EGTOP/2018

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE
AND RURAL DEVELOPMENT
Directorate B. Quality, Research & Innovation, Outreach
B4. Organic

Expert Group for Technical Advice on Organic Production
EGTOP

Food IV final report

The EGTOP adopted this technical advice at the plenary meeting of 6 to 8 June 2018 and submitted the final version on 20 July 2018.

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

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

EGTOP

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

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ACKNOWLEDGMENTS

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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 Group made the following conclusions:

1. The adoption of organic glycerol for any allowed use (i.e. as humectant in gel capsules and other uses already listed) is in line with the objectives, criteria and principles of the organic Regulation 834/2007. Therefore, the restriction "Only when derived from organic production" should be included to Annex VIII, Section A of Regulation 889/2008.

2. The adoption of organic glycerol for use as a surface coating of tablets, only, is in line with the objectives, criteria and principles of the organic regulation in Regulation 834/2007. Therefore, the restriction "Only when derived from organic production" should be included to Annex VIII, Section A of Regulation 889/2008. If market availability is sufficient the group propose to extend the mandatory use of organic glycerol also to the other scopes already allowed.

3. The group is clear that we should only permit organic lecithin (i.e. organic lecithin must be both derived from certified organic agriculture, but also from certified organic processing only). For Carnauba wax and beeswax the same wording "organic" should be used, with the same meaning.

4. The use of any varieties of Bentonite as a processing aid for preparation of foodstuffs of plant origin and of animal origin (mead only) is in line with the objectives, criteria and principles of organic Regulation 834/2007.

5. The group is clear that the wording "Gel or colloidal solution" applied to Silicon Dioxide in Annex VIII A is incorrect & should be deleted. The current wording for application "herbs and spices in dried powdered form, flavourings and propolis," is correct & should be maintained.
The group is not able to recommend adding the word "food supplements" to specific conditions for E551 Silicon Dioxide in Annex VIII A of regulation 889/2008, as the dossier does not contain sufficient information to completely inform this assessment. Furthermore, the group recommends to restrict the potential for use of E551 to products containing less than 1% of crystalline silica. The group also recommends providing workers with information on the health risks and a register to monitor health risks, being established.

6. & 7. The use of L(+) lactic acid from fermentation and of Sodium Hydroxide, as a processing aid for preparation of pea protein, is in line with the objectives, criteria and principles of organic Regulation 834/2007. The addition to Annex VIII Section B of Regulation 889/2008 is recommended. As addition of Sodium Hydroxide & L (+) Lactic acid to Regulation 889/2008 Annex VIII Section B will allow production of organic pea protein extract, the group recommends deletion of "pea protein *Pisum* spp." from Annex IX Section 2.3 and to restrict it from organic origin in Annex VIIIa. The group also recommends allowing the production of protein extract on other plant species and not limiting it only to pea.

8. Overall the group considers that adoption of PGPR as an emulsifier in cigarettes russes & piroulines, is not in line with the objectives, criteria and principles of the organic Regulation 834/2007, for addition to Annex VIII, Section A to Regulation 889/2008.

9. Overall the group considers that adoption of sodium hydroxide for debittering of olives is not in line with the objectives, criteria and principles of the organic regulation in regulation 834/2007, for addition to as a processing aid to Annex VIII, Section B to Regulation 889/2008.

10. Overall the group considers that adoption of E 153 Vegetable carbon, for colouring of cheese is not in line with the objectives, criteria and principles of the organic regulation in regulation 834/2007, for addition as additive to Annex VIII, Section A to Regulation 889/2008, with the exception of traditional uses in Morbier and Ashy Goats Cheese. However, the group agree on the possibility to assess other traditional cheese types (PDO or similar) if a well-documented traditional use is provided.

11. As there are viable alternatives, more in line with organic production, that can be used for stabilization of organic wine against precipitation of tartaric acid crystals (e.g. temperature control, bentonite that is of mineral origin, meta-tartaric acid), the group is inclined to consider not essential the use of KPA. As a consequence, the group does not recommends KPA for addition to Annex VIIIa of 889/2008.

12. The group considers the use of Hydrochloric Acid to produce organic pyrodextrin not in line with the objectives, criteria & principles of Regulation 834/2007.

13. The group is not able to recommend the adoption of maltitol and maltitol syrup as sweeteners listed in Annex VIII A of regulation 889/2008 for bakery wares as the dossier does not contain sufficient information to completely inform this assessment.

14. The group considers that use of Tara gum powder as a food additive (thickener) is in line with the objectives, criteria & principles in Regulation 834/2007 for addition to Annex VIII A of 889/2008. The group recommend that it should be added only in organic quality. This stipulation should be extended to locust bean gum, gellan gum, arabic gum, & guar gum, in the same way as suggested for lecithin above.

15. In principle the group is not in favour of the use of carnauba wax for the proposed use. Nevertheless, the group considers it could be allowed in areas and for productions with mandatory low temperature treatments, and only for the time the quarantine measures are into force, and no alternatives are available. The groups recommends as well that carnauba was use is reported on the label.

General comment regarding the quality of the dossiers:
Generally, dossiers were complete, clear, well produced & contained sufficient information to inform the assessment. However, two dossiers were not sufficiently complete for the group to make sound decisions.

1. TERMS OF REFERENCE

MANDATE submitted for agreement by COP meeting 1 December 2017

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

a) Substances:

1. UK dossier : **Glycerol** for moisturing gelatin capsules food supplements
2. BE dossier : **Glycerol** for moisturing tablets food supplements
3. BE dossier: **Lecithin** clarification if this is the same as "organic lecithins"
4. BE dossier: **Bentonite** clarification if this is the same as calcium bentonite potassium bentonite. Similarly for calcium sulfate and Silicon oxide"
5. BE dossier: **SiO2 in spices**
6. BE dossier: **Lactic acid** for pH regulation in peas
7. BE dossier: **NaOH** for pH regulation in peas; covered by the earlier evaluation for a more general use?
8. BE dossier **PGPR**-polyglycerol polyricinoleate for production of biscuits etc
9. IT dossier : **NaOH,** for debittering of olives;
10. FR dossier: **Vegetable carbon** for cheese making
11. IT dossier: **Potassium poly-aspartate** (for wine making)
12. CZ dossier: **Hydochloric acide** (for the production of pyrodextrines)
13. IT dossier: **Maltitol** & **Maltitol** Syrup (for baked goods)
14. IT dossier: **Tara Gum** (thickener)

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

On Monday June 4 a request of evaluating a change of disposition for Carnauba vax was delivered to the permanent group.

2. CONSIDERATIONS AND CONCLUSIONS

2.1. Glycerol for moisturing gelatin capsules food supplements

Introduction, scope of this chapter

Assessment of Glycerol 'As plasticiser or humectant for use in soft gel encapsulation for use in products of plant and animal origin.'
Assessment as a result of submission of dossiers by BE & GB for the same use.
Glycerol is also known as Glycerin/Glycerine. Propane 1, 2, 3 triol, CAS No: 56-81-5

Authorisation in general production and in organic production

Glycerol is found abundantly in nature in the form of triglycerides, which are the principal constituents of almost all vegetable and animal fats and oils. Glycerol occurs naturally in wines, beers, bread, and other fermentation products of grains and sugars due to formation by yeast as a by-product of fermentation.
EU Conventional: 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. E 422
Used as a thickener, stabiliser, emulsifier, humectant, plasticiser and sweetener.
It is used as a humectant (moisturising agent) in many foods such as tortillas, icing, cakes etc. Also used as a sweetener. Also, to reduce staling, as a thickener/filler in reduced calorie foods and to reduce crystallisation in sugar preparations/icing. Also added to some spirits and liqueurs to improve mouthfeel. Used in soft gel capsules as plasticiser for food supplements. It is also used as a carrier and solvent in plant extracts such as tinctures, oils etc.
Specific purity criteria have been defined in the Commission Regulation (EU) No 231/2012.
Approval in Organic products.
Listed in regulation 889/2008/EC for plant-based products only with the condition "From plant origin. For plant extracts and flavourings"

Agronomic use, technological or physiological functionality for the intended use

Glycerol is reported in both dossiers as essential for the production of soft gel capsules used to encapsulate oils. At present organic oils cannot be encapsulated as the glycerol is not currently permitted in EU organic regulations.

