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

Expert Group for Technical Advice on Organic Production

EGTOP

Final Report On Food (II)

The EGTOP adopted this technical advice at the 9th plenary meeting
of 28 – 30 April 2014

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

With the Communication from the Commission to the Council and to the European Parliament on a European action plan for organic food and farming adopted in June 2004, the Commission intended to assess the situation and to lay down the basis for policy development, thereby providing an overall strategic vision for the contribution of organic farming to the common agricultural policy. In particular, the European action plan for organic food and farming recommends, in action 11, establishing an independent expert panel for technical advice. The Commission may need technical advice to decide on the authorisation of the use of products, substances and techniques in organic farming and processing, to develop or improve organic production rules and, more in general, for any other matter relating to the area of organic production. By Commission Decision 2009/427/EC of 3 June 2009, the Commission set up the Expert Group for Technical Advice on Organic Production (EGTOP).

EGTOP

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

EGTOP Permanent Group

- Alexander Beck
- Keith Ball
- Niels Halberg
- Sonya Ivanova-Peneva
- Lizzie Melby Jespersen
- Nicolas Lampkin
- Giuseppe Lembo
- Robin Frederik Alexander Moritz
- Bernhard Speiser
- Fabio Tittarelli

Contact

European Commission - Agriculture and Rural Development

Directorate B: Multilateral relations, quality policy

Unit B4 – Organics

Office L130 – 03/232

B-1049 BRUSSELS

BELGIUM

Functional mailbox: agri-exp-gr-organic@ec.europa.eu

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 Group are acknowledged for their valuable contribution to this technical advice. The members are:

Sub-Group members:

- Keith Ball (rapporteur)
- Alexander Beck (chair)
- Aase Solvej Hansen,

External experts:

- Burkard Ahlert
- Eugenie Mai-The
- Aneta Zalecka

Secretariat:

- João Onofre
- Luis Martin Plaza
- Suzana Median
- Iva Bažon
- Louis Mahy

All declarations of interest of Permanent Group members are available at the following webpage:

www.organic-farming.europa.eu

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EXECUTIVE SUMMARY

The EGTOP has evaluated a number of topics relevant for the use of flavours in organic products and the production of organic flavours in accordance with the requests set out in the second EGTOP food mandate.

Because there is a risk of misleading the consumer (Article 6(6) and 19(3)) of Council Regulation (EC) No 834/2007) we propose to not permit substances referred to in labelling requirements under Article 16 (6) of the new flavouring regulation (Regulation (EC) 1334/2008). The group proposes to establish a link in the Organic Regulation to the new flavouring regulation. This link should allow flavour extracts (Article 3(2)(d)) and "natural" flavours (Article 3(2)(c)) restricted to those natural flavourings as defined in Article 16(4),(5) of Regulation (EC) No 1334/2008.

Further, we propose to restrict the use of natural flavourings to specific processed food product groups e.g. tea products, sweets, milk products.

The group proposes the following, in order of priority:

1. Flavourings should be calculated as ingredients of agriculture origin.
2. Only organic carriers (ethanol, oil, fat, maltodextrin, etc) should be allowed and included in the calculation of the percentage of agricultural ingredients
3. As long as glycerol and sodium alginate are not available in organic quality they should be allowed as conventional carriers and must not be part of the percentage calculation of agricultural ingredients. (ref. Chapter 7.5, 7.7). In this case and in accordance with Article 19 (2a) of regulation 834/2007, the majority, over 50%, of all ingredients should be from organic origin.
4. Only natural flavourings as defined in Article 16 (4) and 16 (5) of Regulation EC No. 1334/2008 are in the scope of the organic regulation.
5. Regulation EC 1334/2008 (Art 16) establishes a quantitative relationship between the flavouring component responsible for the flavour and taste and the source material referred in labelling qualified as natural. However, for organic flavourings, all of these flavour component must be organic.
6. Additives, solvents and processing aids must be used in organic form when available.

The use of ascorbic acid as a food additive (antioxidant) is in line with the objectives, criteria and principles of organic regulation. Therefore the group does not see any need to change the specific conditions for ascorbic acid. Nevertheless the group highlights that in the implementation, the use of ascorbic acid according Article 4 of Council Regulation (EC) No 834/2007, regarding synthetic products and products from GM origins, should be considered.

The use of tocopherol rich extract as a food additive (antioxidant) in flavours is in line with the objectives, criteria and principles of organic regulation. Therefore the group does not see any need to change the specific conditions for tocopherol rich extract in Annex VIII, with the exception of the need to delete the wording "for fats and oils"

The use of lecithin as a food additive (antioxidant) in flavourings is in line with the objectives, criteria and principles of the organic regulation. Therefore the group does not see any need to change the specific conditions for lecithin, with the exception of the need to add the wording "in organic form only."

The use of citric acid as a food additive is in line with the objectives, criteria and principles of organic regulation for use in flavourings. Therefore the group does not see any need to change the specific conditions for Citric acid.

The use of sodium alginate as a food additive for plant products and for milk based products is in line with the objectives, criteria and principles of organic farming, also for use in flavourings. Therefore the group does not see any need to change the specific conditions for sodium alginate. Organic sources should be preferred.

The use of carrageenan as an additive is in line with the objectives, criteria and principles of the organic regulation for the use in flavourings from a technical perspective. However, because of the newest toxicological findings the group sees the need for a re-evaluation of this additive by EFSA. In line with the precautionary principle, the Group proposes to postpone any decisions on the use of carrageenan until all doubts concerning possible human health effects have been removed. The Group does not recommend the use of carrageenan in organic production until these concerns have been addressed

The use of glycerol as a food additive for plant products is in line with objectives, criteria and principles of the organic regulation also for use in flavourings. However the group sees the need to expand the specific conditions set up in Annex VIII. The previous EGTOP report on Food, recommended changing the wording of the specific condition from “for plant extracts” to “from plant origin”. Now we propose the specification “for plant extracts and flavourings”.

The use of pectin as a food additive is in line with objectives, criteria and principles of the organic regulation also for use in flavourings. Therefore the group does not see any need to change the specific conditions for pectin. Organic sources should be preferred.

The use of HPMC as a food additive for encapsulation of flavourings is not in line with the principles, criteria and objectives of the organic regulation because of the concern that encapsulation of flavourings is misleading to the consumer (Council Regulation (EC) No. 834/2007 Article (6) (c)) and the substance is not necessary for the production (EC Reg 834/2007 Art 21.1.II) of an organic product. The current specific conditions for HPMC should be rephrased to allow encapsulation only for capsules for food supplements.

The group is of the opinion that the use of sodium hydroxide for acidity regulation in flavours is in line with objectives, criteria and principles of the organic regulation. The specific conditions for use of sodium hydroxide should be amended in Annex VIII to read “Surface treatment of Laugengebäck and regulation of acidity in organic flavourings.”

The group considers that the use of magnesium carbonate is in line with objectives, criteria and principles of the organic regulation. There is no need for amendment of the specific conditions of Annex VIII.

The group considers that the use of silicon dioxide is in line with the objectives, criteria and principles of the organic regulation. Natural sources of silicon dioxide should be preferred. The specific conditions for silicon dioxide, currently written as “anti-caking agent for herbs and spices” should be amended by the addition of the following: “... and flavourings”

The use of liquid smoke flavours is not in line with the objectives, criteria and principles of organic regulation because there is no need for their use in line with article 21.1. and there is a risk that the consumer will be misled contrary to Article 6 (c) and 19 (3) of the Council Regulation (EC) No, 834/2007. In particular some consumers may be confused as to whether a

product has been smoked or been treated with smoke flavouring. Wood used for smoking should not be treated with chemical substances at all. Advanced smoking method should be preferred.

The group sees the possibility to neutralise all oils by the mean of NaOH in line with the objectives and principles of organic regulation. Because of the carcinogenic effects of 3-MCDP and the need of refining for a reasonable amount of organic oils, as due to the negative effects from high temperature applications toward formation of 3 MCPD, the group proposes to delete in Annex VIII B for NaOH the specific condition “Oil production from rape seed (*Brassica spp*)” and replace it by “Oil production”.

The group considers that the use of silicon dioxide as anti-caking agent in propolis is in line in line with the objectives, criteria and principles of organic regulation. The specific conditions for silicon dioxide, currently written as “anti-caking agent for herbs and spices” (plus amendments proposed in chapter 7.12) in Annex VIII A should be amended to add and for propolis.

1. BACKGROUND

In recent years, several Member States have submitted dossiers under the second subparagraph of Article 21(2) of Council Regulation (EC) No 834/2007¹ concerning the possible inclusion, deletion or change of deposition of a number of substances in Annex VIII to Commission Regulation (EC) No 889/2008², or more generally, on their compliance with the above-mentioned legislation. Furthermore, several Member States have requested also evaluation of some techniques used in food production in terms of their usefulness to and compliance with the EU organic farming legislation. Besides, in order not to jeopardise the work on the priorities set by the previous mandate, the EGTOP Report on Organic Food 5/2012 did not assess the use of the following: possible changes of the specific conditions for substances already mentioned in Annex VIII for the production of organic flavours. Therefore, the Group is requested to prepare report with technical advice on the matters included in the terms of reference.

2. TERMS OF REFERENCE

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

1. To provide technical advice on matters concerning flavours and their use in organic food processing, in particular:
 - a) FR dossier (2013): Allowance for the use of the following substances listed in Annex VIII in all organic flavourings:
 - Ascorbic acid (E 300) as antioxidant
 - Tocopherol-rich extract (Tocopherols) (E 306) as agent preventing flavourings from oxidation
 - Lecithins (E 322) as emulsifier
 - Citric acid (E 330) as acidity regulator
 - Sodium alginate (E 401) as carrier/stabiliser
 - Carrageenan (E 407) as carrier/stabiliser

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

² Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, OJ L 250, 18.9.2008, p. 1–84

- Glycerol (E 422) as carrier
 - Pectin (E 440 (i)) as stabiliser /emulsifier/carrier
 - Hydroxypropyl methyl cellulose (E 464) as carrier
 - Magnesium carbonates (E 504) as anti-caking agent
 - Sodium hydroxide (E 524) as acidity regulator
 - Silicon dioxide (E 551) as anti-caking agent
- b) Requirements and techniques for the production of organic flavours
- Technical requirements for the production of organic flavours
 - Extraction technologies and solvents
- c) SE dossier (2011): Smoke condensates/smoke flavours

In preparing the final report, the Group may assess if food processing methods included in the EU organic farming regulation are in line with the organic farming principles. 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. Any such proposal(s) should be accompanied by a brief explanation of the reason.

3. GENERAL REFLECTION ON FLAVOURS USED IN ORGANIC FOODS AND “ORGANIC” FLAVOURS

Flavourings are added as ingredient to food in order to improve and/or change the original flavour or to add a new flavour. They are added to significantly influence the sensory profile of a food. Sometimes they help to create completely new types of foods.

To use flavourings in organic food or to produce such flavourings in organic quality means to find a good balance in between working for “producing a wide variety of foods ... that respond to consumers` demand for goods produced” (Article 3 (c) Council Regulation (EC) No 834/2007) and “the exclusion of substances and processing methods that might be misleading regarding the true nature of the product” (Article 6 (c)) Council Regulation (EC) No 834/2007).

Flavours are substances falling under the legal definition of food (Regulation (EC) No 178/2002³ Article 2). Flavouring substances stimulate the taste and flavour receptors. Flavours are constituents of food or can be added as ingredient. Regarding adding them as ingredients, different categories need to be distinguished; flavourings, flavouring substances, natural flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings. (See definitions in Regulation (EC) No 1334/2008⁴). At the moment for the production of organic foods all flavour extracts and natural flavour preparations are allowed with the exception of those produced from or by GMOs (Article 4 (a) (iii) Council Regulation (EC) No. 834/2008).

There is an inherent contradiction between the principles that the organic product should not mislead regarding the true nature and the use of flavours. Using flavours in food production means, in general, that there is a potential to mislead the consumer (Koerber Kv. 1995, Grim H.-U. 1999, Weiss G. 2001, Becker U. 2003) on the true nature of a product or to correct the results of negligence or losses of flavour during processing and handling. Whether this is the case, depends on the specific use of flavouring in production of a specific product and cannot be judged during the evaluation work for additives used for organic flavours within this mandate. The organic consumer has a specific perception toward the restrictive use of flavours in organic foods (Onyango B.M. 2007)

There is a need to adopt the requirements given for flavouring by Article 27 (1) c) of Commission Regulation (EC) No 889/2008 to the new horizontal flavouring regulation (Regulation (EC) No 1334/2008, see chapter 4 of this report). Enabling the production of organic flavours will help to meet the requirements of Organic Regulation. “Organic flavouring preparations” are “food” by definition of Regulation (EC) No 178/2002 and have to be seen within the scope of Organic Regulation (Article 1 of Council Regulation (EC) No 834/2007). They must be produced from organic raw materials using methods, processing aids, carriers, extraction material and additives which fulfil the requirements of the Organic Regulation. To discuss such substances, conditions and requirements-will be the main target of this report.

³ REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

⁴ REGULATION (EC) No 1334/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC

Organic flavourings must meet the criteria given in the Organic Regulation. Several times (Hoffmann S. 2011, Bioland 2008) it was stressed that the requirements for the production of organic food in the Organic Regulation needs to be a partly justified in order to build an adequate framework for “organic flavourings” because of the specific meaning of such substances.

There is a specific characteristic of flavourings compared to other food. In flavouring preparations the "characterising flavour components", responsible for the flavour and taste, is often only present in a very small amount. This has two possible critical consequences based on current Organic Regulation which have a potential to mislead the consumer.

1. There is a risk that the characterising flavour components in an organic flavouring do not come from organic source because the amount of these characterising flavours used is very low. Further on in calculating the proportions of flavourings the flavour ingredients are not calculated as ingredients of agricultural origin within the 95% concept.

2. There is a risk that the characterising flavouring components in an organic flavouring preparation does not come from the named (characterising) plant mentioned on the labelling and therefore mislead the consumer on the main characteristic of the product.

There is a specific group of flavours known as top notes, which are added to fruit preparations to replace flavours and aromas lost during processing (concentration) of the juice. The group is of the opinion that these must be from organic fruit in order for the juice to be labelled as organic.

