: to improve the shining appearance of the product surface (glazing), to reduce the process of re-crystallisation (protective coating), as a surface treatment agent in order to avoid that the products will stick together (agglomeration).

The Group opinion is that if beeswax is used to improve the shining appearance of the product surface, then it can create a contradiction to the authenticity of the food (which would appear to be fresher because of glazing). However, there are applications in confectionary production where the substance is used as surface treatment to avoid that the products stick together or to avoid that they become grey due to sugar crystallization on the surface.

Traditional use and precedents in organic production

Beeswax is already authorized in organic food processing as a technical releasing agent (Annex VIII B) and as a pruning agent (Annex II).

² GRAS (Generally recognized as safe) by the American Food and Drug Administration (FDA).

Aspects of international harmonization of organic farming standards

According to the 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" (Codex Alimentarius, 1999 revision 2010) beeswax is not included in the list of Food additives, but it is included in the list of Processing aids as a releasing agent. According to US National Organic Program (NOP) regulations (NOP: Electronic Code of Federal Regulations 2012), beeswax is allowed to be used as a food ingredient in organic food production for coating of fruits.

Necessity for intended use

In the relevant dossier the necessity for the use proposed is not clearly demonstrated. According to the Group, releasing and glazing are essential for several products to allow releasing from moulds and to avoid sticking together in the package.

Other relevant issues

None

Reflections of the Group

The argument in the dossier to authorise the use of beeswax as a food additive for organic food production is based on the intention to harmonize the use of this practice at European level rather than on technically sound reasons. As a matter of fact, no technical reasons are given in the dossier to support its use as a food additive in organic food production. Beeswax can be found in the products due to its use as a technical processing aid.

The Group recognised that "glazing agent" is translated to "surface coating" on at least the German and the Danish lists of horizontal additive regulation. The definition of "glazing agent" can be found in Regulation (EC) No 1333/2008 (EC, 2008b), Annex I 17, which explains that "glazing agents" (including lubricants) are substances which, when applied to the external surface of a foodstuff, impart a shiny appearance or provide a protective coating". This means that the function of a glazing agent is not only for shiny appearance but it can also have the function of protective coating for prevention of sticking together and minimization of re-crystallisation.

The Group finds that there may be a demand for use of a glazing agent (protective coating) for some confectionary products to avoid them to stick together and to retard sugar crystallization on the surface. Plant oil may not be effective enough alone, so addition of beeswax is necessary. This is in accordance with Article 21 (1) (ii) of the organic Regulation. In addition, beeswax is harmless (no ADI specified) and its use is accepted as *quantum satis*. To minimize pesticide residues, only organic beeswax should be used.

The Group's opinion is that surface treatment of organic fruits with waxes might not be recommended due to conflicts with their authenticity (they look different from original). However, there was no request to assess this specific use in the relevant dossier.

Conclusions

The use of beeswax as a food additive (glazing agent) is in line with the objectives criteria and principles of organic farming as laid down in Council Regulation 834/2007 It should therefore be included in Annex VIII A with the following restrictions:

1. As a glazing agent for confectionary only.
2. From bees managed in accordance to the organic Regulation.

The Group recommends that the authorisation of beeswax in Annex VIII B should also be amended to require use of beeswax only in organic form. Beeswax is available from bees managed in accordance with the organic Regulation.

3.3 Thiamin hydrochloride processing aid (fruit wines and meads) and Diammonium hydrogen phosphate processing aid (fruit wines and meads)

Introduction, scope of this report

The request refers to the possible use of thiamin hydrochloride (TH) and diammonium hydrogen phosphate (DAP) as processing aids, particularly as nutrients for yeast in the production of fruit wines and meads only. Because TH and DAP are used in combination, the two substances are evaluated together.

TH is also known as Vitamin B1. It is an essential vitamin needed by all animals and is only synthesised by plants, bacteria and fungi. DAP is a salt of ammonium hydroxide and phosphoric acid. It is a natural mineral commonly used as a fertiliser, for which use it would not be permitted in organic agriculture. It provides the most readily available form of nitrogen that can be taken up by yeasts.

Note that as mead is produced from honey, which is considered as a foodstuff of animal origin according to the Commission Regulation (EC) No 889/2008 (EC, 2008a) these two substances should therefore be approved for products of both plant and animal origin.

Authorization in general agriculture or food processing

The recently published Commission Implementing Regulation (EU) No 203/2012 amending regulation (EC) No 889/2008 laying down detailed rules for the implementation of the organic Regulation, as regards detailed rules on organic wine (EC, 2012) permits the use of DAP and TH as yeast nutrients in organic wines from grape. The use of both TH and DAP are allowed in the Commission Regulation on wine (EC) No 606/2009 (EC, 2009) for use as yeast nutrients in conventional wine from grape manufacture. Limits on the concentrations of these compounds used in conventional wine production are set. In particular, as far as DAP is concerned, the limits are 1g/l or 0.3 g/l for the secondary fermentation of sparkling wines, while as regards TH the limit is 0.6 mg/l for each treatment. DAP is also included in the International Oenological Code (Oeno 15/2000) for the promotion of alcoholic fermentation. Both that Code and the Food Chemical Codex (FCC, 2012) lay down requirements and conditions of purity for DAP. DAP is also authorized as food additive (E 342), in particular as an acidity regulator in conventional food. TH is a permitted vitamin, required for fortification of bread flour in many EU member states.

Agronomic use, technological or physiological functionality for the intended use

The two compounds (TH & DAP) are commonly used together in conventional production. Their function is to encourage the growth of yeast by providing the essential nutrients needed (Nitrogen as ammonium, vitamin TH and phosphate) to grow and to initiate fermentation. They are added to wine must at the start of fermentation with the purpose to promote the growth of beneficial yeasts. This ensures a rapid start of fermentation before competitive microorganisms, which can cause off-flavours, get a chance to grow. They are also used to ensure the continued growth of yeast, to the extent that they can ferment the majority of the sugars, both from the fruit juice and added sugars, to produce a high alcohol stable product without excess residual sugar. Furthermore, in the manufacture of sparkling wines, they are often added together to the wine when it is bottled. This provides nutrients for the yeast in the bottle that will enable it to produce the carbon dioxide needed for a sparkling wine.

Known alternatives

Ammonium salts are the most readily available nitrogen source for yeast. Other ammonium salts, such as ammonium sulphate, are also available on the market. However, these compounds can create sulphuric off-flavours if used for this purpose. Cost comparisons are insignificant. There is no known alternative to TH that will reproduce exactly its function. While there may be other products, such as protein hydrolysates, that would have similar effect, these are not as efficient and are likely to produce off-flavours. Some fruit wines can be produced without these processing aids.

Origin of raw materials, methods of manufacture

DAP is normally produced by reaction of ammonium hydroxide with phosphoric acid. It is therefore of mineral origin, so there is no GMO risk with this compound. However, it is a highly soluble mineral fertilizer, so it is not in accordance with Article 4 (iii) of the organic Regulation (EC, 2007).

TH is usually produced by chemical synthesis. In the longer term there could be competitive biotechnological methods available, possibly using GMO technology,

Production of ammonia is done by the Haber process, reacting hydrogen usually from natural gas with atmospheric nitrogen at high pressure. Phosphoric acid is manufactured from phosphate rock. It is then reacted with ammonia to produce ammonium phosphate.

Environmental issues, use of resources, recycling

There are no serious environmental issues relating to its production, but it is energy and mineral intensive.

There are no major environmental issues relating to production or use of TH. It is normally manufactured by chemical synthesis.