Necessity for intended use, known alternatives

Technological function in food;
Soft gel capsules provide consumers with an oil-based product in a capsule format which are easy to swallow, disintegrate quickly and can significantly improve the bioavailability of active ingredients, which in liquid form can be unpleasant to take. Soft gel products include oil such as, Flaxseed Oil, Evening Primrose Oil and fish oils and combination products and vary in the quantity of oil contained.
Before the encapsulation process begins, the gelatine for the outer shell covering and the capsule fill material(s) are prepared. Gelatine is permitted under 889/2008 Annex IX. Significant effort has been made to encourage the production of organic gelatine, including allowing specific additives only for this use.
Gelatine consists mainly of a protein that is easily digested by enzymes in the intestinal tract, which allows the active ingredient to be release and absorbed into the bloodstream. The gelatine powder is mixed with water and glycerol then heated and stirred under vacuum.
The glycerol is added to the gelatine and water and acts as a plasticiser in the gelatine compound. Without the glycerol being added to the gelatine and water mixture, the soft gel capsule shell would not be formed within the manufacture process of the health food supplement concerned.

The function of glycerol is extremely important within the manufacturing process of the gelatine soft gel capsule as it enables the fluidity of the shell to be formed and pumped into the soft gel encapsulation machine allowing two thin ribbons of gelatine to be created. These ribbons of gelatine then pass over a series of rollers and are continuously fed between two rotating die cylinders that determine the size and shape of the capsules producing two halves of the soft gel capsule.
If glycerol is not used in the capsules, then the capsules shatter. There are no alternatives for the case above, therefore no organic operators can make gel capsule products.
There is a growing demand for food supplements. Soft gel capsule manufacturing is of special use in dietary supplements that contain ingredients that the body cannot otherwise easily absorb, such as botanical extracts.

Origin of raw materials, methods of manufacture
Glycerol is produced by hydrolysis of fats. The current restriction of "From plant origin" should be retained to ensure that glycerol from animal fat should not be permitted. This would also prohibit the use of glycerol chemically synthesised from propane.
Glycerol is manufactured from plant oils. There is a risk that these could include GM oils e.g. rapeseed oil. GM declarations will be required if non-organic Glycerol is permitted.

Environmental issues, use of resources, recycling
No significant issues of environmental impact would be raised by permitting the use of Glycerol as a humectant in capsules for organic products. Glycerol is widely present in nature & readily biodegradable.
The weight of evidence indicates that glycerol is of low toxicity to aquatic organisms and this conclusion is supported by QSAR predictions. Glycerol is of very low acute toxicity to mammals. It has a low potential for sorption to soil and is not expected to bio accumulate. (1).

Animal welfare issues
None, providing only plant-based glycerol only is used.

Human health issues
Glycerine at pharmaceutical purity is GRAS. (2)
No health issues identified with the pure material. The weight of evidence indicates that glycerol is of low toxicity when ingested, inhaled or in contact with the skin. Glycerol is of a low order of acute oral and dermal toxicity with LD50 values more than 4000 mg/kg bw. Repeated oral exposure to glycerol does not induce adverse effects other than local irritation of the gastro-intestinal tract. Glycerol is not considered to possess genotoxic potential. (2bis)

Food quality and authenticity
Use of glycerol in foods such as breads, cakes, wraps as a humectant may be considered to hide the true nature of the food. Similarly, addition to alcoholic drinks to improve mouthfeel may also be considered as misleading. These applications of glycerol have never been permitted in EU organic regulations and that should not be changed because of this consideration of the use of glycerol as a humectant only for soft gel capsules.

Traditional use and precedents in organic production
Not traditionally used, but widely used currently for several uses as above. Precedent in place for use of Glycerol "For plant extracts and flavourings" in EU organic regulation. The use applied for in this dossier is not dissimilar for the use with plant extracts.

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

Permitted in USDA National Organic Programme standards

Glycerin - Permitted in Non-agricultural (nonorganic) substances allowed as ingredients in or on processed products labelled as "organic" or "made with organic (specified ingredients or food group/s). Section b. Synthetics allowed with the specific condition "produced by hydrolysis of fats and oils.

Not listed as permitted in Appendix 4 of IFOAM Norms.: List of approved additives & processing / post-harvest handling aids

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

Other relevant issues

Organic glycerol is for sale, although there is no clear information on the quantities available. It is produced from organic vegetable oils without the use of prohibited processes. Consideration should be given to requiring the use of certified organic glycerol in a specified time, for all uses, being sure on its availability.

In the long term, the availability of organic glycerol & organic gelatine makes the production of organic soft gel capsules a possibility. This possibility should be evaluated further, and it may be possible to specify that glycerol must be organic & must be combined with organic gelatine to produce organic gel capsules only.

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

There are no significant adverse reasons why glycerol should not be permitted for this use.

It should preferably be required to be used in organic form, providing sufficient organic glycerol can be made available, to encourage organic production & to remove the risk of glycerol derived from GM rapeseed being used.

Consideration was given to whether the sale of capsules, as opposed to individual products or whole foods was desirable. On one hand allowing organic glycerol would allow "organic capsules" which would significantly increase the market for organic supplements, & to allow them to compete with supplements containing non-organic oils etc. On the other it may be more desirable to encourage use of organic wholefoods as sources of essential oils, etc. Overall the former view predominated.

The group would recommend to use just one wording "organic glycerol" as well as for "organic lecithin, organic carnauba wax etc.".

Conclusions

The adoption of organic glycerol for any allowed use (i.e. as humectant in gel capsules and other uses already listed) is in line with the objectives, criteria and principles of the organic Regulation 834/2007. Therefore, the restriction "Only when derived from organic production" should be included to Annex VIII, Section A of Regulation 889/2008.

If market availability is sufficient the group propose to extend the mandatory use of organic glycerol also to the other scopes already allowed.

2.2. Glycerol for moisturing tablets food supplements

Introduction, scope of this chapter
Assessment of Glycerol 'For moisturing food supplements tablets,' as a result of submission of a dossier by BE.
Glycerol is also known as Glycerin/Glycerine. Propane 1, 2, 3 triol, CAS No: 56-81-5

Authorisation in general production and in organic production
Glycerol is found abundantly in nature in the form of triglycerides, which are the principal constituents of almost all vegetable and animal fats and oils. Glycerol occurs naturally in wines, beers, bread, and other fermentation products of grains and sugars due to formation by yeast as a by-product of fermentation.
EU Conventional: 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. E 422
Used as a thickener, Stabiliser, Emulsifier, Humectant, plasticiser and Sweetener.
It is used as a humectant (moisturising agent) in many foods such as tortillas, icing, cakes etc. Also used as a sweetener. Also, to reduce staling, as a thickener/ filler in reduced calorie foods and to reduce crystallisation in sugar preparations/icing. Also added to some spirits and liquers to improve mouthfeel.
Used in tablets to make the surface softer & more palatable, & to reduce the taste of the products in the tablets.
Specific purity criteria have been defined in the Commission Regulation (EU) No 231/2012.
Approval in Organic products.
Listed in regulation 889/2008/EC for plant-based products only with the condition "From plant origin. For plant extracts and flavourings"

Agronomic use, technological or physiological functionality for the intended use
Without glycerol, it is impossible to produce coated tablets for food supplements. The coating is necessary to obtain a smooth tablet and to mask the smell of some ingredients. This also improves the comfort for consumers and patient compliance.