The group has the opinion that in a middle timescale the use of conventional natural flavourings should be completely phased out and that their use should be replaced by organic flavourings. Therefore we ask for a clear legal mechanism to enforce this process.

This process can start with restricting use of conventional natural flavours (Chapter 4 in this report).

Furthermore there is a clear need for defined requirements in order to facilitate the production and processing of organic flavourings (Chapter 5.1).

4. REVISION OF THE CURRENT REQUIREMENT IN EUROPEAN REGULATUION COMMISSION (EC) NO 889 ART 27 (1) (C)

The current Commission Regulation (EC) No 889/2008 Art 27 (1)(c)) refers to the old flavouring regulation. This requirement needs to be adapted to those of the new flavouring Regulation (EC) 1334/2008 (See Annex I).

In the old flavour Directive 88/388/CEE⁵ there was no strict and quantitative relationship between the source material qualified as “natural” on the labelling and the raw material effectively responsible of the final flavour perception and taste, and therefore a risk of misleading consumers.

The new flavour Regulation 1334/2008 does not substantially change the principles for natural flavourings processing. However, this new regulation delivers new labelling requirements with

⁵ COUNCIL DIRECTIVE of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production

more developed possibilities for distinguishing the raw material origin responsible for the flavour. If a source is mentioned, at least 95% of the flavouring component should be obtained from the material referred to. As the use of flavourings should not mislead the consumer, the other maximum 5 % cannot reproduce the flavour profile.

The new flavour regulation defines 3 new labelling wording using the term “Natural” referring to a source material X:

Article 16.4 Natural “X” flavouring

The term "natural" may only be used in combination with a reference to a food, food category or a vegetable or animal flavouring source if the flavouring component has been obtained exclusively or by at least 95% by w/w from the source material referred to.

NB: the 5% part left cannot reproduce the total flavour profile. This means all flavouring compounds are derived from the product they are named after.

Article 16.5 Natural “X” flavouring with other natural flavourings

The term "natural food(s) or food category or source(s) flavouring with other natural flavourings" may only be used if the flavouring component is partially derived from the source material referred to, the flavour of which can easily be recognised.

This means that some of the flavouring compounds are derived from the product they are named after.

Article 16.6 Natural flavouring

The term "natural flavouring" may only be used if the flavouring component is derived from different source materials and where a reference to the source materials would not reflect their flavour or taste.

In this case the source of the flavouring compound is natural but has no relation to the product that the flavour tastes/smells of.

Reflection of the group

The Group has the opinion that consumers expect by buying organic foods that the flavouring component responsible for the flavour and taste of the product should come from the material referred to (named fruit). Therefore it seems to be appropriate to restrict the use of natural flavours to those natural flavours where the identity of the flavour characteristic and the material referred to (named fruit) is guaranteed.

This can be granted by a clear reference to the requirements for source material in labelling of natural flavouring substances and flavouring preparations in Regulation (EC) No 1334/2008.

Private organic foods standards setters (Demeter 2013; BioSuisse 2013) in some European countries have for many years limited the products to which flavours may be added. The group sees that this trend should be continued by establishing this concept in the Organic Regulation.

Current requirements on conventional natural flavours should be restricted and eventually phased out, step by step without disturbing the market

Conclusion

Because there is a risk of misleading the consumer (Article 6 (6) and 19 (3)) of Council Regulation (EC) No 834/2007) we propose to not permit substances referred to in labelling requirements under Article 16 (6) of the new flavouring regulation (Regulation (EC) 1334/2008). The group proposes to establish in Organic Regulation a link to the new flavouring regulation. This link should allow flavour extracts (Article 3 (2) d)) and "natural" flavours (Article 3 (2) c)

restricted to those natural flavourings as defined in Article 16 (4), (5) of Regulation (EC) No 1334/2008.

Further, we propose to restrict the use of natural flavourings to specific processed food product groups e.g. tea products, sweets, milk products.

5. REQUIREMENTS AND TECHNIQUES FOR THE PRODUCTION OF ORGANIC FLAVOURINGS

Flavours are in the scope of organic regulation when they come from agricultural origin. Flavours are foods in accordance with Article 2 of the Regulation (EC) 178/2002. Based on Article 1 (2) b) of organic Council Regulation (EC) No 834/2007 the substances are in the scope of organic regulation and can be produced in organic quality. In a Delphi survey the hypotheses that flavours should be certified organic had high levels of acceptance with of 66.3% agreement (KRETZSCHMAR U. 2006).

The production of flavours and especially of natural flavours has some specifics. Therefore we propose to establish some additional specific requirements for organic flavour processing.

5.1. Proposed additional requirements

Flavours and some carriers are currently not part of the percentage calculation with the 5% concept of organic labelling. Theoretically this means conventional flavours (extracts and natural ones) and some carriers can be used in an organic product without limitation (Article 27 (2) (b)) of Regulation EC 889/2008 and Article 23 (4)(a)(ii) of Council Regulation (EC) 834/2007). This is in the opinion of the group not acceptable for “organic” flavourings because of the potential for misleading the consumers (Article (6) (c) Council Regulation (EC) 834/2007).).

All the carriers positively evaluated in this report have the potential to be produced in organic quality. Nevertheless they are not currently available organically; therefore we propose to allow them in conventional quality. In order to create sensible requirements the majority of the total weight of ingredients of organic flavouring should come from organic origin. Otherwise there is a risk that organic flavours will be made with over 50% of non-organic carriers. This should be seen as a transitional mechanism only while these carriers are not available in organic form.

As proposed in chapter 4, only natural flavourings in accordance to Articles 16 (4) and 16 (5) of the new flavourings regulation should be allowed for organic food processing. Consequently, only those flavourings should be in the scope of organic flavouring certification.

The Group has the opinion that consumers expect by buying organic foods that the flavouring component responsible for the flavour and taste of the product should come from the material referred to (named fruit). This means for organic flavouring that all the compounds responsible for the flavour and taste must be from organic origin.

Proposals

The group proposes the following, in order of priority:

1. Flavourings should be calculated as ingredients of agriculture origin.
2. Only organic carriers (ethanol, oil, fat, maltodextrin, etc.) should be allowed and included in the calculation of the percentage of agricultural ingredients
3. As long as glycerol and sodium alginate are not available in organic quality they should be allowed as conventional carriers and must not be part of the percentage calculation of agricultural ingredients. (ref. Chapter 7.5, 7.7). In this case in accordance with Article 19

- (2)(a) of Council Regulation 834/2007 the majority of the ingredients should be from organic origin. The Group proposes to define this majority as more than 50%.
4. Only natural flavourings as defined in Article 16 (4) and 16 (5) of Regulation EC No. 1334/2008 are in the scope of the organic regulation.
 5. Regulation (EC) No 1334/2008 (Article 16) defines a quantitative relationship between the flavouring component responsible for the flavour and taste and the source material referred in labelling qualified as natural is established. However, for organic flavourings, all of these flavour component must be organic.
 6. Additives, solvents and processing aids must be used in organic form when available.

In general, processing of an organic flavouring must follow the requirements of the regulation including the technical details given in article 27 and Annex VIII of Commission Regulation (EC) No 889/2008.

5.2. Transitional permissions system for conventional flavourings

In order to reduce the use of conventional flavourings and transfer their use to organic flavourings, a mechanism should be established to ensure that if organic flavourings are available in sufficient quantity and quality, they must be used.

6. INTRODUCTION REMARKS TO THE SUBSTANCES UNDER EVALUATION

In the dossier presented to EGTOP all substances mentioned are currently listed in Annex VIII of European Commission (EC) No 889/2008.

For a number of these (Tocopherol rich extract, Glycerol, Silicon dioxide, Sodium hydroxide, Hydroxypropyl methyl cellulose) substance specific conditions in annex VIII are defined. Others (Ascorbic acid, Lecithin, Citric acid, Sodium alginate, Carrageen, Pectin, Magnesium carbonate) are generally authorised for plant derived organic foods. The majority of substances have specific conditions defined for foods from animal origin.

Flavours are predominantly produced from plant material but sometimes animal based materials are involved. This means a number of the substances requested could already be used on the basis of the current regulation for flavours based on (mainly) plant products but not for products based on animal products. The other substances requested are currently limited by Annex VIII not appropriate for application in flavourings. Therefore the target of this report is to clarify the “Specific conditions” for the requested substances.

In general organic flavours and flavourings have to fulfil following technological properties. In order to keep the intensity, quality and diversity of the flavour the organic flavours need to be resistant against; heat applications, reaction with the constituents of food, a low pH, oxidation, storage life, off flavour and must be soluble in different systems (water, fat, solid). Further, the flavour should not have negative influence on the overall appearance of the product for example by haze formation in soft drinks.

It should be noted that in most instances flavourings are used to add flavour and diversity to products but in some instances, such as soya based products the flavourings are used partly to overcome the natural flavours

Based on the list from Hoffmann (2011) the following are the most important areas where flavourings are used in organic products.

Whey drinks
Fruit yoghurts
Quark
Buttermilk products
Desserts
Soya drinks & yoghurts
Fruit products for pastries
Soft drinks
Sweets
Tea.

7. CONSIDERATIONS AND CONCLUSIONS

7.1 Ascorbic acid as antioxidant for organic flavourings

Introduction, scope of this report

The request refers to the possible use of ascorbic acid / L-ascorbic acid (E300) as a food additive (antioxidant) (Annex VIII A to Commission Regulation (EC) No 889/2008 in the production of organic flavourings. Ascorbic acid is currently authorised as food additive in Annex VIII A for food of plant origin and for food of animal origin (only for meat products). It is also authorised in ANNEX VIII A as food additive for organic products of the wine sector.

Authorisation in general food processing and production of flavours

Ascorbic acid is authorised as food additive (E300) in Regulation (EC) No 1333/2008⁶ of the European Parliament and of the Council (EC, 2008b).

Ascorbic acid is authorised as food additive in flavourings in Annex III Regulation (EC) No 1333/2008 following the quantum satis principle. (See definitions below.)

Agronomic use, technological or physiological functionality for the intended use

According to Codex General Standard for Food Additives (GSFA) functional classes of ascorbic acid are:

- Acidity regulator
- Antioxidant
- Flour treatment agent.

“Antioxidant properties of ascorbic acid are exploited in food processing (25% of total production of ascorbic acid) and beverage manufacturing (15%) to prevent pigment discoloration and enzymatic browning, to protect flavour and aroma and to protect or enhance nutrient content” (Hancock, and Viola, 2002)

Specific Uses in Flavouring

According to the relevant dossier ascorbic acid due to its reducing properties can be used to prevent flavourings from oxidation. Because of its hydrophilic nature, it is preferably used in

⁶ REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on food additives

aqueous products (e.g. seafood extracts), in emulsions and/or in flavourings for beverages. It is often used for its synergistic effect with other antioxidants like tocopherols.

Known alternatives

As antioxidant for flavourings in hydrophilic systems ascorbic acid is the only one available in Annex VIII A.

Origin of raw materials, methods of manufacture

According to the definition of Commission Regulation (EU) No 231/2012 ascorbic acid is white to pale yellow, odourless crystalline powder.

Commercial production of ascorbic acid:

Earlier ascorbic acid has been made commercially by extracting it from plants. This is considered the most natural method of production.

Later ascorbic acid was chemically synthesised. Presently it is being made by two processes.

The Reichstein process is a seven step combination of synthesis and microbial conversion. This process is used to produce the majority of commercial ascorbic acid.

The alternative is the more recent double fermentation process. This process is more natural than the Reichstein process, but is subject to concerns regarding the use of genetically modified organisms.

Environmental issues, use of resources, recycling

Although the Reichstein process has all the efficiency advantages that would be expected after >60 years development, it is still highly energy consuming and requires high temperatures and/or pressures for many steps. In addition, most of the chemical transformations involve considerable quantities of organic and inorganic solvents and reagents such as acetone, sulphuric acid and sodium hydroxide. Although some of the compounds can be recycled, stringent environmental control is required, resulting in significant waste disposal costs (Hancock and Viola, 2002).

The use of solvents and precipitation processes during the isolation and purification uses strong acids and alkalis which cause concern.

Animal welfare issues

No specific concerns

Human health issues

An ADI of 0–15mg/kg per kg bodyweight was allocated by the Joint Food Agriculture Organisation and World Health Organisation (FAO/WHO) experts Committee on Food Additives (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53.). The Committee concluded: “Animal studies reveal that ascorbic acid is not toxic after a single or repeated administration of relatively large doses. Studies in man indicate that ascorbic acid has a diuretic effect at 5mg/kg b.w. in children and adults and glycosuria was observed with doses of 30-100mg/kg. Daily doses, of the order of 200mg/kg, have been taken over periods of time for a therapeutic effect which has not been unequivocally demonstrated. The recommended dietary allowances range from 30-75mg with a minimum of 5-10mg/day. It is estimated that the daily intake of ascorbic acid is between 30-100mg from natural sources.”

Food quality and authenticity

Due to the small quantities of flavourings added to food, ascorbic acid as a flavouring additive will not change the authenticity of the foods.

Traditional use and precedents in organic production

Ascorbic acid is currently authorised as a food additive in Annex VIII A for food of plant origin and for food of animal origin (only for meat products). It is also authorised in ANNEX VIII A as a food additive for organic products of the wine sector.

Aspects of international harmonisation 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" ascorbic acid is permitted in food of plant origin provided insufficient natural sources are available (it is permitted, although exclusions of the GSFA still apply). Ascorbic acid is permitted in products of animal origin provided insufficient natural sources are available (only processed meat, poultry, and game products in whole pieces or cuts; Processed comminuted meat, poultry and game products; Edible casings (e.g., sausage casings)).

Permitted under USDA National Organic Programme §205.605 b Synthetics Allowed, without restriction.

In Japanese Organic Standards (JAS), Ascorbic Acid is permitted as an additive with the following condition. Limited to be used for processed foods of plant origin.

Ascorbic acid is permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive without restrictions.

Necessity for intended use

Because of its hydrophilic nature, it is preferably used in aqueous products (e.g. seafood extracts), in emulsions and/or in flavourings for beverages. It is often used for its synergic effect with other antioxidants like tocopherols.