Animal welfare issues

No specific concerns

Human health issues

There are no human health issues relating to the use of either compound as yeast nutrients in fruit wines or meads, due to the concentration limits imposed by the relevant wine legislation on their use and the fact that the yeast will use up most of these compounds during the fermentation.

There is no ADI level for TH defined but an ADI level for diammonium phosphate E 342(ii) of 880mg/kg.

Food quality and authenticity

Consumers of organic products may not expect organically produced wines made from fruit which have been grown without the use of artificial fertilisers, to have small quantities of the same chemicals added to encourage the growth of yeast. Therefore, the Group believes that, in this case, there could be a conflict with the perception of authenticity (the organic Regulation, Article 6(c) (EC, 2007)).

Traditional use and precedents in organic production

These compounds have been used as yeast nutrients in non-organic wine production, since they were identified and their effectiveness detected. Before that, other materials would have been used to encourage fermentation. Some MS have authorised the use of these nutrients in organic fruit wines. Recently, DAP and TH were authorized as yeast nutrients in organic grape wines (Commission Implementing Regulation (EU) No 203/2012 amending regulation (EC) No 889/2008 laying down detailed rules for the implementation of the organic Regulation, as regards detailed rules on organic wine) (EC, 2012). DAP is a fertilizer but it is not allowed in organic production. It is allowed as an attractant in traps.

Aspects of international harmonization of organic farming standards

DAP and TH are not allowed to be used as yeast nutrients by the Codex Alimentarius as well as by the NOP.

Necessity for intended use

These two compounds are needed to ensure that fermentation of fruit wine and mead goes to completion. While there may be other products, such as protein hydrolysates, that would have similar effect, these are not as efficient and are likely to produce off flavours.

The Group is aware of production of fruit wines in some MS without the use of ammonium ions or synthetic vitamins.

Other relevant issues

None

Reflections of the Group

As DAP and TH are allowed in organic grape wine and the technological need is the same in fruit wine and mead, it would be illogical to prevent their use in fruit wines and meads which, in many cases, may have lower yeast nutrient levels than grape wines. In addition, there is an issue of consistency with Commission Implementing Regulation (EU) No 203/2012 of 8 march 2012 amending regulation (EC) No 889/2008 laying down detailed rules for the implementation of the organic Regulation, as regards detailed rules on organic wine (EC, 2012) which permits the use of DAP and TH as yeast nutrients in organic wines.

The Group has information that in some MS the use of these substances is already authorised in the production of organic fruit wine. However, fruit wines produced without using these processing aids have been available for many years. Some private label organisations allowed the use of TH and DAP in sparkling fruit wines.

The Group sees some conflicts with the principles and objectives of the organic Regulation (specifically Article 21 (1) (ii) (EC, 2007)); this is valid in particular for DAP, because some types of fruit wines are already available without its use, so the aspect of necessity of the use is not completely fulfilled. In addition, the use of such nitrogen source for the production of organic yeast is not permitted by the organic regulation. However, there are some wines, particularly sparkling wines and some others (e.g. generally with a low sugar content of the fruit), where the use of these compounds is essential (Article 21 (1) (ii) of the organic regulation (EC, 2007)) for the production of an acceptable product. Therefore, the Group opinion is that DAP and TH should be added to Annex B as permitted processing aids.

Conclusions

The use of thiamin hydrochloride and diammonium hydrogen phosphate as processing aids is in line with the objectives criteria and principles of organic farming as laid down in the organic regulation. They should therefore be included in Annex VIII B as processing aids. These substances should be permitted for foodstuffs of both plant and animal origin with the specific condition that they are permitted only for use in processing of fruit wines including cider and perry and mead.

3.4 Steviol glycosides (E 960)

Introduction, scope of this report

The request refers to the possible use of steviol glycosides (E 960) as additives in the production of organic food. The use of steviol glycosides is regulated since November 11th 2011 by Commission Regulation (EC) No 1131/2011 (EC, 2011). There is a huge demand for steviol glycosides from the processors and traders, and certain MS are already in discussion about a possible authorisation of steviol glycosides. The dossier specifies that the ionic exchange is used for the production of steviol glycosides.

Authorization in general agriculture or food processing

E 960 steviol glycosides are approved as food additive in (EC) N° 1131/2011 since November 11th 2011, with defined ADI and limited use. Its ADI (expressed as steviol equivalent) is 4 mg/kg body weight/day. The maximum use levels are defined in Commission Regulation (EU) No 1131/2011 (amending Annex II to Regulation (EC) No 1333/2008) according to categories of foodstuffs.

Agronomic use, technological or physiological functionality for the intended use

Steviol glycosides are used in conventional production as a sweetener. Steviol glycosides are odourless or having a slightly characteristic odour. It is about 40 - 300 times sweeter than sucrose. The additive is used for diabetics products because steviol glycoside has, like acesulfam-K, aspartam etc., a neutral impact on the glycaemic index. In addition, steviol glycoside is a zero calorie intense sweetener and, in principle, could be used in organic low-sugar diet or zero calorie products.

Known alternatives

As regards the production of organic products, there is at the moment no sweetener authorized without influence on the glycaemic index. Sweet products for diabetics can only be produced with the use of organic fructose. However, the latest scientific evidence questions whether this is a suitable alternative (BFR, 2009)

Sweeteners with calories and a direct influence on the glycaemic index are available in a wide range in organic quality: sugar, fructose, honey, glucose, agave, maple syrup etc.

The use of organic stevia leaves as a sweetener, especially in tea, is in practice since many years in Germany & Switzerland. In other MS, there is controversy over the status of the leaves as a novel food. However, there are concerns over the taste of the leaves and juice alone.

Origin of raw materials, methods of manufacture

Steviol glycosides are obtained from the leaves of the plant *Stevia rebaudiana* Bertoni. The plant is available in certified organic quality.

The isolation process of steviol glycosides starts with the extraction of the leaves with hot water, alcohol or alcoholic solvent. The aqueous extract is passed through an adsorption resin to trap and concentrate the components steviol glycosides. The resin is washed with a solvent alcohol to release the glycosides and the product is recrystallized from methanol or aqueous ethanol. As a minimum, the processing aids calcium hydroxide and ethanol are needed in the isolation of the glycosides.

In the refining step Ion exchange and adsorption resins are normally used. It is unclear to the Group if this latter production step is absolutely needed to reach the required purification level for food additives. The final product may be spray-dried.

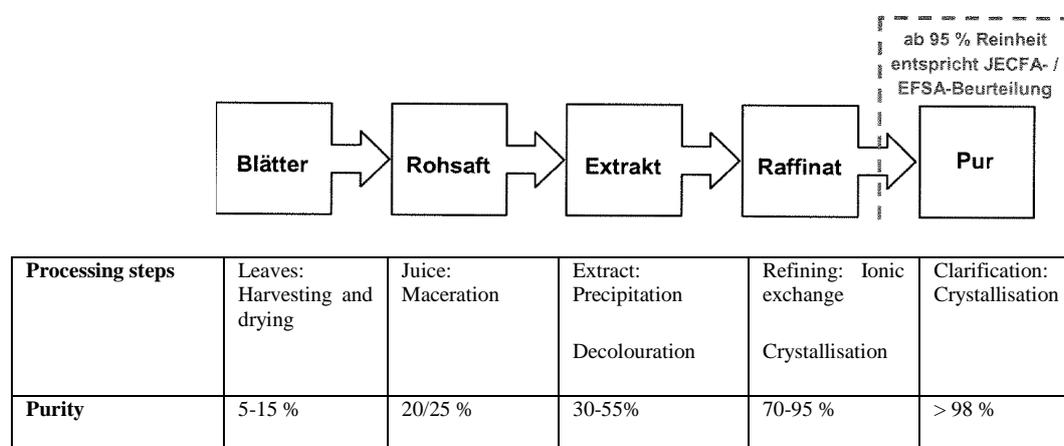


Figure 1: Flow chart isolation of steviol glycosides, Bundesamt für Gesundheit Switzerland, Info Nr. 158 Kennzeichnung und Auslobung des Zusatzstoffes Steviol Glykoside

Environmental issues, use of resources, recycling

Steviol glycosides are 100% biodegradable. The plant residues from the extraction process can be composted. The use of ion exchange is, from the environmental point of view, positive because this technology allows a regeneration of the resins. This means the basic resins can be used several times. The regeneration is done, for example, with NaCl, CaCl, NaOH or HCl. This regeneration creates the main waste streams from this technology. The waste of ethanol would be unproblematic, even if it cannot be reused in the same process.