Necessity for intended use, known alternatives
Without glycerol, it is impossible to produce tablets with coating for food supplements. The coating is necessary to obtain a smooth tablet and to mask the smell of some ingredients. This also improves the comfort for consumers and patient compliance.

Origin of raw materials, methods of manufacture
Glycerol is produced by hydrolysis of fats. The current restriction of "From plant origin" should be retained to ensure that glycerol from animal fat should not be permitted. This would also prohibit the use of glycerol chemically synthesised from propane.
There is a risk that glycerol could be produced from GM sources, e.g. GM oilseed rape. GM declarations from manufacturers would be required for this additive, if a requirement for organic glycerol is not made.

Environmental issues, use of resources, recycling
No significant issues of environmental impact would be raised by permitting the use of Glycerol in food supplement tablets for organic products. Glycerol is widely present in nature & readily biodegradable.

The weight of evidence indicates that glycerol is of low toxicity to aquatic organisms and this conclusion is supported by QSAR predictions. Glycerol is of very low acute toxicity to mammals. It has a low potential for sorption to soil and is not expected to bio accumulate. (1).

Animal welfare issues
None, providing only plant-based glycerol only is used.

Human health issues
Glycerine at pharmaceutical purity is GRAS. (2)
No health issues identified with the pure material. The weight of evidence indicates that glycerol is of low toxicity when ingested, inhaled or in contact with the skin. Glycerol is of a low order of acute oral and dermal toxicity with LD50 values more than 4000 mg/kg bw. Repeated oral exposure to glycerol does not induce adverse effects other than local irritation of the gastro-intestinal tract. Overall, glycerol is not considered to possess genotoxic potential. (2bis)

Food quality and authenticity
Use of glycerol in foods such as breads, cakes, wraps as a humectant may be considered to be hiding the true nature of the food. Similarly addition to alcoholic drinks to improve mouthfeel may also be considered as misleading. These applications of glycerol have never been permitted in EU organic regulations and that should not be changed as a result of this consideration of the use of glycerol for surface coating of tablets.

Traditional use and precedents in organic production
Not traditionally used, but widely used currently for several uses as above. Precedent in place for use of Glycerol For plant extracts and flavourings in EU organic regulation.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Permitted in USDA National Organic Programme standards
Glycerin - Permitted in 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 specific condition “produced by hydrolysis of fats and oils.
Not listed as permitted in Appendix 4 of IFOAM Norms.: List of approved additives & processing / post-harvest handling aids.
Glycerol is not listed as permitted as an additive in Japanese Organic Standards (JAS).

Other relevant issues
Organic glycerol is for sale, although there is no clear information on the quantities available. It is produced from organic vegetable oils without the use of prohibited processes. Consideration should be given to requiring the use of certified organic glycerol in a specified period for all uses.
In the long term the availability of organic glycerol & organic gelatine makes the production of tablets with organic glycerol a possibility. This possibility should be evaluated further, and it may be possible to specify that glycerol for this purpose must be organic.
Concern was expressed as to whether this is a proprietary process to the one company or a general process.

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

Glycerol is manufactured from plant oils. There is a risk that these could include GM oils e.g. rapeseed oil. GM declarations will be required if non-organic Glycerol is permitted.

Concern was expressed that this use as a surface treatment may not be in line with the principle of the regulation in that use to surface coat a tablet it is hiding the true nature of the product within the tablet. However, the purpose of a tablet is not to provide food "in its true nature".

The group agreed that this issue is less clear, than for capsules, but the group is inclined to recommend addition of organic glycerol to annex VIII A of Regulation 889/2008, providing that sufficient organic glycerol can be made available, to encourage organic production & to remove the risk of glycerol derived from GM rapeseed being used.

It should be clear that any additional approval is only for the requested use for surface coating of tablets only, not for any other uses.

Conclusions

The adoption of organic glycerol for use as a surface coating of tablets, only, is in line with the objectives, criteria and principles of the organic regulation in Regulation 834/2007. Therefore, the restriction "Only when derived from organic production" should be included to Annex VIII, Section A of Regulation 889/2008.

If market availability is sufficient the group propose to extend the mandatory use of organic glycerol also to the other scopes already allowed.

2.3. Lecithin clarification if this is the same as "organic lecithin"

Introduction, scope of this chapter
The request refers to the currently used term in the specific conditions in annex VIII for Lecithin. Until the end of 2018 lecithin (E322) is authorised for all organic food of plant origin and for organic food of animal origin (only in milk products) From 2019 onwards it has to be derived from organic raw materials. EGTOP report Food II recommended that it should be added the wording “in organic” form only. The question is, does "derived from organic raw material" mean the same as organic lecithin?.

Authorisation in general production and in organic production
Lecithin is authorised as food additive in Regulation No 133372008 and authorised as food additive in 889/2008/EC Annex VIII A.
Annex VIII stipulates that it shall be derived from organic material.

Agronomic use, technological or physiological functionality for the intended use
For this request the functionality is not relevant. Details are described at EGTOP report Food II.

Necessity for intended use, known alternatives
For current request the use of alternatives is not relevant.

Origin of raw materials, methods of manufacture
For current request the origin of raw materials and methods of manufacture is not relevant. Details to the process can be found at EGTOP report on food II.
The difference between manufacturing lecithin derived from organic raw materials to “organic” lecithin is, that all the processing steps shall be in line with the regulation. Only additives and processing aids authorised in Annex VIII B can be used. In the production of organic lecithin, the use of hydrogen peroxide for bleaching is not permitted as any other solvents.

Environmental issues, use of resources, recycling
None.

Animal welfare issues
None.

Human health issues
For the current request human health issues are not relevant.

Food quality and authenticity
For the current request the quality is not relevant.

Traditional use and precedents in organic production
Organic lecithin has been used in organic production for many years and accepted from conventional origin when organic was not available It fully complies with the regulation 834/2007.

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

Only in the EU regulation it is mandatory that Lecithin is derived from organic raw material. Several regulations permit it only with restrictions:

- Without bleaching,
- Codex Alimentarius (Guidelines for the production, processing, labelling and marketing of organically produced foods Annex 2: 2013),
- Japanese Organic Standards (JAS, 2017),
- IFOAM (Norms for Organic Production and Processing. Appendix 4, 2014),
- Australia (Australian Certified Organic Standard 2017 Version 1)
- Australia and Codex permit the use of lecithin only if it is produced without organic solvents
- No special requirements in the USDA NOP Regulation *§205.606. (2018)*

Other relevant issues
None identified.

Reflections of the Group / Balancing of arguments in the light of organic production principles
There was discussion about whether organic lecithin is suitable for all uses, due to colour, flavour etc. The group is not aware of any uses for which organic lecithin cannot be used.
EGTOP report Food II said that lecithin etc. should be "in organic form only". The wording "only when derived from organic raw materials" is less correct & was not used by EGTOP but was inserted later.
It is more clear to write "organic lecithin" than to write derived from organic raw materials.
For Carnauba wax and beeswax the same wording "organic" should be used, with the same meaning.