Other relevant issues

None

Reflections of the Group

The argument in the dossier to authorise the use of ascorbic acid as a food additive for organic flavourings production is based on technical reasons. In particular ascorbic acid is clearly needed as the best available antioxidant in water based systems.

In the particular case of flavourings the quantity used is small and there should therefore be sufficient ascorbic acid produced from plant material. This material would be considered natural and so more compatible with natural flavourings.

The group expressed general concern over the fact that most commercial ascorbic acid is partially synthesised and the product from fermentation would be preferred if sufficient could be available from fermentation without using GM technology.

Conclusions

The use of ascorbic acid as a food additive (antioxidant) is in line with the objectives, criteria and principles of organic regulation. Therefore the group does not see any need to change the specific conditions for ascorbic acid.

Nevertheless the group would like to highlight that in implementation, use of ascorbic acid according Article 4 of Council Regulation (EC) No 834/2007, regarding synthetic products and products from GM origins, should be considered.

7.2 Tocopherol-rich extracts as agent preventing organic flavourings from oxidation

Introduction, scope of this report

The request refers to the possible use of tocopherol-rich extract (tocopherols) (E306) as food additive (agent preventing flavourings from oxidation) (Annex VIII A to Commission Regulation (EC) No 889/2008 in the production of certain organic flavourings. Tocopherol-rich extract is currently authorised as an antioxidant (Annex VIII A) for organic food of plant and animal origin (only in fats and oils).

Authorisation in general food processing and production of flavours

Tocopherol-rich extract is authorised as food additive (E306) in Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b).

Tocopherol-rich extracts are authorised as food additive in flavourings in Annex III to Reg. 1333/2008 following the quantum satis principle.

Agronomic use, technological or physiological functionality for the intended use

Tocopherol-rich extracts are used as antioxidants in food and in feed.

Specific Uses in Flavouring

According to the relevant dossier tocopherol-rich extract can be used to protect flavourings from oxidation, especially flavourings containing essential oils (esp. from citrus, or having a high aldehyde and/or terpene content that are subject to oxidation) or containing vegetable oils or other fats.

Known alternatives

Organic Rosemary extract may be used as an antioxidant for some oil based systems, but this may provide a flavour itself. It is also not allowed as an antioxidant for flavourings. Commission Regulation (EU) No 1130/2011⁷ also allows Rosemary Extract to be used as an antioxidant for flavours in Annex III Part 4. This use is also permitted in Annex VIII of Commission Regulation (EC) No 889/2008.

⁷ COMMISSION REGULATION (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients

Origin of raw materials, methods of manufacture

According to the definition of Commission Regulation (EU) No 231/2012 tocopherol-rich extract is a product obtained by the vacuum steam distillation of edible vegetable oil products, comprising concentrated tocopherols and tocotrienols. It may contain α -, β -, γ -, and δ -tocopherols and tocotrienols. It is brownish red to red, clear, viscous oil having a mild, characteristic odour and taste. It may show a slight separation of wax-like constituents in microcrystalline form.

“Tocopherols and tocotrienols are extremely valuable compounds because of their activity as anti-oxidising agent. Newer findings have shown that it is only the α -tocopherol form that contributes to the vitamin E activity. Nordic Nutrition Recommendations NNR 2004 [1] and National Academy of Science, Food and Nutrition Board: Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids (2000). http://www.nap.edu/openbook.php?record_id=9810&page=1 and it has become an important additive to all kind of food products. Today, most tocopherols are obtained by vacuum distillation of deodorising-step residues generated in the refining of vegetable oils. Throughout this process, that includes several steps such as solvent recovery and purification, copious amounts of organic solvents and energy are required, and thermal degradation of tocopherol is commonly encountered.

Increasing interest in both, detection and search for new alternative tocopherol extraction and isolation techniques has been observed. Among them, supercritical fluid technology has been applied to extract tocopherols from natural materials such as palm oil, rice bran or soybean, obtaining enrichment factors up to 4 with respect to the solvent-obtained extracts. Residues and by-products have also been used for extraction purposes.” (de Lucas et al 2002)

Environmental issues, use of resources, recycling

For vacuum steam distillation large quantities of organic solvents and energy are required

Commercially tocopherol-rich extract can be extracted from cottonseed, maize, rapeseed, rice germ, soya bean oil, wheat germ, or green leaves and may, therefore, come from genetically modified sources.

Animal welfare issues

No specific concerns

Human health issues

An ADI of 0–2mg/kg bodyweight (calculated as alpha-tocopherol) was allocated for alpha-tocopherol and mixed tocopherols concentrate by the Joint Food Agriculture Organisation and World Health Organisation (FAO/WHO) experts Committee on Food Additives (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53). The Committee concluded: “Though the toxicological studies are less than would normally be required for foreign substances used as food additives, it is considered that alpha-tocopherol is a nutrient. The clinical experience with this vitamin is used as the basis for the evaluation.”

Food quality and authenticity

Due to the small quantities of flavourings added to food tocopherol-rich extract as flavouring additive will not change the authenticity of the foods.

Traditional use and precedents in organic production

Tocopherol-rich extract is currently authorised as an antioxidant (Annex VIII A) for organic food of plant and animal origin (only in fats and oils).

Aspects of international harmonisation 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" tocopherol-rich extract is permitted in food of plant origin, although exclusions of the GSFA still apply. It is permitted in all mixed products of animal origin allowed under the General Standard for Food Additives and Standards adopted by the Codex Alimentarius Commission

Permitted under USDA National Organic Programme §205.605 Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labelled as "organic" or "made with organic (specified ingredients or food group(s)). Section b Synthetics Allowed, with the following conditions: "Tocopherols derived from vegetable oil when rosemary extracts are not a suitable alternative."

In Japanese Organic Standards (JAS) E307b Mixed tocopherols are allowed with the following condition: "In case used for processed foods of animal origin, limited to be used for processed meat."

It is also permitted as an additive in the IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids, as an additive, without restriction.

Necessity for intended use

Technical reasons mentioned in the dossier support the change of disposition in Annex VIII.

Other relevant issues

None.

Reflections of the Group

The argument in the dossier to authorise the use of tocopherol-rich extract as a food additive for organic food production is based on technical reasons.

The group notes that the current entry for tocopherol rich extract in Annex VIII A of Commission Regulation (EC) No 889/2008 refers to its use as an antioxidant for fats and oils only. The wording "fats and oils" seems superfluous as this material will not be used for aqueous products.

The group considers that the organic food sector should be encouraged to produce tocopherol rich extract in certified organic form, from organically grown agricultural ingredients.

Organic Rosemary extract is available as an antioxidant for many systems, but is not applicable to all due to its strong flavour.

Conclusions

The use of tocopherol rich extract as a food additive (antioxidant) in flavours is in line with the objectives, criteria and principles of organic regulation. Therefore the group does not see any

need to change the specific conditions for tocopherol rich extract in Annex VIII, with the exception of the need to delete the wording “for fats and oils”

7.3 Lecithins as emulsifier for organic flavourings

Introduction, scope of this report

The request refers to the possible use of lecithins (E322) (Synonyms: Phosphatides, Phospholipids) as a food additive (emulsifier) (Annex VIII A to Commission Regulation (EC) No 889/2008 (EC, 2008a) in the production of certain organic flavourings. Lecithins are currently authorised as a food additive (Annex VIII A) for all organic food of plant origin and for organic food of animal origin (only in milk products).

Authorisation in general food processing and production of flavours

Lecithins are authorised as food additive (E322) in Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b).

Lecithins are authorised as food additive in flavourings in Annex III Council Directive No 95/2/EC following the quantum satis principle.

Agronomic use, technological or physiological functionality for the intended use

Typical functions of lecithins in food production are: improvement of volume, fat dispersion, anti-stalling, reduction of viscosity, prevention of crystallisation, wetting, dispersion, stabilisation of product, prevention of spattering, browning and dispersion of the sediment.

The surface activity and ultimately the performance of commercial lecithin can be improved by physical, chemical or enzymatic methods. In contrast to normal trade lecithin, which complies with regular trade specifications and is produced straight after the degumming process, special lecithins are defined as products which have been processed in such a way that a specific surface activity has been achieved. (Van Nieuwenhuyzen 1981)

Specific Uses in Flavouring

According to the relevant dossier lecithins can be used as emulsifier for miscibility of flavourings ingredients, which can be hydrosoluble or not. E.g. to mix lipophilic flavouring preparations (e.g. spices or oleoresins) with an aqueous carrier.

Known alternatives

There are alternatives to lecithins, such as mono- and diglycerides, but these are not permitted for use in organic products, in Annex VIII A of regulation 889/2008.

Origin of raw materials, methods of manufacture

Lecithin is a natural lipid and is found in all living cells. It may be found in high quantities in egg yolks and in many oil-producing plants, for example, soya.

In the definition of Commission Regulation (EU) No 231/2012⁸ lecithins are mixtures or fractions of phosphatides obtained by physical procedures from animal or vegetable foodstuffs,

⁸ COMMISSION REGULATION (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council

they also include hydrolysed products obtained through the use of harmless and appropriate enzymes. The final product must not show any signs of residual enzyme activity. The lecithins may be slightly bleached in aqueous medium by means of hydrogen peroxide. This oxidation does not chemically modify the lecithin phosphatides. Lecithins are brown liquids or viscous semi-liquids or powder. Hydrolysed lecithins are light brown to brown viscous liquids or paste.

Animal lecithin products are derived from milk, eggs and brain. Vegetable lecithins, containing primarily Phosphatidyl Choline, PC, Phosphatidyl Ethanolamine, PE and Phosphatidyl Inositol, PI, are derived commercially from oil-bearing seeds such as soybeans, sunflower kernels and rapeseed (Van Nieuwenhuyzen & Mabel 2008).

Note that in the production of organic lecithin the use of hydrogen peroxide for bleaching is not permitted.

Environmental issues, use of resources, recycling

There is significant concern over the fact that the majority of lecithin is produced from soya, which may be subject to significant contamination with GM.

The use of acids and alkalis during production of modified lecithins and extraction solvents such as acetone may create environmental concerns.

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 estimated that acceptable daily intake of lecithins for man is not limited (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53.) In the Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives (Wld Hlth Org. techn. Rep. Ser., 1974, No. 539) and in the FAO Nutrition Meetings Report Series (1974, No. 53) it is stated: "Lecithin is an essential constituent of all cells of the human body. The organism is able to synthesise phosphatides and the pathway of catabolism of lecithin in the organism is well-known. The average diet provides a daily intake of several grams of lecithin (approximately 1-5g).

No information on the LD50 of lecithin has been found in the literature. Rapid infusion into cats of a 1.2% egg-yolk phosphatide emulsion containing 5% glucose (1 ml/kg/min) had no effect on the respiratory and circulatory systems; rapid infusion of soybean phosphatides caused a fall in blood pressure with apnoea (Schuberth & Wretlind, 1961).

Egg-yolk soybean and hydrogenated soybean phosphatides are used for the preparation of fat emulsions for parenteral nutrition. The newer fat emulsions prepared using well-purified phosphatide preparations show a small incidence of side-effects in animals and man. Lecithin can be considered a non-toxic substance, even when given parenterally.

Although fewer toxicological studies have been conducted than would normally be required for substances used as food additives, it is considered that nutritional and clinical experience with lecithin is sufficiently extensive to compensate for the incompleteness of the experimental data. Since many observations have been made in man it is not considered necessary to calculate the safe intake level from animal experiments. The ADI level is "not specified".

Food quality and authenticity

Due to the small quantities of flavourings added to food, lecithins as flavouring additive will not change the authenticity of the foods.

Traditional use and precedents in organic production

Lecithins are currently authorised as a food additive (Annex VIII A) for all organic food of plant origin and for organic food of animal origin (only in milk products).

Aspects of international harmonisation 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 2013) lecithins are permitted for all technical functions with exclusion of bleached lecithins and lecithins obtained with organic solvents. The Codex Alimentarius permits the use of lecithins in organic food of plant origin although, exclusion of the GSFA still apply and in organic food of animal origin (only in: Dairy products and analogues, excluding products of food category 02.002.0; Fats and oils, and fat emulsions; Emulsified sauces (e.g. mayonnaise, salad dressing; Infant formulae and follow-on formulae; Complementary foods for infants and young children.

Permitted in USDA NOP Regulations under §205.606 Non-organically produced agricultural products allowed as ingredients in or on processed products labelled as organic. p) Lecithins – de oiled. No reference to bleaching.

Permitted under Japanese Organic Standards (JAS) with the condition Lecithin (Vegetable-, Yolk-, Fractionated-) “Limited to those obtained without any bleaching treatment and in case used for processed foods of animal origin, limited to be used for dairy products, baby foods derived from milk, fat and oil products or dressing.

Permitted as both an additive and processing aid in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive with the condition “Obtained without bleaches”.

Necessity for intended use

Technical reasons mentioned in the dossier support the use of lecithins for organic flavourings in Annex VIII.

Other relevant issues

None

Reflections of the Group

The argument in the dossier to authorise the use of lecithins as emulsifier for the production of organic flavourings is based on technical reasons. There is a clear need for an emulsifier for use with organic flavourings and lecithin is considered the most appropriate of those available in the organic regulations.

The group considers that organic lecithin is now available and that only this source should be permitted for use as an additive. Organic lecithin is currently being exported in significant quantities from the EU to the US. The prohibition of bleaching in production of organic lecithin and the associated environmental and human health benefits is a further reason for moving to this form of lecithin for all uses in organic products.

Conclusions

The use of lecithin as a food additive (antioxidant) in flavourings is in line with the objectives, criteria and principles of organic regulation. Therefore the group does not see any need to change the specific conditions for lecithin, with the exception of the need to add the wording “in organic form only.”

7.4 Citric acid as acidity regulator for organic flavourings

Introduction, scope of this report

The request refers to the possible use of citric acid (E330) as food additive (acidity regulator) (Annex VIII A of Commission Regulation (EC) No 889/2008 (EC, 2008a) (hereafter called Annex VIII A)) in the production of organic flavourings. Citric acid is currently authorised as a food additive (Annex VIII A) for organic food of plant origin and for organic food of animal origin (only crustaceans and molluscs). It is also authorised as processing aid (Annex VIII B) for organic food of animal origin (only for regulation of the pH of the brine bath in cheese production) and for organic food of plant origin (only for oil production and hydrolysis of starch). Moreover citric acid is in Annex VIII C for the regulation of the pH in production of organic yeast.