The Group has no concerns about the culture of the stevia plant.

Animal welfare issues

No impact

Human health issues

There was a long debate if steviol glycosides have a direct influence on human health, especially on the male fertility and blood pressure, as well as blood sugar. In 1999 the SCF (Scientific Committee of Food) concluded that the scientific documents were not sufficient to conclude that stevia has no negative health impact. However, these concerns were not confirmed by FAO/WHO and EFSA. In 2004, WHO and FAO declared steviol glycosides as unproblematic at a daily consumption of 2mg/kg body weight. In June 2008, the Joint FAO/WHO Expert Committee on Food Additives (JECFA monographs 5) evaluated steviol glycosides toxicologically, standardized at a content of 95%. The Committee defined an acceptable ADI (Acceptable Daily Intake) of 0-4mg/kg body weight steviol glycosides. In 2010, EFSA published its first opinion on the safety of steviol glycosides for human consumption, further to the opinions of the JECFA. In 2011, EFSA (EFSA, 2011) published a second opinion confirming both the safety of steviol glycosides and the initial ADI of 4mg/kg body weight.

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, Davidson, 2008).

Food quality and authenticity

The Group's opinion is that for organic dietary products a sweetener of natural origin in this high quality and high activity (40-300 times sweeter than saccharose) is not yet existing (Articles 3 (b) and 21.1 (ii) of the organic Regulation (EC, 2007)).

With the existing organic sweeteners, the production of products for diabetics is very limited. The issue of possible confusion of the human physiology by the provision of food that does not contain glucose should also be considered as a concern on the authenticity of the product and would not fulfil Article 6 (c) of the organic Regulation.

Traditional use and precedents in organic production

There is no traditional use of steviol glycosides isolated sweetener, but there is a traditional use of stevia leaves in teas.

Aspects of international harmonization of organic farming standards

The use of steviol glycosides is not yet allowed in any organic standard.

Necessity for intended use

Steviol glycosides are intense sweeteners entirely of natural origin and are now authorised. They have a neutral impact on the glycaemic index. They are also a product of natural origin that could replace highly criticised intense chemical sweeteners. In addition, they are a good way of limiting sugar (sucrose, glucose, fructose...) and calorie consumption in food products, thanks to their absence of calories. Referring to article 21.1 of the organic Regulation (EC, 2007) organic sweeteners like sugar, fructose, honey, glucose, agave, maple syrup are available in organic quality.

A sweetener with a neutral impact on the glycaemic index in organic quality is not yet available. This can be considered a particular nutritional purpose as mentioned in Article 6 (b) of the organic Regulation (EC, 2007).

With reference to Article 3 (b) and (c) of the above mentioned Regulation, an organic sweetener in this high quality and high activity (40-300 times sweeter than sucrose) is not yet existing.

Other relevant issues

None

Reflections of the Group

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.

However, the Group considers that steviol glycosides (E 960) do not fulfil the requirement in Article 21 (1) of the organic Regulation, due to the production method. In particular, because of the used purification technology of Ion exchange, which is evaluated as a non physical process, the production of steviol glycosides does not fulfil the requirements set in the above mentioned Article 6 (d): "...may have undergone only mechanical, physical, biological or microbial processes...". A possible use of steviol glycosides e.g. for low calorie organic soft drinks could conflict with the principle mentioned in Art 6 (c) regarding the true nature of the product.

The Group sees the possibility to have organic certified steviol glycosides, extracted from organically grown stevia leaves, with calcium hydroxide and ethanol (allowed in Annex VIII B), without the use of non-permitted chemical processes, (specifically ion exchange and resin adsorption). However, it is not clear whether this process can meet the purity criteria of the additive regulations.

Conclusions

The use of steviol glycosides (E 960) as food additive is not in line with the objectives criteria and principles of organic farming as laid down in the organic Regulation.

If it would be available in organic quality and meet the needed purity criteria of the food additive regulations, without using ion exchange, the Group concluded that steviol glycosides should be included in Annex VIII A, but only for use in foodstuffs for particular nutritional uses.

3.5 Sodium carbonate

Introduction, scope of this report

The request refers to the possible extension of the authorization of sodium carbonate in Annex VIII B (technical processing aid) to the production of starch and gluten.

Authorization in general agriculture or food processing

Sodium carbonate is accepted as a food additive (E 500) and is on the list of generally authorized additives in foodstuffs according to Commission Regulation (EC) No 1333/2008 (EC, 2008b) on food additives. It is used as a pH-regulator, anti-caking agent, raising agent, and stabilizer, and it can be used after the *quantum satis* principle.

Sodium carbonate is listed in Annex VIII B as technical aid for processing of foodstuffs of plant origin with restriction of production for sugar only. It is also listed in Annex VIII A as a food additive (E 500) for food stuffs of plant origin without restrictions and for production of the specific organic products of animal origin such as: fudge (Dulce de leche), soured cream butter and sour milk cheese. Other names for sodium carbonate are soda and soda ash.

Agronomic use, technological or physiological functionality for the intended use

Sodium carbonate (Na_2CO_3) is used in food processing in different applications as a processing aid and as an additive. One important function is the use as "acidity regulator" for drinking water and other foods. This is the application mentioned in the dossier. Furthermore, the substance is also used as an additive, for example as an anti-caking agent or as raising agent for cereal products. Sodium carbonate works as an acidity regulator. The objective of an acidity regulator is to buffer or to change an existing pH level in a food to a certain level. In our case, a salt of an alkaline substance is used to increase the pH level of an acid brine (pH 4) via a neutralising reaction.

For the production of gluten and starch from wheat, milling of the grain and maceration with water is necessary in order to dissolve the starch and the gluten from the cereal matrix. The mechanical starch isolation procedure includes the use of the processes: decantation, washing, selecting and separation by weight. The whole procedure is carried out at temperatures between 40°C and 50°C in open operation systems, and microbial contamination is unavoidable.

Therefore, during conventional processing of starch, sulphur dioxide (SO_2) is used to avoid growth of micro-organisms. Sodium carbonate is able to replace SO_2 in the procedure of production of starch and gluten from organic raw materials.

In the production of organic products, the pH of the starch extraction process must be stabilised to prevent acidification with naturally occurring lactic acid bacteria. Agglomeration of wheat gluten should be avoided during the maceration process and this happens at pH 4. The pH of the process water should be adjusted to 6 ± 0.2 when wheat gluten is to be agglomerated for further isolation, and also to avoid denaturation and sensory variance of the gluten, and this is done with addition of sodium carbonate. Also for production of starch syrup, the pH of the starch (slurry), must be adjusted up to 5.8. This use corresponds to the use of sodium carbonate in sugar production.