Conclusions
The group is clear that we should only permit organic lecithin (i.e. organic lecithin must be both derived from certified organic agriculture, but also from certified organic processing only).

2.4. Bentonite clarification if this is the same as calcium bentonite potassium bentonite. Similarly for calcium sulfate and Silicon oxide

Introduction, scope of this chapter
The request refers to the authorised processing aid Bentonite, because it is not specified which varieties of Bentonite are authorised to use for organic products. A second question is, if it could be authorised as sticking agent for plant oils.

Authorisation in general production and in organic production
Annex VIII 889/2008 Bentonite is authorised as processing aid for plant products and as sticking agent for mead.
It is not specified which variety is authorised. Bentonite is a natural mixture of the different varieties: It is named after the dominant elements potassium, sodium calcium and aluminium.

Agronomic use, technological or physiological functionality for the intended use
Bentonite is used for decolorizing various materials and for clarifying wine, liquor, cider, beer, mead and vinegar. As clarification agent especially, filtration Bentonite is very successful and often used.
Bentonite is as well used for sticking of products in fermentation such as mead. Sticking in this case refers to stopping the fermentation or encouraging it to continue. It is not the same use as "sticking" of plant oils.

Necessity for intended use, known alternatives
There are other clarification/filtration agents as activated carbon, silicon dioxide gel, perlite.

Origin of raw materials, methods of manufacture
Bentonite is a mined absorbent clay.

Environmental issues, use of resources, recycling
None.

Animal welfare issues
None.

Human health issues
None.

Food quality and authenticity
It is used in a food grade quality.

Traditional use and precedents in organic production
It is authorised in the current regulation 889/2008 Annex VIII B as a processing aid and for wine clarification in Annex VIIIa and as feed additive on Annex VI (d).

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

- Codex alimentarius: Bentonite is authorised as processing aid for plant origin.
- IFOAM: allowed as processing aid: only for fruit and vegetable products.
- JAS: as processing aid: Limited to be used for processed foods of plant origin.
- Australian: fruit, vegetable and wine as processing aid.

- Canadian: allowed without restriction as processing aid.
- NOP: allowed with no restriction.

Other relevant issues
None.

Reflections of the Group / Balancing of arguments in the light of organic production principles
Bentonite is fine as clarification, filtration aid but use as a sticking agent may be unclear.
The use of the term sticking in fermentation of products such as mead may refer to encouraging fermentation to continue or stop, i.e. to prevent or correct the fermentation stopping before the correct alcohol level has been reached, or to clear yeast from the fermentation before all sugar has been converted to alcohol. i.e. the fermentation has stuck.
The request to use bentonite as a sticking agent for plant oils is therefore clearly not the same as its permitted use in mead.
The dossier is not clear on what use for bentonite with plant oils as a sticking agent would be for, we are therefore unable to make a clear decision on whether this use should be permitted.
The group is not aware of any issues relating to any variety of bentonite & no differentiation of types of bentonite has been made. Therefore, the group believes that the permission to use bentonite applies to all varieties.
There is a variation in meaning of the translation of the phrase sticking agent into German & French in the regulation 889/2008 Annex VIII B as Verdickungsmittel. This word is also used to mean thickener. In French the phrase "agent colloïdal" is used.

Conclusions
The use of any varieties of Bentonite as a processing aid for preparation of foodstuffs of plant origin and of animal origin (mead only) is in line with the objectives, criteria and principles of organic Regulation 834/2007.

2.5. SiO2 in spices

Introduction, scope of this chapter
Silicon dioxide gel or colloidal solution is permitted in the regulation 889/2008, Annex VIII A, as an additive, permitted to use for herbs and spices in dried powdered form as well as in flavourings and propolis. It is also permitted in regulation 889/2008 Annex VIII B as a processing aid for foodstuffs of plant origin. In the horizontal legislation other wording is used. The question, in the dossier, is if the regulations could be harmonised and the word "food supplements" can be added in Annex VIII A of regulation 889/2008

Authorisation in general production and in organic production
Silicon dioxide is authorised as food additive (E 551) in Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b).
With the amendment of Regulation (EC) No 889/2008 (L 116/8) E 551 Silicon dioxide changed to Silicon dioxide gel or colloidal solution. This means, that amorphous silicon dioxide is not allowed in organic products. But in the specific conditions it is mentioned that it is only authorised in powdered form.
For feed additives (annex VI 889/2008) there are different silicon oxides authorised E551 b colloidal silica and E 551 c Kieselgur.
Silicon dioxide gel or colloidal solution is permitted as processing aids for plant products and for clarification of wine.

Agronomic use, technological or physiological functionality for the intended use
The addition of anti-caking agent such as silicon dioxide is used for herbs and spices and 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 products in general (more details see EGTOP report Food II).
It is as well used as silicon gel or colloidal solution as mentioned in Annex VIIIa for clarification.

Necessity for intended use, known alternatives
As anti-caking agents magnesium or calcium carbonate can be used for herbs and spice as well as for salt.

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
No specific concerns.

Animal welfare issues
No specific concerns.

Human health issues
As mentioned at EGTOP report Food II, Silicon dioxide may be produced in particle sizes less than 100 micron diameter. These are normally considered as nanoparticles. In practice most silicon dioxide particles less than 100 micron 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.
EFSA Report 2018 shows that the safety of silicon dioxide is not as clear, because it may contain nano-sized particles. EFSA scientists warned that, depending on the starting material and the process used to manufacture the additive "it cannot totally be excluded" that some aggregates may be smaller than the nano threshold of 100 nm. (3)
Silicon gel or colloidal solutions are free from nano particles. Therefore, there is no problem for the environment or health

Food quality and authenticity
No applicable concerns.

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.

Authorised use in organic farming outside the EU / 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: i) permitted as a defoamer; ii) 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.

Other relevant issues
None.

Reflections of the Group / Balancing of arguments in the light of organic production principles
EFSA concerns over nano particles in amorphous silicon dioxide were noted. Nevertheless, the group was not inclined to recommend the prohibition of E551 Silicon dioxide, as an anti-caking agent, based on this concern, considering the need for specific uses and the possibility to manage the risk. At the same time the group recommends to restrict the potential for use of E551 to products containing less than 1% of crystalline silica. Moreover the group recommends providing workers with information on the health risks and a register to monitor health risks, being established.
The group is clear that the wording "Gel or colloidal solution" in Annex VIII A is incorrect & should be deleted. The current wording for application "herbs and spices in dried powdered form, Flavourings and propolis," is correct & should be maintained.

I.e. wording in Annex VIII A (Additives) should be E551; Silicon Dioxide, with the conditions: “Herbs and spices in dried powdered form, Flavourings and propolis,”
The use of the wording Gel or colloidal solution in Annex VIII B (Processing aids) is correct & should be continued to allow its use as a processing clarification in production of, for example, beers & fruit wines.
The group is clear that silicon dioxide is allowed in food supplements based on herbs and spices.
It is clear that at present the organic regulation does not permit use of E551 Silicon Dioxide in other plant-based products, for example dried fruit juice powders.
The dossier does not give enough information as to what other powders this additive may be used for. Therefore, the group suggests that dossiers should be submitted for other specific uses of Silicon Dioxide as anti-caking agent in other plant-based powders other than herbs & spices.
Similarly, any request to use E551 in any animal-based products other than propolis should be the subject of new dossiers.