Authorisation in general food processing and production of flavours

Citric acid is authorised as food additive (E330) in Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b).

Citric acid is authorised as food additive in flavourings in Annex III EC reg. 1333/2008 following the quantum satis principle.

Agronomic use, technological or physiological functionality for the intended use

Citric acid in food industry is used because of its: sour flavour, preservative quality and ability to act as a pH buffer.

Approximately 50% of the world's citric acid production is used as a flavour enhancer in beverages. Citric acid is used in soft drinks, teas, juices, and other beverages to create a slightly tart, refreshing flavour and to balance sweetness.

The acidic pH of citric acid also makes it useful as a preservative. Since many bacteria are unable to grow in an acidic environment, citric acid is often added to jams, jellies, candy, canned foods and even meat products as a preservative.

Citric acid is sometimes used to create an acidic environment and facilitate the ripening process when making cheese, particularly mozzarella. Citric acid is also used to adjust the pH of solutions when brewing both beer and wine

Specific Uses in Flavouring

According to the relevant dossier citric acid is used for two main functions and one secondary function:

1. (Main) Use as acid in the technological meaning: it allows the flavourings pH adjustment in order to compensate acidity variations of the natural raw materials and of extracts thereof; for adapting the pH of the flavouring to the specific technological requirements of the flavoured foodstuffs manufacturing. It is especially the case for dairy products (e.g. yoghurt) and beverages.

2. (Main) Use as acids in organoleptic meaning: naturally present in a large variety of fruits, citric acid used in flavourings contributes to the perception of certain flavour (e.g. some red fruits such as cranberries or yellow fruits such as apricot).
3. (Secondary) Citric acid, by decreasing pH of the flavouring, participates in the preservation of the flavouring. This effect could be useful and wanted when the alcoholic level of the flavouring has to be limited (case also of high level of use, or specific requirements of the user)."

Known alternatives

The alternatives to citric acid could be lemon juice (but this is not applicable for flavourings in a powder form).

Origin of raw materials, methods of manufacture

According to the definition of Commission Regulation (EU) No 231/2012 citric acid is produced from lemon or pineapple juice, or by fermentation of carbohydrate solutions or other suitable media using *Candida* spp. or non-toxicogenic strains of *Aspergillus niger*. Citric acid is a white or colourless, odourless, crystalline solid, having a strongly acid taste.

Citric acid is a natural, weak organic acid that is found in many fruits and vegetables, especially citrus. Because citric acid is also a by-product of the citric acid cycle, it is also produced by many living organisms, including fungi.

The supply of natural citric acid is limited and the demand can only be satisfied by biotechnological fermentation processes. Citric acid has been produced using various fungi since 1917 and by yeasts since 1960s. Nowadays, *Aspergillus niger* is almost exclusively used for industrial scale production of citric acid. More than 600,000 metric tons are produced annually worldwide." (Lotfy et al. 2007)

Environmental issues, use of resources, recycling

"The fermentation process is advantageous as it is based on renewable sources, it facilitates use of waste for productive purpose, and useful by-products are formed. It involves very mild environment friendly conditions and also consumes less energy. It also faces some drawbacks some of which are:

- (i) Use of large quantities of water
- (ii) Due to high BOD (biological oxygen demand) the waste requires treatment before disposal.
- (iii) Infection by foreign microbes can reduce the yield...." (Angumeenal & Venkappayya 2013)

On the one hand the biotechnological process of citric acid production using *Aspergillus niger* cause large amounts of wastes, which have to be removed (Moeller et al. 2007), on the other hand the citric acid effluent (CAE) can be utilised as the feedstock for algae growth as a renewable way to produce biodiesel (fatty acid methyl esters, FAME) while removing the carbon, nitrogen and phosphorous components of CAE (<https://sites.google.com/site/biomassgroup18/feasibility-analysis>).

The citric acid industry causes pollution concerns such as COD (chemical oxygen demand) and emissions of soot, sulfur dioxide and citric acid wastewater. China is the largest citric acid producer and exporter in the world. If sugar beet or maize is used as raw materials for fermentation they may be genetically modified.

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 estimated that acceptable daily intake of citric acid for man is not limited (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53.)

In the Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives (Wld Hlth Org. techn. Rep. Ser., 1974, No. 539) and in the FAO Nutrition Meetings Report Series (1974, No. 53) it is stated: "Citric acid is an intermediary substance in oxidative metabolism, being engaged in the tricarboxylic acid cycle. Citric acid occurs in many foods and are normal metabolites in the body (Gruber & Halbeisen, 1948). There is no reason to believe that the use of these citrates as food additives constitutes a significant toxicological hazard to man.

Ingestion of citric acid frequently or in large doses may cause erosion of teeth and local irritation, apparently because of the low pH: the effects also occur with lemon juice which contains about 7% citric acid and has a pH of less than 3. A 1% solution has been used as a cooling drink in fever (Martindale, 1972).

In evaluating the acceptance of citric acid, emphasis is placed on its well-established metabolic pathways. Toxicological studies on animals supplement this information. Citric acid and its calcium, potassium and sodium salts do not constitute a significant toxicological hazard to man." (FAO WHO <http://www.inchem.org/documents/jecfa/jecmono/v05je24.htm>)

Product might still contain mould and sulphur/sulphites not filtered out completely during the production (Sulphur dioxide and other sulphites (also referred to as sulphites), causing asthmatic and allergic reactions.) <http://www.traditionaloven.com/articles/122/>

Food quality and authenticity

Due to the small quantities of flavourings added to food citric acid as flavouring additive will not change the authenticity of the foods.

Traditional use and precedents in organic production

Citric acid is currently authorised as a food additive (Annex VIIIA, Regulation 889/2008) for organic food of plant origin and of animal origin (only crustaceans and molluscs). It is also authorised as processing aid (Annex VIIIB Regulation 889/2008) for organic food of animal origin (only for regulation of the pH of the brine bath in cheese production) and for organic food of plant origin (only for oil production and hydrolysis of starch) and for the regulation of the pH in production of organic yeast (Annex VIIC Regulation 889/2008).

Aspects of international harmonisation 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 2013), citric acid is included in the lists:

1. "Additives permitted for use under specified conditions in certain organic food categories or individual food items" for: food of plant origin - Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes and aloe vera), for seaweeds, for nuts and seeds; for food of animal origin As a coagulation agent for specific cheese products and for cooked eggs, Cheese and analogues, Fats and oils essentially free from water, Egg and egg products.
2. "Processing aids which may be used for the preparation of products of agricultural origin referred to in section 3 of these guidelines - Specific conditions" for pH adjustment.

Permitted in USDA National Organic Standards. §205.605 a Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labelled as “organic” or “made with organic (specified ingredients or food group(s)). a) Non synthetics allowed, with the specific condition: produced by microbial fermentation of carbohydrate substances.

Permitted in Japanese Organic Standards, JAS as an additive with the specific condition: Limited to be used as pH adjuster or used for processed vegetable products or processed fruit products.

Permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive, without restriction.

Necessity for intended use

Technical reasons mentioned in the dossier support the use of Citric Acid for organic flavourings in Annex VIII.

Other relevant issues

None

Reflections of the Group

The argument in the dossier to authorise the use of citric acid as a food additive for organic food production is based on the technical reasons.

There are clearly two sources, the fermentation product and the isolation from natural citrus juices. Many applications may be able to use concentrated organic lemon juice instead of purified citric acid. Citric acid may be isolated as a purified product from natural organic lemon juice, i.e. as organic citric acid. Furthermore, where organic lemon juice is not possible alternative citric acid extracted from organic lemons would be preferable to the current non-organic citric acid from biotechnology. Alternatively organic citric acid may be produced by fermentation of organic molasses.

Conclusions

The use of citric acid as a food additive is in line with the objectives, criteria and principles of organic regulation for use in flavourings. Therefore the group does not see any need to change the specific conditions for Citric acid.

7.5 Sodium alginate as carrier stabiliser for organic flavourings

Introduction, scope of this report

The authorisation, uses, sources and concerns relating to the use of Sodium Alginate (E401) as a carrier/stabiliser in organic flavourings

Authorisation in general food processing and production of flavours

Permitted as Food additive (Reg. (EC) No 1333/2008). Listed in Group 1 which allows use at quantum satis in a wide range of food products.

Already authorised in Annex VIIIA of Regulation (EC) No 889/2008 as food additive in organic foodstuffs of plant origin and milk-based products.

Sodium alginate is authorised as food additive in flavourings in Annex III to EC Reg. 1333/2008 following the quantum satis principle.

Agronomic use, technological or physiological functionality for the intended use

Used as a gelling agent/thickener in foods. Used to improve sliceability in meat products. (This would not be permitted for organic products.)

Specific Uses in Flavouring

Used as a carrier/stabiliser

Known alternatives

Other polysaccharides such as pectin and carrageenan may provide alternatives, but the specific properties of each are not sufficiently clear to be certain that sodium alginate could be replaced by these in all uses in flavourings.

Origin of raw materials, methods of manufacture.

Alginic acid is extracted from seaweed, such as *Ascophyllum nodosum*, by extraction of the seaweed with hot sodium carbonate. This is filtered, with difficulty due to the viscosity, to remove cellulose etc. The alginates can be precipitated as calcium alginate by addition of calcium salts or as alginic acid by addition of acid. Sodium alginate is then manufactured by reacting the calcium alginate or alginic acid with sodium hydroxide.

Environmental issues, use of resources, recycling

Environmental issues relate to harvesting of seaweed, which may or may not be done sustainably. Certified organic seaweed harvesting, for which the harvesting is certified as sustainable is carried out but the use of acids and alkalis in manufacture prevents production of organic Sodium Alginate under current organic regulations. Harvesting issues include both the loss of seaweed itself, the loss of habitat for other wildlife due to harvesting and pollution and other environmental damage due to the harvesting operation.

Environmental issues must also be considered for the manufacture of sodium alginate, such as the use of large quantities of acid and alkali and the manufacture thereof.

Animal welfare issues

None.

Human health issues

None reported at high dosage. (Ref: <http://www.ncbi.nlm.nih.gov/pubmed/1778263>)

No concerns over toxicity, terratogenicity etc. identified.

The ADI has been calculated for humans at 0-25mg/kg b.w., calculated as alginic acid.

Food quality and authenticity

In normal food use, Alginates may be used to add mouth-feel and texture to products such as ice cream, masking issues caused by over processing. Also used in meat production to create mouth-feel in reconstituted ham products (although not permitted for this use in organic production). Also used as a processing aid as a coagulation agent in beers and wines.

Due to the small quantities of flavourings added to food alginates as flavouring additive will not change the authenticity of the foods.

Traditional use and precedents in organic production

No traditional use. Permitted in organic production for use with plant products and milk based animal products.

Aspects of international harmonisation 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 2013), Sodium alginate and Potassium alginate are included in the list in: Table 3: Ingredients of non-agricultural origin referred to in section 3 of these guidelines, 3.1 Food additives, including carriers, without restrictions.

Permitted in US National Organic Programme List of permitted substances §205.605 Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labelled as "organic" or "made with organic (specified ingredients or food group(s))", section b Synthetics allowed.

Permitted as an additive in Japanese Organic Standards (JAS), only for use with plant derived products.

Permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive without conditions.

Necessity for intended use

It is clear that some polysaccharide carriers are needed in flavourings. The respective need for different polysaccharides is not clear. Nevertheless we see a necessity for sodium alginate, particularly in view of our view regarding carrageenan, below.

Other relevant issues

None

Reflections of the Group

There is a potential for Sodium Alginate to be produced in organic quality from organically grown or harvested seaweed. (Ref. <http://www.fao.org/docrep/006/y4765e/y4765e08.htm>).

The group considers that the organic food sector should be encouraged to produce sodium alginate in certified organic form from organically harvested or cultured seaweed.

Conclusions

The use of sodium alginate as a food additive for plant products and for milk based products is in line with objectives, criteria and principles of organic farming also for use in flavourings. Therefore the group does not see any need to change the specific conditions for sodium alginate. Organic sources should be preferred.

7.6 Carrageenan as carrier and stabiliser for organic flavourings

Introduction, scope of this report

This report covers the proposal for addition to Regulation 889/2008 of carrageenan (E407) as a carrier/stabiliser for organic flavourings.

Authorisation in general food processing and production of flavours

Permitted as Food additive (Reg. (EC) No 1333/2008). Listed in Group 1 which allows use at quantum satis in a wide range of food products.

Carrageenan is authorised as food additive in flavourings in Annex III EC reg. 1333/2008 following the quantum satis principle.

Agronomic use, technological or physiological functionality for the intended use

Carrageenan is used in foods as a thickener/gelling agent. Also as a carrier.

The general definition of a carrier is a food additive that is used to dissolve, dilute, extract, disperse, deliver or otherwise physically modify a component, ingredient, food additive or other food, without exerting any other effect on its own.

Specific uses in flavourings

Specific use applied for is as a carrier/stabiliser.

Known alternatives

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

Origin of raw materials, methods of manufacture

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

Environmental issues, use of resources, recycling

Cultivation and harvesting of seaweed may create environmental concerns due to habitat damage, over harvesting or pollution associated with the harvesting or cultivation processes, unless produced from organically cultivated or harvested seaweed.

Preparation of carrageenan will be expected to have less environmental effect than sodium alginate due to the lower use of acids and alkalis.

Animal welfare issues

None.

Human health issues

The human toxicological position of Carrageenan was last evaluated by the EC Scientific Committee on food in 1992. (Ref: http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_35.pdf)

Subsequent studies have shown that low molecular weight carrageenans can cause gut inflammation and may be associated with precancerous changes in the gut.

However, commercial carrageenan is purified to remove the low molecular weight polymers. One key question is whether there is breakdown of the high molecular weight product to low molecular weight in the gut. This may occur due either to simple acid hydrolysis or to enzymatic breakdown caused by production of carrageenase by some gut bacteria. There is significant argument over this issue in current literature. (Ref: http://www.cornucopia.org/DrTobacmanComment_to_NOSB.pdf)

A study reported ulceration of the intestine of guinea pigs fed high doses of carrageenan, but this was not replicated in a study with rats, which identified no irreversible changes and no histopathology.