Known alternatives

The Group's opinion is that it is impossible to produce organic starch and gluten without using a processing aid because the micro-organisms growing have to be stopped or the resulting low pH has to be buffered. Possible alternatives to sodium carbonate are sodium hydroxide (NaOH) and calcium hydroxide ($\text{Ca}(\text{OH})_2$). However, both substances are much stronger bases, and calcium hydroxide also has the weakness of precipitating too fast in the production process. Sulphur dioxide is used in conventional processing of starch to avoid spoilage by microorganisms during the isolation process. Sulphur dioxide is not permitted as a processing aid in organic production and is an agent with specific risks. Sodium carbonate is an alkaline substance and is the most appropriate substance which could be used as a buffering agent (processing aid - acidity regulator).

Origin of raw materials, methods of manufacture

Carbonates are mineral substances which are widespread in nature. Sodium carbonate (Na_2CO_3) is commonly referred to as soda ash because it was originally obtained from the ashes of burnt plants (seaweed). Currently, it is one of the top industrial chemicals in terms of volume, and it is mostly used in the manufacture of glass. Nowadays, it is produced in large quantities from salt (sodium chloride) and limestone (calcium carbonate, CaCO_3). In a first step, a NaCl brine will be transferred to sodium hydrogen carbonate and in a second step, sodium hydrogen carbonate can be transferred to sodium carbonate by heating. The production is based on simple inorganic chemical processes.

Environmental issues, use of resources, recycling

There are plenty of raw materials in nature for the production of sodium carbonate, so there are no problems with limitation of natural resources. Sodium carbonate is neutralized in the process to sodium hydrogen carbonate (NaHCO_3) and to carbonic acid (H_2CO_3). There should be no problem with the process water as the pH is neutral.

Animal welfare issues

No specific concerns.

Human health issues

The JECFA committee has not fixed an ADI for sodium carbonate. Teratology studies with mice, rats and rabbits were without negative results. Carbonates are natural parts of the human body and food. Toxicological effects can only be demonstrated with very high intake.

No human health issues are related to the use of sodium carbonate in food in general as this chemical is neutralized in the food. This ingredient can be used in food without other limitations than the level must not exceed current good manufacturing. According to JECFA, the ADI for sodium carbonate is without limitations.

Food quality and authenticity

Sodium carbonate will not change the authenticity of the food.

Traditional use and precedents in organic production

Sodium carbonate is already authorised as both a food additive (Annex VIII A) and a processing aid (Annex VIII B) in the EU organic food production.

It can be used as a food additive (E 500) for preparation of foodstuff of plant origin and for production of the specific organic products of animal origin such as fudge (Dulce de leche), soured cream butter and sour milk cheese.. The use of sodium carbonate as a processing aid is allowed to be used for processing of foodstuffs of plant origin with restriction for production of sugar only.

Aspects of international harmonization of organic farming standards

The table below shows the actual regulatory situation of the use of sodium carbonate and indicates that there are different restrictions.

Table 1. Organic and regulatory status:

Common name(s):	Sodium carbonate	
	Additive	Processing aid
Codex Alimentarius	Listed with product group references	Listed with product group references
European Union Commission Regulation (EC) No 889/2008	Listed (restricted in animal products)	Listed - but restricted to sugar production
US National Organic Program	Listed (not synthetic)	Listed (not synthetic)
IFOAM Basic Standards 2002)	Listed (no restriction)	Listed (no restriction)

Necessity for intended use

Organic starch and gluten cannot be produced without using a processing aid because the micro-organisms growing have to be stopped or the resulting low pH has to be buffered. Possible alternatives to sodium carbonate are sodium hydroxide (NaOH) and calcium hydroxide (Ca(OH)₂). However, both substances are much stronger bases, and calcium hydroxide also has the weakness of precipitating too fast in the production process. Therefore, sodium carbonate is a suitable alternative.

Other relevant issues

Consumer studies and reports of consumer organisations do not show any negative perception from consumers towards sodium carbonate.

Reflections of the Group

Sodium carbonate is a widely used chemical in regulation of pH by the food industry, and there seems to be no problems with addition of sodium carbonate as a processing aid in the processing of organic starch and gluten.

The Group is aware that there are other possible uses of this compound as a processing aid. Ca(OH)₂ is authorised in organic production as processing aid in the preparation of food stuff of plant origin. However, the Group considers that sodium carbonate, which is also included as food additive in Annex VIII A without restrictions for plant products, is preferable to calcium hydroxide as a processing aid because sodium carbonate is a less strong and reactive agent.

The Group considers the manufacturing of sodium carbonate as a simple inorganic chemical reaction. Although the manufacturing of sodium carbonate is a chemical reaction, the process is not considered by the Group to be in contradiction to the organic Regulation (EC, 2007), because it is a process which occurs in nature.

Organic starch and gluten cannot be produced without sodium carbonate and there are no suitable alternatives, this is in line with Article Article 21 (i) and (ii) of the organic Regulation.

Conclusions

The use of sodium carbonate as a processing aid in the production of starch and gluten is in line with the objectives, criteria and principles of organic farming as laid down in the organic Regulation. It should therefore be included in Annex VIII B.

In addition, the Group concluded that this compound should be allowed without any specific conditions in Annex VIII B.

3.6 Wood fibres as filter aid

Introduction, scope of this report

The request concerns the use of wood fibres as filter aid (processing aid). Common names for wood fibres are wood chips, wood shavings, wood flour, sawdust and lignocellulose.

Authorization in general agriculture or food processing

Cellulose, which may be derived from wood, is already included in Annex VIII B as processing aid. Wood fibres accomplish with the IFOAM Norms for Organic Production and Processing version 2005 (IFOAM, 2005) point 6.3.4, which assumes that filtration equipment shall not contain asbestos or utilize techniques or substances that may negatively affect the product. The Codex Alimentarius categorises technical aids (CAC/MISC 3) in an "Inventory of Processing Aids", Appendix A to the "Codex Inventory of all Compounds Used as Processing Aids" and gives the common names wood flour/sawdust as examples of clarifying agents and filter aids (Codex Alimentarius, 1999 revision 2010) .

Wood fibres are used as filter aid, i.e. as processing aids in precoat filtration for solid/liquid separation. Filter aids do not remain in final products, because the filter aids have to be removed completely. Therefore, EU Regulations for food additives are non-applicable for filter aids. Under Article 1(3) of Directive 89/107/EEC (EEC, 1989) relating to processing aids, the user himself is responsible for the use of such aids, which may not affect the finished product.

Agronomic use, technological or physiological functionality for the intended use

Wood fibres are widely used as filter aid in the production of foodstuffs such as molasses, beer, wine, fruit juice, spirits, liqueurs, gelatine or vinegar. They are used as processing aid for solid/liquid separation. The fact that wood fibres can be used for so many different purposes is one of their advantages. By varying the length of the fibres and employing grinding technology and classification, it is possible to influence additional processing characteristics in a customised manner.

Wood fibres are stirred uniformly into the non-filtrate (the foodstuff to be cleared) and are then separated along with the other solids by a precoat filter. Precoat filter systems have always proven effective to remove impurities/solids in solid/liquid separation, eg. the production of glucose, with approx. 5kg of wood fibres per tonne of glucose (dry matter content).

As the dosage of the filtering aid is determined by the type of solid matter to be separated, its percentage may vary considerably, from 0.01 to 3 %, depending on each application. Pursuant to Directive 87/107/EEC Article 1 (3) on processing aids, the user is responsible for assuring that their application does not adversely affect the final product.