Conclusions
The group is clear that the wording “Gel or colloidal solution” applied to Silicon Dioxide in Annex VIII A is incorrect & should be deleted. The current wording for application “herbs and spices in dried powdered form, flavourings and propolis,” is correct & should be maintained
The group is not able to recommend adding the word "food supplements" to specific conditions for E551 Silicon Dioxide in Annex VIII A of regulation 889/2008, as the dossier does not contain sufficient information to completely inform this assessment.
Furthermore, the group recommends to restrict the potential for use of E551 to products containing less than 1% of crystalline silica. The group also recommends providing workers with information on the health risks and a register to monitor health risks, being established.

2.6. Lactic acid for pH regulation in peas

Introduction, scope of this chapter
Plant protein extract faces a huge demand for food and feed processing as functional ingredient and as an alternative for meat protein. Organic farming follows the same trend. Moreover, peas protein is listed in annex IX as an ingredient which can be used as non-organic due to the weak availability.

Authorisation in general production and in organic production
Lactic acid (E270) is authorised as an additive in EU regulation 1129/2011 for a wide range of product.
In organic production it is also authorised as a cleaning and disinfection product (Annex VII EC 889/2008), as an additive (Annex VIII without any restriction for plant and animal products), as a processing aid only for pH regulation in brine for cheese making, in Annex VIII C for yeast production, in Annex VIIIa for wine-making and in Annex VI as preservative of feed.

Agronomic use, technological or physiological functionality for the intended use
According to the flowchart, pH regulation for production of pea protein extract seems to be an unavoidable step and thus may need some processing aids to be done finely. It involves a first step of alkalinisation and then an acidification by lactic acid.

Necessity for intended use, known alternatives
Swanson describes two main process for protein extraction in legumes:
- Dry method: Milling and air-classification, are designed to differentiate starch-rich legume seeds into two populations of particles differentiated by both size and density. Protein concentrates produced by air-classification of peas or lentils generally contain 38-65% protein.
- Wet method: Solubilisation of legume flour in an alkaline solution (pH 9-10, ca. 1.0 N NaOH), separation of insoluble by centrifugation and precipitation of protein isolates by acidification of the supernatant near the isoelectric point, of the globulins, pH of 4.5. Flocculated and precipitated proteins are collected by centrifugation. Pea isolates prepared with this process contain 90-95% protein by definition, with an overall protein yield of 80%. (4)

Origin of raw materials, methods of manufacture
Lactic acid is produced industrially by bacterial fermentation of carbohydrates (sugar, starch) and give 99.9% of L (+) lactic acid. Alternatively, by chemical synthesis from acetaldehyde, that is available from coal or crude oil and which gives racemic ratio of 1:1 L/D-Lactic acid.

Environmental issues, use of resources, recycling
The biological method of production is by fermentation from milk whey, beet juice, or from glucose from starch (cereals, potatoes) with bacteria such as *Lactobacillus spp*, giving lactate & carbon dioxide or acetic acid and ethanol.
The chemical method uses hydrogen cyanide and acetaldehyde and forms lactonitrile by hydrolysis. Hydrolysis performed by hydrochloric acid and ammonium chloride forms as a by-product. Japanese concern Musashino is one of the last big manufactures of lactic acid by this route.

Animal welfare issues

None identified.

Human health issues
There is no health concerned about lactic acid. There is a not limited ADI which have been set by JECFA in 1979 and it is considered as GRAS by FDA since 1978.
The FDA reports "there is no evidence of potential toxicity of the L-isomer for individuals of any age. However, premature infants fed formulas acidified with DL-lactic acid (or, in one instance, D(-) lactic acid), have reported to develop metabolic acidosis and growth retardation. Results of studies of full-term infants are conflicting and difficult to interpret"(5).

Food quality and authenticity
No concerns identified.

Traditional use and precedents in organic production
Lactic acid bacteria (LAB) have been used in food fermentations all over the world for millennia. Not only have there been no obvious harmful effects of this enormous exposure to the bacteria, but also the LAB are, in fact, an integral part of food safety, the keeping quality, and the nutritional quality of many perishable foodstuffs. Especially in the developing countries, these bacteria are of paramount importance for the safety of many foodstuffs (6).

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Authorised in NOP regulation: Non-synthetics allowed: Acids (Alginic; Citric - produced by microbial fermentation of carbohydrate substances; and Lactic).
Authorised in JAS regulation: Limited to use for processed vegetable or rice products, for sausage as casing, for dairy products as coagulating agent, and for cheese in salting as pH adjuster.
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 and processing aid without restriction.

Other relevant issues
None identified.

Reflections of the Group / Balancing of arguments in the light of organic production principles
The group discussed the possibility of lactic acid derived from organic agricultural ingredients, but was unable to reach a conclusion as to whether this was technically possible. The regulatory aspects of certification of such a process was also considered without resolution.
The group recommends that a question be prepared for future EGTOP regarding possibilities for requiring organic certification for carbon-based additives & processing aids. This should investigate not only the demand for these, but also the technological possibility, other additives & processing aids required & the regulatory possibilities since additives and processing aids may not be foods so may not be subject to the requirements of organic regulation. Examples of compounds for which these questions are applicable in this report alone are lactic acid, lecithin, tara gum, maltitol, glycerol etc.
The group considered the source of lactic acid. It is clearly preferable that the lactic acid should be from fermentation, rather than from chemical sources, but this leaves open the risk of lactic acid derived from GMOs. GM declarations would therefore be required.

Therefore the wording L (+) lactic acid should be used in Annex VIII of the regulations.
The group considered whether other methods of producing plant protein concentrates were available but does not have sufficient information. The dossier is not clear on possible methods, or raw materials other than peas.
The group reports the fact that protein extracts can be obtained from several plant species and there is no reason to restrict the decision to pea.

Conclusions
The use of L(+) lactic acid from fermentation, as a processing aid for preparation of pea protein, is in line with the objectives, criteria and principles of organic Regulation 834/2007. The addition to Annex VIII Section B of Regulation 889/2008 is recommended. As addition of Sodium Hydroxide (see below) & L (+) Lactic acid to Regulation 889/2008 Annex VIII Section B will allow production of organic pea protein extract, the group recommends deletion of "pea protein *Pisum* spp." from Annex IX Section 2.3 and to restrict it from organic origin in Annex VIIIa.
The group also recommends allowing the production of protein extract on other plant species and not limiting it only to pea.

2.7. NaOH for pH regulation in peas; covered by the earlier evaluation for a more general use

Introduction, scope of this chapter
Plant protein extract faces a huge demand for food and feed processing as functional ingredient and as an alternative for meat protein. Organic farming follows the same trend. Moreover, peas protein is listed in annex IX as an ingredient which can be used as non-organic due to the weak availability.

Authorisation in general production and in organic production
Sodium hydroxide is authorised as a food additive (E524) in Regulation (EC) No 1130/2011 amending Annex III to Regulation (EC) no 1333/2008 of the European Parliament and of the Council following the *quantum satis* principle.
NaOH or lye is already authorised in organic farming as processing aid for sugar processing and vegetal oil processing (except for olive oil) only.

Agronomic use, technological or physiological functionality for the intended use
The intended use is to perform the alkalinisation/acidification step which allow protein precipitation.

Necessity for intended use, known alternatives
According to the flowchart, pH regulation for pea protein extract seems to be an unavoidable step and thus may need some processing aids to be done finely. It involves a first step of alkalinisation and then an acidification.

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

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

Animal welfare issues
None identified.