Studies of the carcinogenicity of carrageenan in rats have shown no effect. In addition, the results of assays for the genotoxicity of carrageenan have been negative. A proliferative response of the mucosa of the gastrointestinal tract of rats fed two forms of carrageenan at 2.6 or 5% of the diet has been reported; the response was reversible in the study in which 5% carrageenan was given. (Ref: <http://www.inchem.org/documents/jecfa/jecmono/v042je08.htm>)

There was evidence that carrageenan can affect the immune response of the gastrointestinal tract; however, no validated tests for assessing the nature and potential consequences of such an effect were available. (Ref: <http://www.inchem.org/documents/jecfa/jecmono/v042je08.htm>)

No ADI has been set and the high molecular weight product is generally regarded as safe.

Food quality and authenticity

Like sodium alginate, carrageenan has been used in pates and processed meats to correct texture and sliceability missing from highly processed meat products. This use would not be permitted in organic products. It is also used to increase viscosity of ice creams, dressings etc. It can therefore be used to hide processing defects.

Due to the small quantities of flavourings added to food carrageenan as flavouring additive will not change the authenticity of the foods.

Traditional use and precedents in organic production

Carrageenan has been used as a gelling agent and clarification agent for many years. It is permitted for use as an additive in organic products under regulation 889/2008. The permission for use as an additive in animal derived products is limited to dairy products only.

Aspects of international harmonisation of organic farming standards

Permitted under §205.605 of the US National Organic Programme. Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labelled as “organic” or “made with organic (specified ingredients or food group(s)). Section a. Non Synthetics allowed.

Permitted in Japanese Organic Standards (JAS). Table 1. Food additives. Limited for animal products to dairy products only.

Permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive.

Necessity for intended use

It is clear that some polysaccharide carriers are needed in flavourings. The respective need for different polysaccharides is not clear. It may be therefore that carrageenan is not required in flavours, due to the availability of alternatives.

Reflections of the Group

In view of the concerns over immune & inflammatory response in the intestinal tract and the availability of similar polysaccharides as additives in the organic farming regulations the group considers that the presence of carrageenan in Annex VIII A of regulation 889/2008 should be reconsidered.

The group sees a potential contradiction to the requirement of Article 3 (c) of EC Reg. 834/2007 that organic products should not harm human health.

Further on because of the positive evaluation of other carriers and stabilisers within this report, where no such concerns occur, the group do not see a necessity (Art 21 (1) (i) and (ii) EC Reg. 834/2007) for accepting carrageenan as an another carrier and stabiliser because of its specific technological properties

There is a potential for carrageenan to be produced in organic quality from organically grown or harvested seaweed. The group considers that if it is to continue to be permitted, the organic food sector should be encouraged to produce carrageenan in certified organic form from organically harvested or cultured seaweed.

Conclusions

The use of carrageenan as an additive is in line with the objectives, criteria & principles of organic regulation for use in flavourings, from the technical perspective.

However, because of newest toxicological findings the group sees the need for a re-evaluation of this additive by EFSA. In line with the precautionary principle, the Group proposes to postpone any decisions on the use of carrageenan until all doubts concerning possible human health effects have been removed.

The Group does not recommend the use of carrageenan in organic production until these concerns have been addressed.

7.7 Glycerol as carrier for organic flavourings

Introduction, scope of this report

This report covers the application for addition of glycerol (E422) as a carrier for use in organic flavours.

Authorisation in general food processing and production of flavours

Permitted as Food additive (Reg. (EC) No 1333/2008). Listed in Group 1 which allows use at quantum satis in a wide range of food products.

Already authorised in Annex VIII A of Regulation (EC) No 889/2008 as food additive in organic foodstuffs with the specific condition, "For plant extracts". Therefore not permitted for use with animal products.

Glycerol is authorised as food additive in flavourings in Annex III EC Reg. 1333/2008 following the quantum satis principle and is therefore authorised for the use in flavourings.

Agronomic use, technological or physiological functionality for the intended use

It is used as a humectant (moisturising agent) in many foods such as tortillas, icing, cakes etc. This use would not be permitted in organic products. It is also used as thickener and as a carrier and solvent in plant extracts such as tinctures, oils etc.

Specific Uses in Flavouring

Glycerol is used in flavourings to carry and dissolve flavour components for liquid flavourings or as a carrier for flavour components onto solid compounds.

It is also used as a solvent to extract specific flavours from plant materials.

Known alternatives

Ethanol may be an alternative carrier and solvent for some plant extracts, but it does not have the same range of solubilising ability as glycerol and is unacceptable to some due to religious constraints. Further, glycerol has specific technological properties because of the high evaporating temperature compared to other carriers available for organic flavours and has therefore a specific relevance. (Hoffmann, 2011)

Origin of raw materials, methods of manufacture.

Glycerol is manufactured from fats and oils by two processes. Firstly by saponification, which involves heating the fat or oil with alkali, such as sodium or potassium hydroxide. This produces the respective salt of the fatty acid and glycerol.

The alternative is production as a by-product of the manufacture of biodiesel, whereby oils are transesterified with enzymes producing the pure fatty acid which forms biodiesel and glycerol as a by-product. (Yang, et al 2012)

Environmental issues, use of resources, recycling

There is an excess production of glycerol as it is a by-product of biodiesel manufacture.

Animal welfare issues

None

Human health issues

Glycerol is of low toxicity when ingested, inhaled or by contact with the skin. (Ref: <http://www.inchem.org/documents/sids/sids/56815.pdf>)

There is no published evidence to indicate that glycerol is carcinogenic or harmful in any other way.

It is a natural constituent of all animals as a basic molecule produced in energy metabolism and used in production of fats.

The risk of contaminants must be considered particularly if glycerol is to be derived as a by-product from the production of bio-diesel, where the purity of raw materials may lack control.

Food quality and authenticity

Glycerol may be used to make products appear moist and retain that feel for longer, e.g. baked goods and tortillas. It may also be used to improve mouth-feel of alcoholic drinks & liqueurs and to substitute for fats in low calorie products etc. so can be used to create non-authentic qualities in foods. However, none of these uses would be permitted in organic foods.

Due to the small quantities of flavourings added to food glycerol as a carrier will not change the authenticity of the foods.

Traditional use and precedents in organic production

Glycerol is not a traditional ingredient, as its isolation and characterisation were fairly recent and it was not traditionally extracted from saponified fats. It is only used in organic production as a carrier and solvent for plant extracts. It is naturally produced in several foods including wines, due to formation by yeast as a by-product of fermentation. However, its uses has been permitted in organic production since the inception of EU regulation 2092/91.

Aspects of international harmonisation of organic farming standards

Permitted under §205.605 of the US National Organic Programme. Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labelled as “organic” or “made with organic (specified ingredients or food group(s)). Section b. Synthetics allowed, as glycerine with the specific condition that it is only allowed if produced by hydrolysis of fats and oils. This would appear to preclude the use of glycerine (glycerol) made by transesterification of oils.

NOT permitted as an additive in Japanese Organic Standards (JAS).

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

Necessity for intended use

Glycerol is an ideal solvent and carrier for ingredients of flavours due to its low toxicity, high capacity to dissolve oil and water based components, its high evaporation point and its non-extraction/dissolution of undesirable plant materials such as tannins. It is also acceptable to religious minorities and infants where ethanol would be an unacceptable alternative.

Further glycerol when used as a carrier for flavourings in heated products such as baked products, helps to prevent evaporation of the flavours.

It is clear that some solvents are required in flavourings, other than water and ethanol. Glycerol has significant advantages in some cases over and above water & ethanol.

Other relevant issues

None

Reflections of the Group

The group sees a necessity for having glycerol available as a solvent and carrier for organic flavourings because of its specific technological properties.

The previous EGTOP discussed the origin of glycerol. That group was of the opinion that the source of glycerol should be restricted to plant derived material. There is a potential for glycerol to be produced in organic quality from organically grown plant oils. The group considers that the organic food sector should be encouraged to produce glycerol in certified organic form from organically grown crops. The group like to refer to the recommendations made on glycerol in the first EGTOP food mandate.

Conclusions

The use of glycerol as a food additive for plant products is in line with objectives, criteria and principles of the organic regulation also for use in flavourings. However the group sees the need to expand the specific conditions set up in Annex VIII.

The previous EGTOP report on Food, recommended changing the wording of the specific condition from “for plant extracts” to “from plant origin”. Now we propose the specification “for plant extracts and flavourings”.

7.8 Pectin as stabiliser and carrier for flavourings***Introduction, scope of this report***

This report covers the application of Pectin (E440(i)) as a stabiliser/emulsifier/carrier in organic flavours.

Authorisation in general food processing and production of flavours

Permitted as Food additive (Regulation (EC) No1333/2008). Listed in Group 1 which allows use at quantum satis in a wide range of food products.

Permitted as a food additive (E440) for use as gelling agent, emulsifier, stabiliser and thickener. It is permitted in two forms E440a which is non-amidated and E440b which is amidated.

Non-amidated pectin E440a is available in pure pectin form E440a(i) or in sodium, potassium or ammonium forms as E440a (ii), (iii) or (iv) respectively.

Of these only E440a(i) is permitted as an additive in Commission Regulation (EC) No 889/2008. It is permitted for plant based products and for milk based products in the section of animal derived products.

Pectin is authorised as food additive in flavourings in Annex III EC Reg. 1333/2008 following the quantum satis principle.

Agronomic use, technological or physiological functionality for the intended use

It is used in foods as gelling and thickening agent, especially jams, marmalades.

Specific Uses in Flavouring

Used as a carrier/ bulking agent in flavourings.

Known alternatives

Other similar polysaccharides such as carrageenan, alginates etc. have similar functions, but they are not available in organic form. However the detailed comparison of the properties of each are not clearly available to make the comparison as to whether some would do all functions.

Origin of raw materials, methods of manufacture

The main raw-material for pectin production is citrus peel or apple pomace, the by-products of juice production.

From these materials, pectin is extracted by adding hot dilute acid (eg Hydrochloric Acid Ref <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1259415/?page=3>) at pH-values from 1.5–3.5. During several hours of extraction, the protopectin loses some of its branching and chain-length and goes into solution. After filtering, the extract is concentrated in vacuum and the pectin may be precipitated by adding ethanol or isopropanol. Alcohol-precipitated pectin is then separated, washed and dried. (Williams P., et al 2011)

Environmental issues, use of resources, recycling

It is a valuable by-product of juice production. No significant environmental issues

Animal welfare issues

None

Human health issues

Pectin is reported as having positive effects on human health as it is a soluble fibre. It is associated with reduction in blood cholesterol, by binding cholesterol in the gut. It has a probiotic effect, by stimulating growth of gut micro-organisms.

There is no proposed ADI “except for good manufacturing practice” (Ref: <http://www.inchem.org/documents/jecfa/jecmono/v46aje55.htm>)

Food quality and authenticity

Traditionally used to prepare jams, fruit jellies, etc.

Due to the small quantities of flavourings added to food pectin as flavouring additive will not change the authenticity of the foods.

Traditional use and precedents in organic production

Pectin has been used unknowingly to create thickened preserves for many hundreds of years, for example by the addition of quince or apple to strawberries during manufacture of jam to help thickening. Since characterisation it has been sold as a preparation for thickening jams and preserves.

Aspects of international harmonisation of organic farming standards

Permitted in National Organic Programme List of permitted substances §205.606 of the US. Non-organically produced agricultural products allowed as ingredients in or on processed products labelled as “organic.” (Non-amidated only)

Permitted as an additive in Japanese Organic Standards (JAS).

Permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive. Unmodified, ie non-amidated form only.

Necessity for intended use

It is clear that some polysaccharide carriers are needed in flavourings. The respective need for different polysaccharides is not clear. Nevertheless we see a necessity for Pectin.

Reflections of the group

Polysaccharides are required for organic flavourings and pectin would appear to be one of the most preferable. In particular it is produced as a by-product of food production and has none of the potential environmental concerns provided by harvesting of seaweeds.

There is a large potential for pectin to be produced in organic quality from organically grown crops (citrus or apples.)

The group considers that the organic food sector should be encouraged to produce pectin in certified organic form from organically harvested crops.

Conclusions

The use of pectin as a food additive is in line with objectives, criteria and principles of the organic regulation also for use in flavourings. Therefore the group does not see any need to change the specific conditions for pectin.

Organic sources should be preferred.

7.9 Hydroxypropyl methyl cellulose as carrier for organic flavourings

Introduction, scope of this report

The request refers to the possible use of Hydroxypropylmethyl cellulose (E464) 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 (organic flavours). Hydroxypropylmethyl cellulose is currently authorised in Annex VIII A of Regulation (EC) No 889/2008 as Food additive as encapsulation material for capsules in organic foodstuffs of plant and animal origins.

Authorisation in general food processing and production of flavours

Hydroxypropylmethyl cellulose (HCMC) is authorised as food additive (E464) in Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b).

Food categories in which Hydroxypropylmethyl cellulose can be used (following the quantum satis principle) are listed in Annex II Part E of this Regulation.

Hydroxypropylmethyl cellulose is authorised as food additive according to EC Regulation 1333/2008 and authorised as carrier for flavourings in Annex III.

Agronomic use, technological or physiological functionality for the intended use

Hydroxypropylmethyl cellulose is used in food as a thickening agent, stabiliser or emulsifier.

Typical functions of Hydroxypropylmethyl cellulose in food production are:

Improvement of volume, stabilising hot emulsions and suspensions, delayed release of flavours, and resorption of vitamins in the intestine, improving the creaminess of ice cream and better adhesion and lower fat intake in sauces and dips, for example. However it is not permitted for these uses in organic production. (Ref; Annex VIIIA of regulation 889/2008).

Specific Uses in Flavouring

This additive is used as a carrier, for encapsulation or pre-coating, and increases the thermal stability, resistance to abrasion and stability during storage of the flavourings.

Known alternatives

The additive hydroxypropylmethyl cellulose is currently not available in organic quality. Its use is compatible with the principles of organic food processing. Alternatively, organic gelatine could be used.