The most relevant applications in the food sector are for filtration of beverages (beer, wine, fruit juice, spirits, liqueurs), foods (sugar, liquid sugar, glucose, dextrose, fructose, maltose, pectin, edible oil, fats, gelatine, alginates, agar agar, rennet, yeast, vinegar).

Known alternatives

Natural silicates such as diatomaceous earth, perlite, cellulose etc. are alternatives to wood fibres, to filter foodstuffs. Diatomaceous earth and perlite are listed in Annex VIII B, as well as cellulose.

Mineral filter aids dissolve, especially at low and high pH values, releasing iron ions, which can pass into the filtrate and speed up oxidation in beer.

Origin of raw materials, methods of manufacture

Wood fibres are natural products. The raw material consists of various native species of wood such as pine, spruce, oak, beech which is composed of various proportions of cellulose, hemicellulose and lignin etc.

The general manufacturing process includes the following basic operations: pre-grinding, milling, classification, palletising to obtain a sufficiently fine end product, the wood fibres. Wood is available from certified, sustainably managed sources.

Environmental issues, use of resources, recycling

The environmental impacts of forestry are highly variable, depending on management practices. Wood fibres from certified, sustainably managed sources are available. The wide range of options for environmentally acceptable disposal of the filter cake is a further advantage. In food production, the filtration residue generally contains ingredients which can be used in animal feed. Incineration, fertilisation and composting are other possible means of cost-effective disposal or recycling. For filter cakes disposed of by incineration, filter aids based on wood have a significant advantage over their mineral counterparts. As wood fibres are purely plant derived, they have a high calorific value for feed purposes. They also may be burned as fuel leaving virtually no residue.

Wood powders should be produced in a demonstrably sustainable manner. Certification of sustainability for wood products is available.

Given the low weight of wood fibres and the so-called low wet cake density, the specific consumption in comparison to mineral filter aids can be reduced by up to 70 % which, in turn, leads to reduced amounts of waste.

Animal welfare issues

None

Human health issues

Filter aids must be removed completely. The wood used must not have been subject to any preservative treatment and pesticide contamination. The starting material must also satisfy strict hygiene requirements, e.g. it must not exhibit any fungal growth. Some wood species naturally contain toxic materials. These risks must be eliminated in wood powders used for filtration. In addition, these substances are considered safe in terms of occupational health.

Food quality and authenticity

Wood fibres are a natural processing aid, which do not remain in the final product, so there are no concerns regarding food quality or authenticity.

Traditional use and precedents in organic production

Cellulose, which may be derived from wood, is already included in Annex VIII B as processing aid. Sawdust is authorized as a soil conditioner (Annex I). Wood fibres are used widely as filter aids in the conventional production of foodstuffs, e.g. molasses, beer, wine, fruit juice, spirits, liqueurs, gelatine, vinegar, etc. They are used as processing aids for solid/liquid separation.

Wood fibres are, for example, also used as filter aids to produce glucose and can be used in the pre-coat filtration of other foods. The fact that wood fibres can be used for so many different purposes is one of their advantages. By varying the length of the fibres and employing grinding technology and classification, it is possible to influence additional processing characteristics in a customised manner.

Minimal processing of virgin wood pulp allows the obtained powder to be classified as organic and is authorised by the United States Department of Agriculture (USDA) to produce organic foods or food labelled "made with organic..".

Aspects of international harmonization of organic farming standards

Wood fibres comply with IFOAM basic standards. In 1991 the Codex Alimentarius (EC, 1991) categorised technical aids (CAC/MISC 3) in an "Inventory of Processing Aids", Appendix A to the "Codex Inventory of all Compounds Used as Processing Aids" establish wood flour/sawdust as examples of clarifying agents and filter aids. Wood fibres are not mentioned as processing aid and are not-applicable as additive, in the US NOP.

Necessity for intended use

The Group opinion is that physical filter aids are necessary in the organic production. In Annex VIII B there are filter aids authorised, but they are all mineral. Wood fibres appear to be preferable to some of those and for some applications, for example activated carbon for beer filtration. Unlike mineral filter aids, wood fibres, due to their fibrous structure, fissured surface and high pore volume in the filter cake, often achieve higher flow rates and longer filter service life.

Other relevant issues

None

Reflections of the Group

Overall the Group believes that physical filter aids are necessary in organic production. In particular the group opinion is that wood fibres are preferable to some of the filter aids already listed in Annex VIII B, for some applications. Therefore their use is in line with the requirements of Article 21 (1) (i) of the organic Regulation.

Conclusions

Wood fibres as processing aid, specific filter aid, are in line with the aims and principles of the Organic Regulation. Therefore the Group proposes inclusion of wood fibres in Annex VIII B, as filter aid in the foodstuffs production of both plant and animal origin. The entry should include the following restrictions:

1. The source of timber should be restricted to certified, sustainably harvested wood.
2. Wood used must not contain toxic components (post-harvest treatment, naturally occurring toxins, toxins from micro-organisms).

3.7 Ion Exchange and adsorbent resins used for production of a carob-based sweetener

Introduction, scope of the report

The mandate is based on a request for using ion-exchange and adsorption technology for the production of a “natural fruit sweetener” based on carob with a high purification level.

Authorization in general agriculture or food processing

Ion-exchange and adsorption technology are widely used in processing of food and for water treatment in the EU (ECC Reg. 1935/2004) (EC, 2004). The new organic wine regulation (ECC Reg. 203/2012) (EC, 2012) forbids the use of cation exchangers to ensure the tartaric stabilization, but authorises the use of ion exchange resins for the must preparation in Article 4(b) for a transition period³.

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 immobilized 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 are in use, cation exchange resins and anion exchange resins.

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 demineralization, decolouring, removal of contaminants, 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.

³ “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.”

Known alternatives

Annex VIII B 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 by ion exchange of sodium ions from whey for use in infant formulas.

Origin of raw materials, methods of manufacture

Today a variety of synthetic cross-linked polymeric resins are in use. The technological properties of the resins are defined by the functional groups.

Among the used substances there are polyacrylate, polystyrol, styrene-divenylbenzene or polyacrylamide. In particular, the dossier mentions also the use of highly porous copolymer styrene – DVB (divenylbenzene) and sulfonated divenylbenzene styrene copolymer and defines the functional groups as “tertiary amines” and “sulfonic acid”.

All these materials are synthesized products of petrochemical origin.

Environmental issues, use of resources, recycling

From an environmental perspective, it is positive that this technology allows a regeneration of the resins. This means that the basic resins can be used several times. The regeneration is done for example with NaCl, CaCl, NaOH or HCl. On the other hand, this regeneration creates the main waste streams from this technology.

Animal welfare issues

No specific concerns

Human health issues

The Committee of ministers of EU stated that: “Considering that ion exchange and adsorbent resins used in the processing of foodstuffs may, by reasons of migration of resin constituents to the foodstuffs, pose under certain conditions a risk to human health” (Council of Europe/Resolution AP (97) 1 1997). The Committee set up requirements for the substances allowed as well as requirements for the detection and for upper limits of substances migrating from such technical resins. This means there is a risk of migration of constituents from the resins used in ion-exchange and adsorption technology. On the other hand such migration events are regulated by (Reg. (EC) No 1935/2004 (EC, 2004).

Food quality and authenticity

From the request concerning production of a carob-based sweetener in the dossier, 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 refinement process seeks to remove “impurities” from the food. In this case, naturally occurring minerals, vitamins, protein, colour and flavour are the “impurities”. The products contain no organic acids, minerals, pigments, vitamins, amino-acids, proteins, or flavours, but only soluble carbohydrates (sugar, oligo-saccharides and polyols). The nutritional quality of the product is very low, which is not in line with Article 3 (b) of the organic Regulation.