Human health issues
No residue should be detectable in the final product (processing aid). However, no ADI have been set for NaOH.

Food quality and authenticity
The protein extract is used as an ingredient in processed food, so the extraction method should not impact the food quality of the product.

Traditional use and precedents in organic production
None identified.

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

JAS regulation: authorised as additive but limited to be used for processing sugar as pH adjustment agent or used for grain processed foods.
NOP regulation: synthetic ingredient authorised in NOP regulation except for lye peeling of fruit and vegetable.
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 and processing aid for sugar processing and for the surface treatment of traditional bakery products.

Other relevant issues

None identified.

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

The group considered whether other methods of producing plant protein concentrates were available but does not have sufficient information. The dossier is not clear on possible alternative methods.
The group considered that in the absence of alternative to perform alkalinisation step, NaOH could be included in the Annex VIII B as a processing aid for pea and other plant protein extraction.
Indeed, protein concentration could be done without additives or aids with the physical method, less efficient but still more in line with organic principles. But the need to step to 100% organic feed preferably of local origin requests supply of more and more concentrated proteins.
As pea and other plant protein extract can be obtained by organic processing, it must be then removed from the Annex IX and be restricted to organic origin in Annex VIIIa.

Conclusions

The use of Sodium Hydroxide, as a processing aid for preparation of pea protein, is in line with the objectives, criteria and principles of organic Regulation 834/2007. The addition to Annex VIII Section B of Regulation 889/2008 is recommended. As addition of Sodium Hydroxide & L (+) Lactic acid to Regulation 889/2008 Annex VIII Section B will allow production of organic pea protein extract, the group recommends deletion of “pea protein Pisum spp.” from Annex IX Section 2.3 and to restrict it from organic origin in Annex VIIIa.
The group also recommends allowing the production of protein extract on other plant species and not limiting it only to pea.

2.8. PGPR-polyglycerol polyricinoleate for production of biscuits etc.

Introduction, scope of this chapter
This chapter concerns the application & dossier from BE requesting the allowance of E 476. Polyglycerol polyricinoleate (PGPR) specifically as an emulsifier for fat and oil emulsions used in production of cigarettes russes/piroulines.
PGPR is alternatively known as 1,2,3-Propanetriol, homopolymer. CAS Number: 29894-35-7

Authorisation in general production and in organic production
E 476 is authorised as a food additive in the European Union (EU) according to Annex II XX for the following uses:
-Cocoa and chocolate products as covered by Directive 2000/36/EC;
-Other confectionery including breath freshening microsweets;
-Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4;
-Sauces;
-Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions.
According to Annex III, Part 2 of Regulation (EC) No 1333/2008, E 476 is also authorised:
-as an emulsifier in preparations of food colours E 100 curcumin and E 120 cochineal, carminic acid, carmines and E 163 anthocyanins at the maximum levels of 50,000 mg/kg in the food colour preparations and at 500 mg/kg in the final food only in:
- Surimi and Japanese-type fish products (Kamaboko)
- (for the food additive E 120 cochineal, carminic acid, carmines);
- meat products, fish pastes and fruit preparations used in flavoured milk products and desserts (for the food additives E 163 anthocyanins, E 100 curcumin and E 120 cochineal, carminic acid, carmines).
Specific purity criteria have been defined in the Commission Regulation (EU) No 231/2012.
Not permitted for any organic production

Agronomic use, technological or physiological functionality for the intended use
Used as a releasing agent, emulsifier.

Necessity for intended use, known alternatives
The dossier produced by BE on behalf of one producer, maintains that there is no other suitable additive/processing aid for the specific use in the production of the specific cigarette russes/piroulines.
Another additive E322 Lecithin is also used to make water in oil emulsions. However, the dossier says that this is not able to make emulsions with sufficiently high water content for this application.

Origin of raw materials, methods of manufacture
PGPR is a mixture of reaction products formed by the esterification of polyglycerols with condensed castor oil fatty acids. (7)
Wilson et al. (1998) (7bis) and Bastida-Rodriguez (2013) (8) described a process for the manufacture of PGPR, involving the following four steps:
<u>i) Preparation of the castor oil fatty acids</u>
The castor oil fatty acids are produced by hydrolysing castor oil with water and steam at a pressure of approximately 2.8 MPa without a catalyst; the resulting fatty acids are freed from glycerol by water washing. Castor oil contains, as main fatty acids: ricinoleic acid (80- 90%), oleic acid (3- 8%), linoleic acid (3- 7%) and stearic acid (0- 2%).

ii) Condensation of the castor oil fatty acids

The castor oil fatty acids are condensed by heating the castor oil fatty acids at a temperature of 205- 210° C under vacuum and a CO2 atmosphere (to prevent oxidation) for approximately 8 h. The reaction is controlled, by monitoring the acid value, until an acid value of 35- 40 mg KOH/g (i.e. about 4- 5 fatty acid residues per molecule of condensed substance).

iii) Preparation of polyglycerols.

According to Bastida-Rodriguez (2013), the polyglycerol portion can be prepared by three routes: (1) by polymerisation of glycerol using a strong base as a catalyst, (2) by polymerisation of glycidol, which leads to linear polyglycerols or (3) by polymerisation of epichlorohydrin, followed by hydrolysis, which also leads to linear polyglycerols. Polyglycerols produced by polymerisation of epichlorohydrin contain reduced proportions of cyclic components.

iv) Partial esterification of the condensed castor oil fatty acids with polyglycerols

The final stage of the production involves heating of an appropriate amount of polyglycerol with the polyricinoleic acid. The reaction takes place immediately following the preparation of the latter and in the same vessel, while the charge is still hot. The esterification conditions are the same as those for fatty acid condensation. The process is continued until a sample withdrawn from the reaction mixture is found to have a suitable acid value (i.e. ≤ 6 mg KOH/g) and refractive index, as required by the specifications.

Tenore (2012) (8bis) described a new process for the manufacturing of PGPR using as starting materials polyglycerols and castor oil fatty acids obtained as described by Wilson et al. (1998). In this new process, non-polymerised ricinoleic acid is combined with polyglycerols (preferably with a molecular weight in the range of 160- 400 g/mol) at a ratio of about 11:1 (w/w). Non-polymerised ricinoleic acid is condensed to polyricinoleate which is then, in a one-step process, reacted with polyglycerol.

Water is continuously removed under reduced pressure (about 0.068 MPa). The condensation, the contemporaneous co-polymerisation and the interesterification is conducted at a temperature of 200° C.

The condensation and co-polymerisation reactions are maintained until the PGPR in the reaction mixture reaches the characteristics complying with EU specifications. It is indicated by the author that in this new process a catalyst is not necessary, but that the reaction rate can be increased using either a basic catalyst (sodium or potassium hydroxide) or an acidic catalyst (phosphoric or phosphorous acid). It is also indicated that an enzymatic catalyst (lipase approved for food applications; not further specified) can be used. When the enzymatic catalyst is used, the reaction temperature is reduced to 75° C.

Gomez et al. (2011) (9) described the enzymatic biosynthesis of polyglycerol polyricinoleate (E 476) starting from polyglycerol and polyricinoleic acid using Rhizopus arrhizus lipase as a catalyst. The reaction takes place in the presence of a very limited amount of aqueous phase. It is stated that no organic solvent was necessary to solubilise the substrates, allowing a reaction medium solely composed of the required substrates. In the process, lipase is immobilised by physical adsorption onto an anion exchange matrix. PGPR produced by this process had an acid value of 16 mg KOH/g which was far above the required EU specification for this parameter (i.e. acid value < 6 mg KOH/g), However, when synthesised under controlled atmosphere in a vacuum reactor with dry nitrogen intake, the PGPR reaction product obtained in this way had an acid value of 4.9 mg KOH/g, complying with the EU specifications. It is stated that the method is a starting point for using the enzymatic procedure in the industrial biosynthesis of PGPR.