Origin of raw materials, methods of manufacture

Hydroxypropylmethyl cellulose is cellulose obtained directly from strains of fibrous plant material and partially etherified with methyl groups and containing a small degree of hydroxypropyl substitution.

The chemical belonging to the group of hydroxypropylmethyl cellulose is a derivative of cellulose (E460). In contrast to this hydroxypropylcellulose is readily soluble in water. It gives a viscous liquid consistency, and when heated, forms strong gels. Their chemical structure gives the compound beyond emulsifying and stabilising properties.

There are significant quantities of organic cottonseed available from which HPMC could be prepared.

Environmental issues, use of resources, recycling

The production of HPMC uses waste raw materials such as cellulose fibres from seeds.

However organic solvents and strong acids are used in the manufacture of HPMC from the cellulose fibres

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 proposed an unconditional ADI of 0–30 mg/kg body weight is proposed, but a conditional limit is proposed for dietary or calorie control purposes. (Ref: <http://www.inchem.org/documents/jecfa/jecmono/40abcj18.htm>)

Food quality and authenticity

Due to the small quantities of flavourings added to food hydroxypropylmethyl cellulose as flavouring carrier will not change the authenticity of the foods. However, it is clear that encapsulated flavours may be used to hide the authentic nature of the food.

Traditional use and precedents in organic production

The function of hydroxypropylmethyl cellulose as a thickening agent which has a good solubility in cold water and which is forming gels at higher temperatures. This is different to other thickeners as gelatine, carrageen and pectin. Hydroxypropylmethyl cellulose is currently authorised in Annex VIII-A of Regulation (EC) No 889/2008 as an encapsulation material for capsules.

Aspects of international harmonisation 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" hydroxypropylmethyl cellulose is not permitted in food of plant origin.

Not permitted in US National Organic Programme List of permitted substances §205.606

Not listed as a permitted additive in Japanese Organic Standards (JAS).

NOT permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 –

Other relevant issues

None

Necessity for intended use

It is clear that HPMC is required for encapsulation of flavourings as there are no compounds that will carry out the same function in particular due to its temperature stability. (Ref Council Regulation (EC) No 834/2007 Article 21(1)(i)).

However the group expressed concerns that encapsulation of flavours for organic foods may not be in agreement with the principles of organic regulation. Council Regulation (EC) No 834/2007 21(1)(ii) as it is possible to produce and preserve the food without these substances.

Reflections of the Group

To increase flavour of organic products, operators may use more or better organic ingredients, add flavours or add encapsulated flavours.

The objective of encapsulation is to increase the keeping time of flavours. This technology is only available to larger producers, limiting choice of products and hiding the true nature of the product. (Ref Article 6 (c) Reg. 834/2007). Its availability also reduces the use of organic food ingredients. This happens because flavourings may be used to replace some organic ingredients.

Further, the consumer cannot verify the quality of flavour of encapsulated products by smell, as the aroma is only released on solubilisation. This is considered as misleading. (Ref Article 6 (c) Reg. 834/2007).

Finally it is possible to produce and preserve the food without these substances and therefore the substance does not fulfil the requirements set by Council Regulation (EC) No 834/2007 Art 21(1)(i).

Annex VIII of regulation 889/2008 confirms that HPMC is currently allowed for use as an "encapsulation material for capsules". This is not clear. We propose to clarify the wording to the extent that the term "capsules" is currently intended to cover food supplements. There should be specific reference to the relevant legislation on supplements.

We propose that HPMC should only be allowed for encapsulation of food supplements. There is a potential for HPMC to be produced from organically grown crops, but not in certified organic form due to the reagents needed to convert cellulose to HPMC.

Conclusions

The use of HPMC as a food additive for encapsulation of flavourings is not in line with the principles, criteria and objectives of the organic regulation because of the concern that encapsulation of flavourings is misleading to the consumer (Council Regulation (EC) No. 834/2007 Article (6) (c)) and the substance is not necessary for the production (EC Reg. 834/2007 Art 21(1)(ii)) of an organic product.

The current specific conditions for HPMC should be rephrased to allow encapsulation only for capsules for food supplements.

7.10 Sodium hydroxide as acidity regulator for organic flavourings

Introduction, scope of this report

The request refers to the possible use of sodium hydroxide (E 524) as a food additive (Annex VIII A to Commission Regulation (EC) No 889/2008 (EC, 2008a). Sodium hydroxide is currently listed in Annexes II and III to Regulation (EC) No 1333/2008 as food additive as a material for acidity regulation in organic foodstuffs.

Authorisation in general food processing and production of flavours

Sodium hydroxide is authorised as food additive (E464) in Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b).

Sodium hydroxide is authorised as food additive in flavourings in Annex III to EC reg. 1333/2008 following the quantum satis principle.

Agronomic use, technological or physiological functionality for the intended use

Sodium hydroxide is used for application in food and during processing of food. It increases the pH of foodstuff. Sodium hydroxide can stabilise flavourings when they are affected by acidity.

Known alternatives

The additive sodium hydroxide is not available in organic quality. In the preparation is a chemical reaction not related to the principles of organic food processing.

Origin of raw materials, methods of manufacture

Sodium hydroxide is an artificial product and is produced from sodium chloride by electrolysis. The electrolysis is done in different ways, i.e. membrane, amalgam or diaphragm technology.

Environmental issues, use of resources, recycling

The electrolytic conversion of sodium chloride to sodium hydroxide and chlorine produces reactive chlorine molecules that are hazardous. However, this risk is managed if correctly produced and handled according to EU environmental legislation. Further the amount of sodium hydroxide in flavours is miniscule and there are no environmental concerns in that production, due to the small quantity involved and the fact that no emissions result.

Animal welfare issues

No specific concerns

Human health issues

Not limited ADI level.

Food quality and authenticity

Due to the low level of flavourings added to foodstuff, the carry-over of sodium hydroxide will be very low and has no technological function in the foodstuff.

Traditional use and precedents in organic production

Sodium hydroxide is used in the production of pretzel, pretzel sticks and pretzel rolls (Laugengebäck) to get the typical brown colour at the surface. The use in peeling fruits and vegetables is also common, but this use is not permitted in organic production.

Other relevant issues

None

Aspects of international harmonisation 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".

Permitted in National Organic Programme List of permitted substances §205.606 of the US. Non-organically produced agricultural products allowed as ingredients in or on processed products labelled as "organic" with the following condition; prohibited for use in lye peeling of fruits and vegetables.

Permitted as an additive in Japanese Organic Standards (JAS), as an additive and post-harvest treatment with the condition: For sugar processing and for the surface treatment of traditional bakery products.

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

Necessity for intended use

The group does see the necessity for the use of sodium hydroxide for acidity regulation in organic flavourings. I.e. the requirements of Articles 21(1)(i) & 21(1)(ii) of regulation 834/2007 are both fulfilled.

Reflections of the Group

The group considers that there is a necessity for this use. There is therefore a need to revise the specific conditions whereby it is currently only allowed for surface treatment of Laugengebäck.

Conclusions

The group is of the opinion that the use of sodium hydroxide for acidity regulation in flavours is in line with objectives, criteria and principles of the organic regulation. The specific conditions for use of sodium hydroxide should be amended in Annex VIII to read “Surface treatment of Laugengebäck and regulation of acidity in organic flavourings.”

7.11 Magnesium carbonates as anti-caking agent for organic flavourings

Introduction, scope of this report

The request refers to the possible use of magnesium carbonates (E504) as 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 (organic flavourings). Magnesium carbonates are currently authorised in Annex VIII A of Regulation (EC) No 889/2008 as anti-caking agent in organic foodstuffs of plant origin.

Authorisation in general food processing and production of flavours

Magnesium carbonate is authorised as food additive (E504) in Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b).

Magnesium carbonate is authorised as food additive in flavourings in Annex III EC Reg. 1333/2008 following the quantum satis principle.

Agronomic use, technological or physiological functionality for the intended use

Magnesium carbonate is added to flavourings based on carriers such as maltodextrin and sugar as an anti-caking agent to prevent the caking of the carriers due to absorption of water. This use is considered essential.

Magnesium carbonates

- prevents caking,
- enhances the flowing ability of powder flavourings,
- makes mixing of the flavouring in the foodstuff easier.

Known alternatives

An alternative to magnesium carbonate as an anti-caking agent is silicon dioxide, which has significant advantages over magnesium carbonate as it is effective at lower proportions and as it does not have any adverse effect on pH of the additive or reaction with constituents that could cause “off flavours”.

The additive magnesium carbonate is not possible in organic quality as it is a mineral and not of agricultural origin.

Origin of raw materials, methods of manufacture

Magnesium carbonate occurs naturally in drinking and mineral water as "hardness", in rocks mostly as a companion of calcium and in seawater at an average concentration of 1.4g/l Mg. Pure magnesium carbonate is extracted from dolomite (Magnesium & calcium carbonate) by the Pattinson process. (Ref: <http://www.mercury->

[emissions.com/brome/brome.nsf/viewAllByUNID/6BE203A282A84F44C22570C800315201/\\$file/The_Pattinson_Process.pdf](http://emissions.com/brome/brome.nsf/viewAllByUNID/6BE203A282A84F44C22570C800315201/$file/The_Pattinson_Process.pdf)

Environmental issues, use of resources, recycling

No significant environmental issues caused by Magnesium carbonate are evident. It is widely available in various forms and its use is not reported to cause any concerns. Disposal of small amounts of Magnesium carbonate would not be expected to create any environmental concerns. High concentrations of Magnesium in water contribute to water hardness which has been associated with cardiovascular disease but the contribution of Magnesium carbonate in organic food would be minor in this respect.

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 estimated that acceptable daily intake of magnesium carbonate for man is not limited (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53.)

It is clear that milling of magnesium carbonate will result in creation of some nanoparticles. Most will agglomerate after production, but some may be left (Kohlhuber 2010). On the basis of presently available information there is no indication of health concerns, however the indication that magnesium carbonate for this use may contain nanoparticles should result in a re-evaluation of the safety of this ingredient.

Food quality and authenticity

Due to the low level of flavourings added to foodstuffs, quantities of magnesium carbonate carried over to the foodstuffs are very low and have no more technological function in it.

Aspects of international harmonisation 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" Magnesium carbonate is permitted in food of plant origin.

Permitted in National Organic Programme List of permitted substances §205.606 of the US. Non-organically produced agricultural products allowed as ingredients in or on processed products labelled as "organic" with the following condition; for use only in agricultural products labelled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labelled as "organic".

Permitted as an additive in Japanese Organic Standards (JAS), as an additive and post-harvest treatment with the condition: Limited to be used for processed foods of plant origin

Permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive, without conditions.

Necessity for intended use

The conclusion of all is that there is a necessity for magnesium carbonate for production of organic flavourings.

The dossier submitted makes the case for its use as anti-caking agent for flavourings. The group agrees with this case.

Other relevant issues

None

Reflections of the Group

The group agrees with the request in the dossier for addition of magnesium carbonate as an anti-caking agent for organic flavours.

Conclusions

The group considers that the use of magnesium carbonate is in line with objectives, criteria and principles of the organic regulation. There is no need for amendment of the specific conditions of Annex VIII.

7.12 Silicon dioxide as anti-caking agent for organic flavourings

Introduction, scope of this report

The request refers to the possible use of silicon dioxide (E551) as 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 (organic flavours). Silicon dioxide is currently authorised in Annex VIII A of Regulation (EC) No 889/2008 as anti-caking agent in organic foodstuffs.

Authorisation in general food processing and production of flavours

Silicon dioxide is authorised as food additive (E551) in Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b).

Silicon dioxide is authorised as food additive in flavourings in Annex III EC reg. 1333/2008 following the quantum satis principle.

In accordance to Commission Regulation (EU) No 257/2010⁹ silicon dioxide will be reevaluated by EFSA before 31 of December 2016.

Agronomic use, technological or physiological functionality for the intended use

The addition of anti-caking agent such as silicon dioxide is essential in most of powder flavouring, mix of liquid flavouring materials on a powder carrier (maltodextrins, sugars, etc.). Silicon dioxide prevents caking, enhances the flowing ability of powder flavourings & makes mixing of the flavouring in the foodstuff easier.

⁹ COMMISSION REGULATION (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives

Known alternatives

An alternative could be magnesium carbonate or talc but the quantities needed to obtain the same result are much higher (i.e. 10-15% of talc compared with 0.1-0.3% silicon dioxide) and the use of talc is restricted to 1% in health supplements.

Origin of raw materials, methods of manufacture

Silicon dioxide occurs naturally as a mineral and is the most common mineral of earth's crust. Artificially produced silicon dioxide is mostly an amorphous substance. For manufacturing of the product a chemical reaction is used either by a vapour hydrolysis process, yielding fumed silica, or by a wet process, yielding precipitated silica, silica gels, or hydrous silica.

Environmental issues, use of resources, recycling

Mineral with no significant environmental issues.

Animal welfare issues

No specific concerns

Human health issues

Prolonged inhalation of silica dust may be associated with irritations of the respiratory tract. Therefore personal protection during production or use is necessary. Silicon dioxide is used for more than 40 years in food technology and the structure and the scale of particles have not changed in this time. It seems to be safe in food and the ADI level is not specified.

Silicon dioxide may be produced in particle sizes less than 100micron diameter. These are normally considered as nanoparticles. In practice most silicon dioxide particles less than 100micron tend to agglomerate to produce non-nanoparticles, but this cannot be guaranteed. The production of nanoparticles is a by-product of the production process, rather than a direct objective of the production. No specific legal approval of silicon dioxide as a nanoparticle is currently required.

Some papers do indicate possible health concerns with nanoparticles of silicon dioxide (Kohlhuber 2010)

Food quality and authenticity

Due to the low level of flavourings added to foodstuffs, quantities of silicon dioxide carried over to the foodstuffs are very low and have no more technological function in it.

Traditional use and precedents in organic production

Silicon dioxide has been used in agriculture traditionally. According to Annex VIII A of regulation 889/2007, it is permitted for use as an anti-caking agent in organic agriculture for herbs and spices only

Aspects of international harmonisation 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" Silicon dioxide is permitted in food.

Permitted in National Organic Programme List of permitted substances §205.606 of the US. Non-organically produced agricultural products allowed as ingredients in or on processed

products labelled as “organic” with the following condition; Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.