The Group argues that in this case, when the product has totally lost its natural characteristics because of the high purification level, there is the risk to mislead the consumer on the true nature of the product. The consumer will never identify the sweetener with the source, fruits. This is not in line with Articles 6 (c) and 19(3) of the Organic Regulation. Therefore both technologies 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,” possibly misleading the consumer (Articles 6 (c) and 19(3) of the above mentioned Regulation).

When ion exchange and adsorbents resins are used in starch saccharification processes and in the production of rectified must concentrate and other fruit concentrates to produce a neutrally tasting sweetener, this can be considered as a similar case as for sweeteners based on carob.

In the case where ion exchange and adsorbent resins are used for the preparation of organic raw materials like starch or whey for infant food, we are facing a different situation, because according to the ECC Directive 141/2006 (EC, 2006) the end product has to fulfil specific dietary requirements. At present this requirement can only be fulfilled efficiently by the use of ion exchange and adsorbents resins.

In addition, it should be noted that in the case of ion exchange processes, the ions that are added (usually H⁺ and/or OH⁻) are derived from acids or alkalis that in most cases are not permitted as additives themselves in Annex VIII A, or which have very limited specific uses. E.g. hydrochloric acid, HCl, which is permitted only as a processing aid in brine baths for cheese, or sodium hydroxide, NaOH, which is permitted only as an additive for surface treatment of baked products and as a processing aid in sugar and vegetable oil production.

Traditional use and precedents in organic production

These techniques have been commercially available for almost 30 years. Looking at the organic processed food products it has to be mentioned that, because of legal uncertainty, ion exchange and adsorbent resins are currently accepted in some MS for processing of organic products.

Aspects of international harmonization of organic farming standards

In the USA, there was a debate on the possible use of ion exchange and adsorbent resins for organic processing. The Group has information that some types of applications of ion exchange and adsorbent resins are accepted under the NOP rules. Codex Alimentarius “guideline on organic foods” (Codex Alimentarius, 1999 revision 2010) does not address the topic of ion exchange and adsorbent resins.

Necessity for intended use

To produce highly purified sweeteners from fruit raw materials with the requested purification level is only possible with the help of ion exchange and adsorbent resins.

The Group recognizes that organic starch saccharification 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, when ion exchange and adsorbent resins are used for the preparation of organic raw materials like starch or whey for infant food, we are facing another situation. Because of Council regulation (EC) No 141/2006 (EC, 2006) the end product has to fulfil specific dietary requirements.

Therefore, in this case minerals are removed in order to fulfil the requirement of the infant formula legislation. This requirement can today only be fulfilled efficiently by the use of ion exchange and adsorbents resins.

Other relevant issues

Different reports (CRAIAA 2012/Beck 2000) highlight that there is an ongoing uncertainty on the legal status of ion-exchange and adsorption technology. It is not clear if this technology should be considered as a processing aid or as a technical system (material used for food processing). This is producing a situation where those technologies are accepted for organic processing in some MS, while in others they are not authorised. Some operators have built expensive processing plants for organic production based on ion exchange and adsorption resin technologies.

Reflections of the Group

Ion exchange and adsorbent resins have been used for processing of organic foods for many years in some MS while in others their use was not allowed. The Group notices that this situation can lead to commercial conflicts.

The mandate is based on a dossier focused on the request of using ion exchange and adsorption technology for the production of a “natural fruit sweetener” based on carob. Several other requests were also received. The Group took a final decision only on the request made in the dossier. Other requests and information were considered, but there was insufficient information to make complete decisions.

As specified in the mandate, ion exchange is considered by the EC as a processing aid, not a technique. The Group opinion is that in the case of ion exchange this is not correct, as new ions, from the resins, are deliberately added to the product, so the composition of the product is changed. Therefore, ion exchange should be considered as a technology. The Group admit that for adsorption resins the issue is less clear.

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. (Article 6 (c) of the organic Regulation (EC, 2007))

The Group opinion is that each proposed application must be carefully evaluated on the basis of technical dossiers. A complete dossier is currently only available for the production of a specific carob derived sweetener with a high purification level. Other possible applications like demineralization of whey for baby food, starch saccharification products and for production of rectified must concentrate were not discussed because of lack of complete dossiers.

The Group opinion is that the use of ion exchange and adsorption resins as processing aids to produce carob derived sweetener should not be allowed in organic production both because of the high purification levels, which this process implies and which could lead to misleading of the consumer, as well as because of the chemical processes involved. In particular, ion exchange does not fulfil the requirements for mechanical, physical and microbiological processes, as mentioned in Article 21 (1) of the organic Regulation.

Conclusions

The Group concludes that the use of ion exchange and adsorption resins as processing aids to produce carob derived sweetener 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 and the process involved (Articles 6 (c) and 21 (1) of the Organic Regulation, respectively).

Therefore the Group's opinion is that ion exchange and adsorbents resins cannot be added as a processing aid in Annex VIII B for carob derived sweeteners.

3.9 Other issues

3.9.1 Comments and amendments concerning the use of some of the substances listed in Annex VIII A and B to Commission Regulation (EC) No 889/2008.

Introduction

The Commission asked the Group additional questions concerning amendments to the specific conditions for potassium nitrate (E 252), glycerol (E 422), pectin (E 440), sulphur dioxide (E 220) and potassium metabisulphite (E 224), tartaric acid (E 334) in Annex VIII A. In addition, the Group also suggested some specific amendments to Annex VIII B.

Reflections of the Group

It is clear that the aim of the organic Regulation (Articles 4 (b) and 6 (b) is to have a restricted list of substances in Annex VIII, in line with the principle that organic food should be produced with the minimum use of additives and processing aids. On the other hand, the development of new processing techniques and processing aids is an ongoing process. Until now, there is little attention to the needs of the organic processing sector to develop new processing and additive use strategies. This development should cope with the fast growing diversity of organic foods which is in line with the aims given in Article 3 (b) and (c) of the organic Regulation (EC, 2007). Due to the fast growing "diversity" of organic foods caused by the market expansion and by the enlargement of the European community, the Group finds that the limitations in the last column of Annex VIII, and the current grouping in animal and plant origin have to be revised to produce a wide variety of organic foods. This will help the organic sector to provide a broad range of high quality organic foods as targeted by Article 3 (b) and (c) of the above mentioned legislation.

Conclusion

The Group is of the opinion that a basic set of currently authorised additives ("basic tool box"; see table VIII A and B) should be provided to the organic processing operations without further restrictions in order to facilitate the sector in creating a wide variety of high quality organic foods (Articles 3 (b) and (c)).

All the additional or amended conditions suggested by the Group are in line with the relevant EU transversal legislation. Detailed comments and proposals are explained in table 2.

Table 2. Comments and amendments concerning the use of some of the substances listed in Annex VIII A and B to Commission Regulation (EC) No 889/2008.

Certain products and substances for use in production of processed organic food, yeast and yeast products referred to in Article 27(1)(a) and Article 27(a)

Note: A: authorized under Regulation (EEC) No 2092/91 and carried over by Article 21(2) of the organic Regulation B: authorized under the organic Regulation

SECTION A — FOOD ADDITIVES, INCLUDING CARRIERS For the purpose of the calculation referred to in Article 23(4)(a)(ii) of Regulation (EC) No 834/2007, food additives marked with an asterisk in the column of the code number, shall be calculated as ingredients of agricultural origin.