In subsequent publications, the same authors (Ortega et al., 2013; Ortega-Requena et al., 2014) (10; 10bis) described improved methods using lipases from R. arrhizus , Rhizopus

oryzae and Candida antartica , resulting in the production of a PGPR with an acid value of 4.91, 5.31 and 1.30 mg KOH/g, respectively.
The non-enzymic process is complex, presumably requires significant energy input, and uses unspecified catalysts.
The possibility of enzymic processes is present, but that includes the use of enzymes adsorbed onto an ion exchange matrix.
While there may be organic castor oil & glycerol there appears no possibility of production of PGPR in organic certified form, even using the enzymic method.

Environmental issues, use of resources, recycling
Significant energy usage will be required to produce this compound.
The castor oil plant is grown in various parts of the world, including India & China. Concerns have been expressed over the replacement of food crops with castor oil plantation & with environmental issues associated with the pressing & purification of the oil, in particular the fate of the ricin present in the castor oil seeds. (11)
Castor oil may be produced by solvent extraction, using methanol. (12)

Animal welfare issues
None applicable

Human health issues
GRAS (13) No evidence of carcinogenicity etc.
The EU ADI level 25mg PGPR/kg bw per day, recently increased from 7.5mg/kg PGPR/kg bw per day. (14)

Food quality and authenticity
Not a traditional compound. First introduced in1950s.
Not a concerns regarding authenticity in the case of manufacture of cigarettes russes/piroulines. In other cases, such as its use in chocolate where it can be used to replace cocoa butter & enable chocolate to flow better, these uses could be considered hiding the true nature of the chocolate. The dossier confirms that these uses are not considered appropriate for use in organic production, but there is a concern that allowing the use in baked products opens the way for other applications for the same compound & for applications for similar emulsifiers.

Traditional use and precedents in organic production
No precedent for this product. Organic oils are now, or will soon be, required for greasing/releasing in organic production.
The application is on the behalf of one single BE operator

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Currently not authorised in annex VIII of Regulation EC 889/2008.
Not authorised as an additive in US National Organic Program.
Not authorised as an additive in Japanese Organic Standards (JAS).
Not authorised in IFOAM norms for organic production and processing. Appendix 4 - Table 1: List of approved additives & processing/post-harvest handling aids

Other relevant issues

There is a potential issue regarding approval of PGPR for production of cigarettes russes & piroulines. This is because PGPR is useful for many other uses such as greasing & releasing in baked goods & for improving flow characteristics of chocolate etc. These are areas for which currently only organic oils or lecithin are permitted. It would be expected that there would be several other applications for uses of PGPR as releasing agents etc. in other applications, simply because PGPR is likely to be cheaper and in some cases more effective than pure organic oils. Also, for similar compounds for specific uses other than these applied for in this case.

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

The group is aware that some biscuits similar to cigarettes russes/piroulines can be produced without the use of this additive. (15)

Conclusions

Overall the group considers that adoption of PGPR as an emulsifier in cigarettes russes & piroulines, is not in line with the objectives, criteria and principles of the organic Regulation 834/2007, for addition to Annex VIII, Section A to Regulation 889/2008.

2.9. NaOH, for debittering of olives

Introduction, scope of this chapter

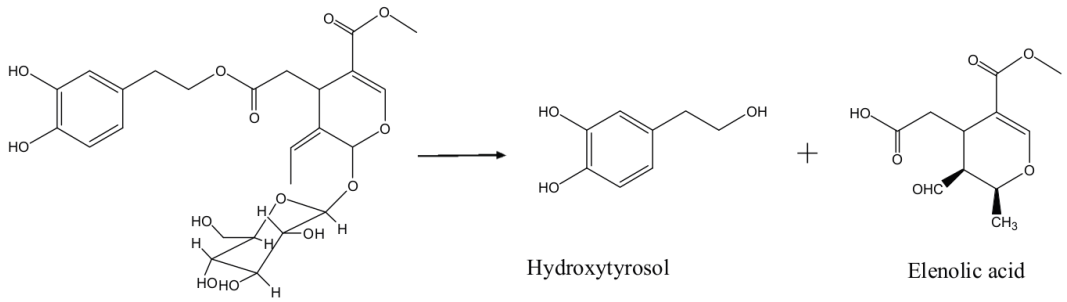
This chapter concerns the IT dossier requesting addition of the use of sodium hydroxide for the debittering of olives only to Annex VIII B of regulation 889/2008.

Authorisation in general production and in organic production

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

NaOH or lye is already authorised in organic farming as processing aid for sugar processing and vegetable oil processing (but excepting olive oil).

Agronomic use, technological or physiological functionality for the intended use



Oleuropein Hydroxytyrosol Elenolic acid

The intended used is to reduce bitterness by hydrolysing oleuropein according to the reaction above.

Necessity for intended use, known alternatives

There is a known and historic alternative which consist of steeping olives in water with ashes added. However, migration of substances from ashes to olive have to be considered. This process is no longer acceptable.

Acid and base could lead to oleuropein degradation, enzymatic hydrolysation could also lead to debittering (Ozdemir, 2014; Jiao-Jiao, 2015) (16; 17)

Two alternative processes would be allowed in organic processing:

- pour olive in water during several days (20 days) and change water twice a day, then put olive in brine for fermentation;
- pour olive directly in brine and wait for bittering to disappear as long as 8 months to 2 years depending on varieties and oleuropeine rate;

In both processes, debittering is not fully mastered and can lead to browning and softening.

Origin of raw materials, methods of manufacture

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

Environmental issues, use of resources, recycling

The electrolytic conversion of sodium chloride to sodium hydroxide and chlorine is potentially one of the most damaging processes used due to the production of reactive chlorine molecules that are used in the production of toxic materials, either deliberately or as by-products of other processes.

However, this risk is managed if correctly produced and handled according to EU environmental legislation.

Animal welfare issues
None

Human health issues
No residue should be detectable in the final product (processing aid). No ADI has been set for NaOH.

Food quality and authenticity
The food quality should not be affected as no residue is left in the final product.

Traditional use and precedents in organic production
This process, is traditionally used in certain types of Italian olive production i.e. large green olives. Alternatives using washing with water and/or brine or flavouring using herbs are used in other types of production.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
JAS regulation: authorised as additive but limited to be used for processing sugar as pH adjustment agent or used for grain processed foods.
NOP regulation: synthetic ingredient authorised in NOP regulation except for lye peeling of fruit and vegetable.

Other relevant issues
None identified.

Reflections of the Group / Balancing of arguments in the light of organic production principles
The group discussed in what cases enzymic or other processes could be used instead of lye treatment, for debittering olives. The dossier is insufficiently detailed on this point.
The group is inclined to prefer enzymic (non-GM) or other techniques such as washing with water and/or salt.
The group is not inclined to allow lye debittering of olives when a significant quantity of organic olives is currently produced without this process.

Conclusions
Overall the group considers that adoption of sodium hydroxide for debittering of olives is not in line with the objectives, criteria and principles of the organic regulation in regulation 834/2007, for addition to as a processing aid to Annex VIII, Section B to Regulation 889/2008.