It is permitted as an additive in Japanese Organic Standards (JAS), as an additive and post-harvest treatment with the condition: Limited to be used for processed foods of plant origin as gel or colloidal solution.

Permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids in amorphous form only, as a post-harvest treatment only. Not permitted as an additive.

Necessity for intended use

Already authorised (in Annex VIII of regulation 889/2008) for herbs and spices, silica is used in many formulations for health supplements but only if they contain herbs or spices. During storage of powder systems, silica reduces caking and blocking.

Other relevant issues

None

Reflections of the Group

Natural sources of silicon dioxide must be preferred to synthetic products. Ref A4 of regulation 834/2007.

It is clear that milling of silicon dioxide will result in creation of some nanoparticles, but production of synthetic silicon dioxide will create a greater proportion of these. Most will agglomerate after production, but some may be left (Kohlhuber 2010). A re-evaluation process of the substance by EFSA is ongoing. On the basis of information available there is no clear indication of health concerns.

Conclusions

The group considers that the use of silicon dioxide is in line with the objectives, criteria and principles of the organic regulation. Natural sources of silicon dioxide should be preferred. The specific conditions for silicon dioxide, currently written as “anti-caking agent for herbs and spices” should be amended by the addition of the following: “... and flavourings”

(See requirements in chapter 9.2)

8. Smoke condensates/smoke flavours

Introduction, scope of this report

The request refers to the possible use of smoke condensates/smoke flavours in organic food products according to Council Regulation (EC) no 834/2007.

Smoke condensates/smoke flavours are currently not authorised to be used in or on organic foods in EU.

Definitions:

Smoke condensates are products obtained by controlled thermal degradation of wood in a limited supply of oxygen (pyrolysis), subsequent condensation of the resulting smoke vapours, and fractionation of the resulting liquid products (WHO, 2009).

According to *Regulation (EC) 2065/2003*¹⁰ on smoke flavourings used or intended for use in or on foods, the following definitions are stated in art. 3:

- 1) “*primary smoke condensates*” shall refer to the purified water-based part of condensed smoke and shall fall within the definition of “*smoke flavourings*”.
- 2) “*primary tar fraction*” shall refer to the purified fraction of the water-insoluble high-density tar phase of condensed smoke and shall fall within the definition of “*smoke flavourings*”.
- 3) “*primary products*” shall refer to primary smoke condensates and primary tar fractions.
- 4) “*derived smoke flavourings*” shall refer to flavourings produced as a result of the further processing of primary products and which are used or intended to be used in or on foods in order to impart smoke flavour to those foods.

Authorisation in general agriculture or food processing

According to *Regulation (EC) 2065/2003 on smoke flavourings used or intended for use in or on foods*, the Scientific Committee on Food concluded that because of the wide physical and chemical differences in smoke flavourings used for flavouring food, it is not possible to design a common approach to their safety assessment and, accordingly, toxicological evaluation should focus on the safety of individual smoke condensates (8).

Smoke flavourings therefore should undergo a safety assessment through a Community procedure before placing on the market or used in or on foods within the Community in order to protect human health (2065/2003 (4)).

With reference to Art. 4(1) in the reg. 2065/2003: the use of smoke flavourings in or on foods shall only be authorised if it is sufficiently demonstrated that

- it does not present risks to human health,
- it does not mislead the consumers

Derived smoke flavourings must be evaluated by the European Food Safety Authority (EFSA), and a list of primary products authorised for the production of derived smoke flavourings shall be established (2065/2003, Art. 6(1)). The risk assessment of smoke flavourings is carried out by EFSA’s Panel on food contact materials, enzymes, flavourings and processing aids (CEF).

Until the list of authorised primary products is established, only primary products for which a valid application has been submitted before 16 June, 2005 can continue to be placed on the market (Reg. 2065/2003, Art 20).

In the first phase, EFSA received applications for 16 notified primary products that were already on the market. 14 of those were considered as valid applications and subject to evaluation. The other two applications were not considered to be valid and therefore were withdrawn from the market. After the start of the evaluation, applications for three more notified products were withdrawn from the market, thus EFSA having to evaluate only 11 notified products (EFSA 2012a).

¹⁰ REGULATION (EC) No 2065/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 10 November 2003 on smoke flavourings used or intended for use in or on foods

For only three of the evaluated products, the margin of safety were large enough not to give rise to safety concerns at the levels of use as specified by the applicants, whereas for the others, a safety concern was raised (EFSA 2012a).

When evaluating the safety of smoke flavourings, the CEF-panel did not anticipate that smoke flavourings would be used in food specifically designed for infants (0-12 months) and young children (12-36 months). Therefore the safety of use of the evaluated primary products in food for infants and young children was not assessed (EFSA 2012b).

Each smoke flavouring (primary products) is authorised for specific products, conditions for its use in or on food products and levels of use for the specific products (Reg. (EC) No 2065/2003, Art. 6(2)).

Agronomic use, technological or physiological functionality for the intended use

Smoke flavourings are used to improve or modify the odour and taste of foods. Liquid smoke flavourings are increasingly added to food to replace the flavour and taste from traditional smoking or to impart smoke flavour to foods that are traditionally not smoked (such as soups, sauces or confectionary) (EFSA J. 2012a;10(10):s1007). Smoked flavour is also used to give flavour to e.g. soy tofu, which has traditionally never been smoked.

Technical application

Smoke condensates can be used in a variety of ways (SE dossier 2011):

- 1) Showered: The smoke is showered on the food and thereby the smoke comes in contact with the food for a certain period of time as the smoke condensate is circulated through nozzles or cascade pans to provide even coverage of the smoke on the food.
- 2) Directly addition: Smoke flavour can be added directly to the food as in a sauce, in a meat emulsion, injected into hams and bacon, or to a seasoning blend that can be applied to a food.
- 3) Smoke regeneration: In this method, the smoke and air are forced through a high pressure nozzle to break the smoke into gaseous particles. These particles come out of the nozzle as a dry cloud. The smoke will be regenerated into a smokehouse for a period of time to fill the smokehouse. When it is full, the regeneration system is turned off and the circulation fans are turned on. The fans evenly distribute the smoke cloud throughout the chamber.
- 4) Dipping: With dipping, the food is immersed into a solution of smoke condensate for a specific period of time.

By using smoke flavourings one can prevent the drying loss which normally takes place during the smoking process and the production time can be reduced. The traditional smoking process is normally combined with drying whereby the weight of the product is reduced. By using smoke flavourings, the food product does not lose weight and this affects the quality and the price of the product. A reduction of processing time is regarded as an advantage as it can often reduce the price of the product sold to the consumer or give a better profit to the producer (Council of Europe Publishing 1992a).

Labelling

Consumers should be informed if the smoky taste of a particular food is due to the addition of smoke flavourings. The labelling should not confuse the consumer as to whether the product is smoked conventionally with fresh smoke or treated with smoke flavourings (Reg.1334/2008(27)).

The list of ingredients for a food product should be labelled "smoke flavouring(s)", or "smoke flavouring(s) produced from "food(s) or food category or source(s)"" (e.g. smoke flavouring produced from beech), if the flavouring component contains smoke flavourings and imparts a smoky flavour to the food (1334/2008 Art. 29, Annex III, 1).

Known alternatives

Traditional smoking of foods is a known alternative for smoke flavourings and is already approved for use for production of organic foods.

Smoking of foods such as meat and fish has been used for centuries and its main purpose was originally to preserve food by drying in the fireplace. Later on the process was developed and changes in combination with other processes to obtain satisfactory shelf-life of food. Most food items have both been smoked or either salted, dried, fermented or preserved in another way too, as smoking alone does not ensure the food's proper lifespan (Council of Europe Publishing 1992a). The traditional smoking has in addition to flavour also influence on the water activity by reducing the water content resulting in prolonged shelf life and changed texture.

Application of liquid smoke flavours does not have the same effect on water activity as the drying process. Therefore, products prepared with liquid smoke flavours will end up in a different product and must be handled differently to naturally smoked products to avoid microbiological risks.

The traditional smoking methods are characterised by the temperature used (Council of Europa, 1992a):

Cold smoking where the temperature normally is 18-20°C. The process is typically used for salmon, salamis, kippers, hams and special cheese. A cold smoking process may last for several weeks. Normal cold smoking process lasts for 6-24 hours.

Warm smoking by a temperature around 40°C is used for bacon, sirloin and some types of sausage.

Hot smoking is a combination of strong heating and smoke, which gives a temperature in the product of 70-90°C. Warm smoking is a combination of drying, cooking and smoking process. This process normally takes hours, but the smoking part of the process is only part of this time. Products like herrings, eel and some sausages are smoked by this way.

Research is still ongoing to improve the industrialised direct smoking methods to decrease the content of polycyclic aromatic hydrocarbons (PAH) available (Schwägele and Jira 2010, Hitzel et al 2013, Pohlmann et al 2013). Ciecierska and Obiedziński (2007) compared different direct smoking methods used for smoking of meat, and they found that irrespectively of smoking method applied, the content of benzo[a]pyrene's was much lower than maximum tolerable limit of 5 µg/kg, which was set for smoked meat products in Commission Regulation (EC) No.

208/2005¹¹). Ziegenhals (2008) has directly compared liquid smoke flavours, traditional smoke methods (Glimmrauch) and advanced smoke methods (Friction smoke). Friction smoke means, the smoke generator produces aromatic smoke by pressing a wooden stick (dimensions 8 x 8 x 70/100 mm) onto a fast rotating, diagonally-toothed friction wheel. The wooden stick is pressed pneumatically by means of a wood clamp. Such advanced smoking methods resulted in the same level of contamination with PAH in the final products as the application with liquid smoke flavours. Both were much better than traditional smoking methods (Glimmrauch) (Ziegenhals 2008)

Origin of raw materials, methods of manufacture

The smoke condensates are obtained by condensing smoke and they may be further fractionated, purified or concentrated. The purpose of the fractionation steps is to obtain products of interesting olfactory properties and to reduce the concentration of undesirable by-products of the smoke. The smoke condensates are generally not used as such for the flavouring of food but are used as the basis for smoke flavouring preparations (Council of Europe Publishing 1992b).

Smoke is generated from wood. The chemical composition of smoke is complex and depends among other things on the type of wood used, the method used for developing smoke, the water content of the wood and the temperature and oxygen concentration during smoke generation 2065/2003 (6).

There is a list of wood traditionally used for smoke preparation and which is acceptable for production of smoke flavourings (Council of Europe Publishing 1992b):

The wood used for production of primary products shall not have been treated, whether intentionally or unintentionally, with chemical substances during six months immediately preceding felling or subsequent thereto, unless it can be demonstrated that the substance used for the treatment does not give rise to potentially toxic substances during combustion (2065/2003, Art. 5,1).

Herbs, spices, twigs of juniper and twigs, needles and cones of *Picea* may be added if they are free of residues of intentional or unintentional treatment or if they comply with more specific Community legislation. The source material is subjected to controlled burning, dry distillation or treatment with superheated steam in a controlled oxygen environment with a maximum temperature of 600 °C (2065/2003 Annex I, 1).

The smoke is condensed with a condenser temperature of less than 60°C. The smoke condensate is then further cooled to room temperature and water is added (Dossier SE2011).

Water and/or, without prejudice to other Community legislation, solvent may be added to achieve phase separation. Physical processes may be used for isolation, fractionation and/or purification to obtain the following phases (2065/2003, Annex I, 2):

(a) a water-based "primary smoke condensate" mainly containing carboxylic acids, carbonylic and phenolic compounds, having a maximum content of:

Benzo[a]pyrene 10 µg/kg

¹¹ COMMISSION REGULATION (EC) No 208/2005 of 4 February 2005 amending Regulation (EC) No 466/2001 as regards polycyclic aromatic hydrocarbons

Benz[a]anthracene 20 µg/kg

(b) a water-insoluble high-density tar phase which during the phase separation will precipitate, and which cannot be used as such for the production of smoke flavourings but only after appropriate physical processing to obtain fractions from this water-insoluble tar phase which are low in polycyclic aromatic hydrocarbons, already defined as "*primary tar fractions*", having a maximum content of:

Benzo[a]pyrene 10 µg/kg

Benz[a]anthracene 20 µg/kg

(c) a "water-insoluble oily phase".

If no phase separation has occurred during or after the condensation, the smoke condensate obtained must be regarded as a water-insoluble high-density tar phase, and must be processed by appropriate physical processing to obtain primary tar fractions which stay within the specified limits.

According to 2065/2003 Art. 5(2), the water-insoluble oily phase which is a by-product of the process shall not be used for the production of smoke flavourings.

Environmental issues, use of resources, recycling

PAH may be formed when burning organic material and are widespread in the environment (Council of Europe Publishing 1992a). They are primarily formed by incomplete combustion or pyrolysis of organic matter during various industrial processes. For smokers, the contribution from smoking may be significant, while for non-smokers the major route for exposure is consumption of food (EFSA, 2008).

Total diet studies from UK and other countries, however, show that the largest amount of carcinogenic PAH-components in the food do not come from smoked fish and meat products, but from plant foods polluted from the air. (Council of Europe Publishing 1992a). Generating smoke, whether for natural smoking or for production of condensates generates carbon dioxide, although the source is sustainable.

Animal welfare issues

No specific concerns

Human health issues

The major contributors to intakes of PAH are cereals and cereal products (owing to high consumption in the diets) and vegetable fats and oils (owing to higher concentrations of PAH in this food group). Generally, despite their usually higher concentration of PAH, smoked fish and meats and barbecued foods do not contribute significantly, particularly as they are small components of the diet. However, they do make larger contributions leading to higher PAH intakes where these foods make up a large part of the diet (WHO 2009).

Smoked foods in general give rise to health concerns, especially with respect to the possible presence of polycyclic aromatic hydrocarbons (PAH). Because smoke flavourings are produced

from smoke which is subjected to fractionation and purification processes, the use of smoke flavourings is generally considered to be a less significant health concern than the traditional smoking process. However, the possibility of wider applications of smoke flavourings in comparison to conventional smoking has to be taken into account in safety assessments (Reg. 2065/2003, (6))

The composition of smoke is very complex, more than 400 volatile substances having been identified in wood smoke. The chemical composition depends among other things on the temperature of the smoke generation, the kind of wood used, the method used for developing the smoke, the water content in the wood, and addition of air and water. From a health point of view, the most important chemical substances in smoke are nitrogen oxides and polycyclic aromatic hydrocarbons (Council of Europe Publishing 1992a).