Discussion and conclusions for the proposals of the experts to annex VIII A	Code	Name	Plant origin	Animal origin	Proposed changes to Specific conditions
<p>One request was about the meaning of the wording: "in fruit wines without added sugar".</p> <p>The Group found that the specific conditions need to be amended as in the proposed changes due to the following reasoning:</p> <p>There are other sour fruits with low sugar content and high acidities used to produce fruit wines, where the addition of sugar is needed.</p> <p>Therefore the limitation of the addition of sulphur dioxide to sugar added wines to only cider and perry is too narrow.</p>	E 220 or E 224	Sulphur dioxide Potassium metabisulphite	X X	X X	<p>In fruit wines (*) without added sugar (including cider and perry) or in mead: 50mg (**)</p> <p>In fruit wines (*) and mead with and without added sugar):100 mg (**)</p> <p>(*) In this context, "fruit wine" is defined as wine made from fruits other than grapes. (including cider and perry)</p> <p>(**) Maximum levels available from all sources, expressed as SO₂ in mg/l.</p>

Discussion and conclusions for the proposals of the experts to annex VIII A	Code	Name	Plant origin	Animal origin	Proposed changes to Specific conditions
<p>The Group propose to have a general regulation for the use of sulphur dioxide and potassium metabisulphite for the production of fruit wine as well as mead with and without added sugar 100 mg (**)/l</p> <p>(* In this context, "fruit wine" is defined as wine made from fruits other than grapes. (including cider and perry)</p> <p>(**) Maximum levels available from all sources, expressed as SO₂ in mg/l.</p> <p>Another request was about the use of E 220 and E 224 in mead.</p> <p>Mead is an animal product; therefore the restrictions under Specific Conditions fully apply to animal products. This means E 220 and E 224 are only accepted for one animal product which is mead.</p>					
<p>The Group has studied the request on sodium nitrite and potassium nitrate and in particular if under specific conditions the chemical references to NaNO₂ and NaNO₃ are correct.</p> <p>It is a common practice and defined in standardized analytical methods to relate all ingoing and residual nitrite NO₂ and nitrate NO₃</p>	<p>E 250 or E 252</p>	<p>Sodium nitrite Potassium nitrate</p>		<p>X X</p>	<p>For meat products (1):</p> <p>For E 250: indicative ingoing amount expressed as NaNO₂ : 80 mg/kg</p> <p>For E 252: indicative ingoing amount expressed as NaNO₃ : 80 mg/kg</p>

Discussion and conclusions for the proposals of the experts to annex VIII A	Code	Name	Plant origin	Animal origin	Proposed changes to Specific conditions
to the sodium form (NaNO ₂ and NaNO ₃). This provides an easier comparison of data. The current specification under specific conditions is correct.					For E 250: maximum residual amount expressed as NaNO ₂ : 50 mg/kg For E 252: maximum residual amount expressed as NaNO ₃ : 50 mg/kg
The Group is of the opinion that sodium citrate should belong to the above mentioned “basic tool box” for organic processing. For example, sodium citrate reduces acrylamide formation in baked products based on whole cereal where the acrylamide formation, because of the natural ingredients, is relatively high. The issue of acrylamide is very relevant for consumers because of its carcinogenic potential. Further on, sodium citrate has a high relevance for the binding properties of pectin in fruit based jam depending on the pH of the product. Therefore, the group proposes to accept this substance as a food additive in both animal and plant products without any further restriction(Article 3 (b), (c) of regulation 834/2007).	E 331	Sodium citrate	X	X	
The Group is of the opinion that citric acid should belong to the above mentioned basic tool box. The Group has the knowledge that citric acid is	E 330	Citric acid	X	X	Crustaceans and mollusks(2)

Discussion and conclusions for the proposals of the experts to annex VIII A	Code	Name	Plant origin	Animal origin	Proposed changes to Specific conditions
<p>also needed for the production of various products of animal origin. It is accepted for plant products and as a processing aid in Annex VIII B. For example, the substance is playing a role in the production of cooked eggs. Furthermore the group has the opinion that citric acid, as an organic acidity regulator, should be part of the basic tool box for organic processing. Citric acid is an additive, which is mainly produced by biotechnological means. Therefore, the Group proposes to accept this substance as a food additives also for products of animal origin without any further restriction to enable production of a wide variety of foods (Article (3) (c) of Council Regulation (EC) No 834/2007).</p>					
<p>Concerning the use of tartaric acid in mead, the Group is of the opinion that tartaric acid should also be permitted for use in mead as an acidulate. Its use is necessary for the production of mead. (Article 21 (1) (ii) Its use is already approved in grape and fruit wines according to Commission Regulation (EC) No 203/2012 (EC, 2012)</p>	E 334	Tartaric acid (L(+)-)	X	X	Animal product for mead only
<p>One request was about the use and origin of glycerol.</p> <p>Glycerol is a substance which can have different origins. The substance can be produced from</p>	E 422	Glycerol	X		From plant origin. For plant extracts

Discussion and conclusions for the proposals of the experts to annex VIII A	Code	Name	Plant origin	Animal origin	Proposed changes to Specific conditions
<p>petrochemical processes, or it can be produced by chemical reactions from animal fat or plant oil and fat. Glycerol is widely used in different types of operations. Because of this situation the Group is of the opinion that it is appropriate to restrict the source of glycerol in the organic Regulation. In particular, the origin of glycerol should be restricted to plant material, not from petrochemical or animal origin (Articles (3) (b), (c) of land 21 (1) of the organic Regulation).</p> <p>The Group has no further information on the request for use in fruit juices or capsules and sees the questions put forward as a legal question of implementation of the regulation. The Group may be able to give a recommendation if the question is specified and technical details provided.</p>					
<p>The Group was asked an opinion on the use of pectin for better slicing of organic ham.</p> <p>Pectin is a substance of plant origin, which is used mainly as thickener in all types of products. Under “specific conditions” there is a restriction on the use of this food additive for animal products to milk products only. There is a request to accept pectin for general use in animal products. The Group sees no necessity for using</p>	E 440* (i)	Pectin	X	X	Milk-based products (2)

Discussion and conclusions for the proposals of the experts to annex VIII A	Code	Name	Plant origin	Animal origin	Proposed changes to Specific conditions
<p>pectin for slicing of ham. In the Group's opinion on the use in slicing of ham is, that the addition of pectin means to bind more water in the product. This conflicts with Article 6 (c) of the organic Regulation, regarding the true nature of the product. The Group proposes to leave the existing restriction for use as an additive in animal products to milk based products only.</p>					
<p>Based on the evaluation of sodium carbonate as processing aid the Group is of the opinion that this substance should belong to the above mentioned basic tool box. Sodium carbonate is a mildly alkaline substance produced out of mineral origin (see the sodium carbonate chapter above). At the moment it is allowed as additive for plant products without restrictions. For animal products the use is restricted to 3 specific products, where Sodium carbonate is working as a buffering substance. Similar milk based products are produced in other EU countries as specialties. Therefore the specific condition concerning sodium carbonate should be deleted, to enable a wide variety of foods to be produced. (Article 3 (c) of Council regulation (EC) No 834/2007 (EC, 2007)).</p>	E 500	Sodium carbonate	X	X	Dulche de leche' ⁽³⁾ and soured cream butter and sour milk cheese ⁽²⁾

SECTION B — PROCESSING AIDS AND OTHER PRODUCTS, WHICH MAY BE USED FOR PROCESSING OF INGREDIENTS OF AGRICULTURAL ORIGIN FROM ORGANIC PRODUCTION