Nitrogen oxides

The nitrogen oxides in smoke can react with myoglobin in meat and give colour to the food, or these gasses may react with amines from the food and form nitrosamines. Nitrosamines are among the most carcinogenic substances which have been studied in animals. Nitrogen oxides should not be present in smoke condensates (Council of Europe Publishing 1992a).

Polycyclic aromatic hydrocarbons

The PAH-component benz(a)pyrene and approximately 10 other components from this group have proved to be both mutagenic and carcinogenic in experimental studies. Depending on which way the substances have been administered to the test animals, they can cause cancer of skin, lung, mammalian tissue, stomach, intestine, liver or lymph. The carcinogenic effects of these components have been seen after doses of only a milligram per kg. bodyweight per day (Council of Europe Publishing 1992a).

High amount of PAH can be found especially on the surface of smoked products, and mainly on products smoked for a long time with direct smoking at higher temperatures (Council of Europe Publishing 1992a). Often the surface of the smoked product is not eaten as the fish skin and surface of hams. The content of PAH in the inner part of smoked meat is low (Ciecierska and Obiedziński, 2007).

Test of smoke flavourings for toxicity

According to the “Guidance on submission of a dossier on a Smoke Flavouring Primary Product for evaluation by EFSA”, smoke flavourings should be individually tested for toxicology and the toxicological data presented. This should comprise 1) “Subchronic toxicity” by a 90-day feeding study in rodents, preferably in rats; 2) “Genotoxicity” i) a test for induction of gene mutation in bacteria; ii) a test for induction of gene mutations in mammalian cells *in vitro*; iii) a test for induction of chromosomal aberrations in mammalian cells *in vitro* (EFSA 2004).

As a summary of the findings of the EFSA in evaluation of smoke condensates, only three of the 14 products evaluated were found that to have large enough margin of safety not to give rise to safety concerns (EFSA, 2010).

In a summary of the opinions on smoke flavourings adopted by EFSA's CEF panel in 2009, the reported toxicological effects were: "increase in kidney weight in rats"; "increased kidney weights in female rats"; "increase in relative kidney weight and related changes in blood biochemistry and haematology"; "reduction in white blood cell count (both sexes) and reduction of lung weight in male rats"; "decreased body weight gain in rats (both sexes)".

Food quality and authenticity

There is a potential in the use of smoke flavourings to mislead the consumer in contradiction of article 6(c) and 19(3) of Council Regulation (EC) No 834/2007 because consumers expect that traditional smoking methods were applied.

This may be handled by clear appropriate labelling as required by regulation 2065/2003, but how this should be labelled is not clearly spelled out as to the nature of that labelling.

Traditional use and precedents in organic production

There is no precedent of using smoke flavours in organic food production.

Aspects of international harmonisation of organic farming standards

The use of smoke flavourings seems not to be allowed in the USA and Canada as only flavours that can be labelled as natural are allowed in organic food.

The USDA National Organic Program (NOP) and the Canadian Organic Regime (COR) allow only the use of certain natural substances, including flavours, in products labelled as "Organic" or "Made with Organic" (Quality Assurance International 2013).

The question "Can natural smoke flavouring be listed as natural flavour?" was raised to USDA Food science Inspection Service (FSIS), and they answered: "No, the labelling of natural smoke flavourings is covered by 9 Code of Federal Regulations 317.2 (j) (3) and 381.119 (a) and by Policy Memo 117, "Smoke Flavouring." Natural smoke flavouring may not be listed as "natural flavour" or "flavour" in the ingredients statement. It may be declared as "natural smoke flavouring" or "smoke flavouring." Artificial smoke flavouring must be labelled as such." (USDA Food science Inspection Service, 2010)

In US natural liquid smoke flavour derived from wood chips and physical processes, and condensed in water would be considered a "natural flavour" listed on 7 CFR 205.605(a) and can therefore be used for the processing of organic foods. Synthetic liquid smoke flavours are prohibited. There is at least one USDA certified organic liquid smoke on the market. The NOP does currently not require the use of organic natural flavours for organic products as long as the flavours as below 5% of the weight of the product net of water and salt.

According to US FDA, Code of Federal Regulations (CFR) Title 21 Food and drugs, Chapter 1, subchapter B, Food for human consumption. Art. 6, 2013, the smoke flavours are defined as artificial flavours:

"Any pyroligneous acid or other artificial smoke flavours used as an ingredient in a food may be declared as artificial flavour or artificial smoke flavour. No representation may be made, either directly or implied, that a food flavoured with pyroligneous acid or other artificial smoke flavour has been smoked or has a true smoked flavour, or that a seasoning sauce or similar product

containing pyrolygneous acid or other artificial smoke flavour and used to season or flavour other foods will result in a smoked product or one having a true smoked flavour”.

Necessity for intended use

Due to the authorisation of traditional smoking methods for organic foods there is no need for smoke flavours in the sense of article 21(1)(i),(ii) of regulation 834/2007.

Other relevant issues

None.

Reflections of the Group

The group has the opinion that there is no need to introduce smoke flavours into the organic regulations because there is the clear alternative of smoking processes already allowed in organic food production (Reg. 889, art. 26.1, 834 art. 21 (i), (ii)).

Allowing smoke flavours will create conflict within the organic regulations by potentially misleading consumers (834, art 6(c)). Products with added smoked flavour are different from smoked products. The changed product profile has an effect on the microbiological stability compared to the traditional products.

There does not seem to be an evident for better toxicological profile from liquid smoke flavours compared to updated traditional smoking method to be used today. Only three of the primary smoke products tested by EFSA had margins of safety large enough not to give rise to safety concerns at the levels of use.

Conclusions

The use of liquid smoke flavours is not in line with the objectives, criteria and principles of organic regulation because there is no need for their use in line with article 21(1) and there is a risk that the consumer will be misled contrary to Article 6(c) and 19(3) of Council Regulation (EC) No 834/2007. In particular some consumers may be confused as to whether a product has been smoked or been treated with smoke flavouring.

Wood used for smoking should not be treated with chemical substances at all. Advanced smoking method should be preferred.

9. Other issues

9.1. Neutralisation of oils by sodium hydroxide

Introduction

Currently sodium hydroxide (NaOH) is only accepted as processing aid in Annex VIII B of European Commission (EC) No 889/2008 for sugar production and for the production of oil from rape seed. NaOH in oil refinement is used for neutralisation therefore for removal of Free Fatty Acids (FFA) and impurities.

When refinement is required for organic oils in order to remove unacceptable taste and smell as products of fat oxidation and FFA, it is done by deodorisation because of the limits for processing aids set by organic regulation.

Depending on the degree of impurities and level of FFA the temperatures up to 260°C needs to be applied for a successful deodorisation. The heat application leads to formation of 3 MCPD (3-Chlor-1,2-propandiol) in relevant amounts (Lindhauer M. G. 2011) Actual scientific findings have concluded that 3-MCPD is a carcinogen substance (BFR 2012.). Because of that, the 3 MDCP level of organic refinement oil has a tendency to be higher than in oil from conventional production.

If NaOH, which is currently only accepted for the neutralisation of organic rape oil, could be used for the production of organic oils from other sources, FFA could be neutralised and a high temperature deodorisation avoided with the consequence of lower 3-MCPD levels in organic refined oils.

Reflections of the group

The group considers that this subject does need urgent discussion and therefore accepts this topic to be evaluated in this mandate.

Currently NaOH is only allowed for rapeseed oil. But the issue discussed here could be relevant for all types of oils (sunflower, flax, grapeseed oils).

From a food safety point of view there is a need to reduce the presence of carcinogenic substances in food as much as possible. NaOH is a simple inorganic substance, easily neutralised. NaOH does not cause environmental or health concerns. In an appreciation of values it seems to be more acceptable to allow NaOH than to accept the risk of a presence of carcinogen substances in organic food.

The group considered whether processing such as deodorisation or other refinement should be labelled. The consumer understands terms such as cold pressed, virgin oil etc., but would be likely to be put off by phrases such as refined, deodorised etc.

Conclusion

The group sees the possibility to neutralise all oils by the mean of NaOH in line with the objectives and principles of organic regulation. Because of the carcinogenic effects of 3-MCDP and the need of refining for a reasonable amount of organic oils, as due to the negative effects from high temperature applications toward formation of 3-MCPD, the group proposes to delete in Annex VIII B for NaOH the specific condition “Oil production from rape seed (*Brassica spp*)” and replace it by “Oil production”.

9.2 E 551 Silicon dioxide as anti-caking agent for propolis

In chapter 7.12, we have discussed the topic of silicon dioxide (SiO_2) as an anti-caking agent for organic flavours. For the next mandate already proposed for spring 2014 another SiO_2 dossier is delivered by France. Again the dossier is asking for changing the specific conditions of SiO_2 for plant products. This time the applicant is asking for allowing SiO_2 as anticaking agent for

propolis and health supplement made out of propolis. The technological conditions for the use of SiO₂ (see Chapter 7.12) are quite similar to those in herbs spices, flavours or other applications in powders.

Furthermore we find that, based on information based of legislative and traditional background in the different member countries, it is often not clear what exactly is a spice or herb or what has to be seen as a fruit or vegetable. This causes misunderstanding in the market and problems among the producers. Clarification is needed.

Reflections of the group.

See Chapter 7.12

Conclusion

The group considers that the use of silicon dioxide as anti-caking agent in propolis is in line in line with the objectives, criteria and principles of organic regulation.

The specific conditions for silicon dioxide, currently written as “anti-caking agent for herbs and spices” (plus amendments proposed in chapter 7.12) in Annex VIII A should be amended to add "and for propolis".

9.3. Topics for consideration in the future

The group is of the opinion that important topics such as the use of enzymes, the potential presence of Nano-particles in additives in Annex VIII and the unrestricted use of micro-organisms and technical enzymes should be added to future agendas for EGTOP food subgroups.

10. LIST OF ABBREVIATIONS / GLOSSARY

Annex VIII	Annex VIII of Regulation 889/2008
The Group	Experts of the sub group on Food EGTOP
MS	Members States
Quantum satis	The term “quantum satis” is applied to usage for a large number of additives. “Quantum satis” indicates that no maximum level is specified. However, additives must be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided that they do not mislead the consumer. Ref http://www.fsai.ie/faqs/additives/food_additive_legislation.html#quanu

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Annex I

Directive 88/388/CEE on flavours

A.1. Definition of Natural flavouring substances and flavouring preparation and the process allowed to produce them

Art. 1) paragraph 2) point b)i- and c)

2)-[...]

(b) 'flavouring substance' means a defined chemical substance with flavouring properties which is obtained:

(i) by appropriate physical processes (including distillation and solvent extraction) or enzymatic or microbiological processes from material of vegetable or animal origin either in the raw state or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction and fermentation)

c) 'flavouring preparation' means a product, other than the substances defined in (b) (i), whether concentrated or not, with flavouring properties, which is obtained by appropriate physical processes (including distillation and solvent extraction) or by enzymatic or Microbiological processes from material of vegetable or animal origin, either in the raw state or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction

and fermentation)

A.2. Requirement set for the use of the term “natural” in labelling

Art. 9 paragraph 1 point d) and paragraph point 2)

[...]

2. Without prejudice to paragraph 1 (d), the word ‘natural’, or any other word having substantially the same meaning, may be used only for flavourings in which the flavouring component contains exclusively flavouring substances as defined in Article 1 (2) (b) (i) and/or flavouring preparations as defined in Article 1 (2) (c). If the sales description of the flavouring contains a reference to a foodstuff or a flavouring source, the word ‘natural’, or any other word having substantially the same meaning, may not be used unless the flavouring component has been isolated by appropriate physical processes, enzymatic or microbiological processes or traditional food- preparation processes solely or almost solely from the foodstuff or the flavouring source concerned.

Commission regulation (EC) no 1334/2008

Ref. Art. 3) paragraph 2 – c).

[..]

(c) ‘natural flavouring substance’ shall mean a flavouring substance obtained by appropriate physical, enzymatic or microbiological processes from material of vegetable, animal or microbiological origin either in the raw state or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II. Natural flavouring substances correspond to substances that are naturally present and have been identified in nature;

B.2. A quantitative and explicit relationship between the flavouring component responsible for the taste and the source material referred to in labelling qualified as ‘natural’ // NEW !

Considering (25) and (26)

(25) Flavouring substances or flavouring preparations should only be labelled as ‘natural’ if they comply with certain criteria which ensure that consumers are not misled.

(26) Specific information requirements should ensure that consumers are not misled concerning the source material used for the production of natural flavourings. In particular, if the term natural is used to describe a flavour, the flavouring components used should be entirely of natural origin.

In addition, the source of the flavourings should be labelled, except when the source materials referred to would not be recognised in the flavour or taste of the food. If a source is mentioned, at least 95 % of the flavouring component should be obtained from the material referred to. As the use of flavourings should not mislead the consumer, the other maximum 5 % can only be used for standardisation or to give a, for example, more fresh, pungent, ripe or green note to the flavouring. When less than 95 % of the flavouring component derived from the source referred to has been used and the flavour of the source can still be recognised, the source should be revealed together with a statement that other natural flavourings have been added, for example cacao extract in which other natural flavourings have been added to impart a banana note.

[B.3] Definition of requirements for 3 new labeling wording using the term “Natural” referring to a source material X // NEW !

Article 16 point 4), 5) and 6).

Article 16.4 Natural “X” flavouring

The term "natural" may only be used in combination with a reference to a food, food category or a vegetable or animal flavouring source if the flavouring component has been obtained exclusively or by at least 95% by w/w from the source material referred to.

NB : the 5% part left cannot reproduce the total flavour profile.

Article 16.5 Natural "X" flavouring with other natural flavourings

The term "natural food(s) or food category or source(s) flavouring with other natural flavourings" may only be used if the flavouring component is partially derived from the source material referred to, the flavour of which can easily be recognised.

Article 16.6 Natural flavouring

The term "natural flavouring" may only be used if the flavouring component is derived from different source materials and where a reference to the source materials would not reflect their flavour or taste.