Discussion and conclusions for the proposals of the experts to annex VIII B	Name	Plant origin	Animal origin	Specific conditions
<p>Based on the evaluation of Sodium Carbonate as processing aid the Group is of the opinion that this substance should belong to the above mentioned basic tool box. Sodium carbonate is an important alkali buffering substance in food processing. The Group has information that there is an essential need for using this substance in starch processing (see separate evaluation) and for example in pH correction of salt baths in some cheese specialties (Edelschimmelkäse) or for the neutralization of e.g. palm fat. Therefore, the Group proposes to accept this substance without any restriction for animal and plant products as processing aid.</p>	Sodium carbonate	X	X	Sugar(s) production
<p>The Group has information that this substance is needed for the production of various products of animal origin. For example, the substance plays a role in the processing of eggs (white powder).</p> <p>The Group is of the opinion that citric acid as an organic acidity regulator should be a part of the basic tool box for organic processing. Therefore the group proposes to accept this substance as processing aid for both plant & animal products without any restrictions.</p>	Citric acid	X	X	For the regulation of the pH of the brine bath in cheese production⁽¹⁾ Oil production and hydrolysis of starch⁽²⁾

3.9.2 Processing aids which are generally available in organic form

Introduction

Ethanol, gelatine, vegetable oils and rice meal are listed in Annex VIII B. They can thus be used as processing aids in non-organic form. When they are used as food ingredients, however, they must be in organic form. The new additive Regulation (EC) No 1333/2008 (EC, 2008b) in article 3 (b) (i) excludes “normal food” from falling under the definition of “processing aids”.

Reflections of the Group

The Group opinion is that the following substances: ethanol, gelatine, vegetable oils and rice meal listed in annex VIII B are widely available in organic form and their continuing use in non-organic form as processing aids is therefore unnecessary and contrary to the principles of organic farming as detailed in Article (4)(b)(i) of the organic Regulation.

The additive Regulation (EC) No 1333/2008 (EC, 2008b) in Article 3 (b) (i) excludes “normal food” from falling under the definition of “processing aids”.

Conclusion

The Group recommends that these substances should only be used in organic form, even if they are listed in Annex B to Commission Regulation (EC) No 889/2008.

3.10 Outstanding issues

In order not to jeopardize the work on the priorities set by the mandate, the Group could not assess the use of the following substances, based on an additional requests made from the EC: ozone as post harvest treatment of plant products, acetic acid as processing aid in the fish production as well as possible changes of the specific conditions for substances already mentioned in Annex VIII for the production of organic flavours. In particular for the latter, the Group proposes to issue a separate mandate concerning flavours. In order to deal with the various outstanding issues and also due to the fast development in organic processing, the Group propose to organize regularly an EGTOP meeting on food processing.

3.11 Template for dossiers concerning Organic Food

The Group considered that it would be helpful to develop some interpretative guidelines to support the dossier template. The document presented in Annex 1 to this report includes in part A a questionnaire and in part B a section incorporating the criteria for assessment of consistency with the EU organic regulation.

4. LIST OF ABBREVIATIONS / GLOSSARY

Annex VIII	Annex VIII of Regulation 889/2008
Annex VIII A	Annex VIII of Regulation 889/2008, food additives
Annex VIII B	Annex VIII of Regulation 889/2008, processing aids
The Group	EGTOP Experts
ADI	Acceptable daily intake
DAP	Diammonium phosphate
GMO	Genetically modified organism
EC	European Commission
MS	Members States (of the European Union)
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organisation
NOP	National Organic Program (of the USA)
SCF	Scientific Committee on Food
TH	Thiamin hydrochloride
JECFA	Joint FAO/WHO Expert Committee on Food Additives
FAO/WHO	Expert Committee on Food Additives
USDA	United States Department of Agriculture
WHO	World Health Organisation

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EC, 2004 Regulation (EC) No 1935/2004 of the European parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, p 4-17

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EC, 2008b. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 16-33

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Annex 1: TEMPLATE FOR DOSSIERS CONCERNING ADDITIVES, PROCESSING AIDS OTHER MATERIALS USED IN FOOD PROCESSING
Part A
**DOSSIER CONCERNING THE REQUEST TO AMEND ANNEX VIII
 Certain products and substances for use in production of processed organic
 food, yeast and yeast products**

Articles 21 (2) of Council Regulation (EC) No 834/2007.

" Where a Member State considers that a product or substance should be added to, or withdrawn from the list referred to in paragraph 1, or that the specifications of use mentioned in this paragraph should be amended, the Member State shall ensure that a dossier giving the reasons for the inclusion, withdrawal or amendments is sent officially to the Commission and to the MS."

General information on the request

Nature of the request	<input type="checkbox"/> Inclusion <input type="checkbox"/> Deletion <input type="checkbox"/> Change of disposition
	<input type="checkbox"/> Annex VIII A <input type="checkbox"/> Annex VIII B <input type="checkbox"/>
Request introduced by	[Member State]: Contact e-mail:
Date	

Please indicate if the material provided is confidential.

Requested inclusion;

Name	Description, compositional requirement, conditions for use

1. Identification

Identification of substance, terminology, synonyms physical condition/properties

Chemical name(s):
Other names:
E number:
Substance group/Additive category:

2. Basic toxicological data

ADI level:
Data of JECFA /SCF evaluation:
Short summary:

3. Origin and production of the substance

Active ingredients:
Possible carriers:
Origin of raw materials (including aspects of mining/harvesting them), production methods:

4. Technology

Application in food and or during food processing:
Intended use/food:
Technological function in food:
Used in food products in general:
Necessity of the proposed substance or treatment for the production of organic food:
Possible alternative substances or treatments:

5. Legal Status

Food in general:
Organic regulatory status (EU, Codex Alimentarius, USA, national, others):
Private standards:

6. Consistency with objectives and principles of organic production

Please use the check list in part B of this Annex to indicate consistency with objectives and principles of organic production, as well as criteria and general rules, laid down in Council Regulation (EC) 834/2007 Title II and Title III as applicable.

7. Other aspects

Potential of misleading the consumers regarding the true nature of the product:
Influence of the substance or treatment to the quality of the product:
Environmental issues relating to the production and use:
Socio-economic issues relating to production and use:
Ethical issues relating to production and use:
Various aspects, further remarks:

CHECKLIST FOR CONSISTENCY

with objectives and principles of organic production with reference to specific articles in the organic regulation

Part B

Criteria	Specific articles in Reg. 834/2007	Fulfilled? Yes / no / not applicable	Detailed qualification
Not a GMO and not produced from or by GMOs	Art. 9(1)		
Alternatives authorized are not available; (not available in sufficient quantities or qualities on the market/ advantages and disadvantages	Art 21 (1) (i)		
Only in case of essential technological need or for particular nutritional purposes; Without having recourse to them, it would be impossible to produce or preserve the food or to fulfil given dietary requirements	Art 6 (b) Art 21 (1) (ii)		
The substances and processing methods are not misleading regarding the true nature of the product	Art 6 (c)		
The products and substances are to be found in nature and may have undergone only mechanical, physical, biological, enzymatic or microbial processes. (natural or naturally-derived substances;)	Art 21 Art 4 (b) (ii)		
Strict limitation of the use of chemically synthesized inputs to exceptional cases	Art 4 (c)(i) (ii) (iii)		

Report on Organic Food

Aim at producing products of high quality.	Art 3 (a)		
Helps to produce a wide variety of foods that respond to consumers' demand	Art 3 (b)		
Others: please specify			