2.10. Vegetable carbon for cheese making

Introduction, scope of this chapter
The mandate is based on a request from FR for addition of the substance vegetable carbon for use as natural colour in organic cheese production. Extension of the authorisation of this substance for new categories in the Commission Regulation (EC) No 889/2008 Annex VIII A Vegetable Carbon E 153. Used as natural food colour in edible cheese rind.

Authorisation in general production and in organic production
The food additive vegetable carbon is authorised for use in ripened cheese (legislation: (EU) No 1129/2011, (point 1.7.2) in conventional food. In addition, vegetable carbon is authorised as food colour in Group II at *quantum satis* for the following categories:
• Unripened cheese excluding products falling in category 16 (1.7.1) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013)
• Edible cheese rind (1.7.3) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013)
• Whey cheese (1.7.4) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013)
• Processed cheese (1.7.5) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013)
• Cheese products (excluding products falling in category 16) (1.7.6) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013)
Permitted for used in organic "Ashy goat cheese" and "Morbier cheese" according to Commission Regulation (EC) No 889/2008 Annex VIII section A.

Agronomic use, technological or physiological functionality for the intended use
Traditionally, the Morbier cheese (France) consists of a layer of morning milk and a layer of evening milk. When making cheese, cheesemakers would end the day with leftover curd that was not enough for an entire cheese. Thus, they would press the remaining evening curd into a mould and spread ash over it to protect it overnight. The following morning, the cheese would be topped up with morning milk.

Necessity for intended use, known alternatives
Nowadays, the cheese is usually made from a single milking and the traditional ash line is replaced with vegetable dye from medicinal vegetable carbon.

Origin of raw materials, methods of manufacture
Description of vegetable carbon according to the Commission Regulation (EU) No 231/201:
Vegetable activated carbon is produced by the carbonisation of vegetable material such as wood, cellulose residues, peat and coconut and other shells. The activated carbon thus produced is milled by a roller mill and the resulting highly activated powdered carbon is treated by a cyclone. The fine fraction (40800) from the cyclone is purified by hydrochloric acid washing, neutralised and then dried. The resulting product is what is known traditionally as vegetable black. Products with a higher colouring power are produced from the fine fraction by a further cyclone treatment or by extra milling, followed by acid washing, neutralising and drying. It consists essentially of finely divided carbon. It may contain minor amounts of nitrogen, hydrogen and oxygen. Some moisture may be absorbed on the product after manufacture.
Description: Black, odourless powder.

Environmental issues, use of resources, recycling
No negative impact.

Animal welfare issues
No relevance. Absence of extensive animal toxicological data.

Human health issues
EFSA has concluded that vegetable carbon at the reported use and use levels is not of safety concern.
EFSA Journal (2012): Scientific Opinion on the re-evaluation of vegetable carbon as a food additive (18).

Food quality and authenticity
Natural food colour substance. It contributes to traditional products (cheese) identity.

Traditional use and precedents in organic production
Used in organic "Ashy goat cheese" and "Morbier cheese" according to Commission Regulation (EC) No 889/2008 Annex VIII section A.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
(Non-organic) Vegetable carbon is authorised as a food additive in the EU and previously evaluated by the EU Scientific Committee for Food (SCF) in 1977 and 1983 (SCF 1977, 1984) and by the Joint FAO/WHO REF Expert Committee on Food Additives (JECFA) in 1970, 1977 and 1987 (JECFA 1971, 1978, 1987).
Neither JECFA nor the SCF established an acceptable daily intake (ADI) for vegetable carbon, but the SCF concluded that vegetable carbon could be used in food.
E153. It is approved for use as additive 153 (Carbon blacks or Vegetable carbon) in Australia.

Other relevant issues
The actual limitation is based on traditional practices and/or cheese requirements in PDO/PGI schemes (ex: Morbier). But with the development of the organic cheese sector (+7,1% increase of the production in 2014 in France), new products could be proposed on the market to maintain the positive development of the organic sector.
The last 15 years there has been a large increase in farmhouse cheese making, and there are between 25 and 30 farmhouse and artisan cheesemakers making organic cheese in Norway. Restrictions of use of additives to specific kinds of milk (use of vegetable carbon in goat cheese, but not in cow and sheep milk), might limits the possibility of developing new products. The group is aware that Morbier is a semi-soft cows' milk cheese of France. Similarly, Carboncino is made in Italy's Piedmont region, at the dairy Caseificio dell'Alta Langa near Alba. Classified as a "tre latti" cheese, it is a soft, rich and creamy Italian cheese made of blended sheep, cow and goat's milk and uses a vegetable charcoal covering.

Reflections of the Group / Balancing of arguments in the light of organic production principles
The group consider that in general organic foods should be produced without E-code colours & that there is a presumption that they might hide the true nature of the food. The use applied for is solely for colouring/marketing of the product, which, unlike Ashy Goats cheese & Morbier are not traditional products.
The group considers that it is clear that the use of vegetable carbon according to this application has no technological function in the cheese.
The use of an ash layer to prevent deterioration between a day's two separate milking is no longer required.

However, the group agree on the possibility to assess other traditional cheese types (PDO or similar) if a well-documented traditional use is provided.

Conclusions

Overall the group considers that adoption of E 153 Vegetable carbon, for colouring of cheese is not in line with the objectives, criteria and principles of the organic regulation in regulation 834/2007, for addition as additive to Annex VIII, Section A to Regulation 889/2008, with the exception of traditional uses in Morbier and Ashy Goats Cheese.

2.11. Potassium poly-aspartate (for wine making)

Introduction, scope of this chapter
Assessment of Potassium Poly-aspartate (for wine making) as an additive in production of organic wine.
Consideration of the IT dossier regarding addition of this compound.
Alternative name: L-Aspartic Acid, Homopolymer, potassium salt. CAS number: 64723-18-8.
Abbreviated to KPA in this document.

Authorisation in general production and in organic production
KPA was adopted as a permitted additive in non-organic products as E 456 by regulation 2017/1399, July 2017.
Not authorised in any organic production as far as we are aware.

Agronomic use, technological or physiological functionality for the intended use
Approval for use is requested for stabilisation of organic wine against precipitation of tartaric acid crystals.

Necessity for intended use, known alternatives
Other methods used for tartaric stabilisation include long term chilling, or use of other additives such as mannoproteins, carboxymethylcellulose etc.
EGTOP considered an application to add yeast mannoproteins as a permitted additive in wines in 2015 and recommended addition, in organic form, once the availability (or not) had been established.
Yeast mannoprotein for tartaric stabilisation is expected to be added to annex VIIIa, subject to COP approval.
This application indicates that mannoproteins are not preferable to KPA in terms of cost, effectiveness or environmental cost.

Origin of raw materials, methods of manufacture
The raw material for KPA is aspartic acid, which is produced by fermentation, currently using non-GM micro-organisms. It will need to be established that the organism is non-GM & the substrates used are not GMOs as part of any certification approval for use of this compound.
KPA is produced from aspartic acid by heating and the addition of potassium hydroxide.
In theory KPA could be produced using organic substrates, but the requirement for addition of potassium hydroxide would, at present prevent the production of KPA in certified organic form.

Environmental issues, use of resources, recycling
The dossier received on KPA relies partly on the "Stabiwine" report on additives & techniques for tartaric stabilisation of wine. It indicates that, overall, use of KPA to stabilise wine produces significantly less greenhouse gas, waste water etc than the main alternative available to organic wineries, long term cold storage. In general, KPA had similar environmental impact to the other additives available.
Of the additives considered in the Stabiwine project report only metatartaric acid is currently permitted in organic wine.
The Stabiwine report indicates that KPA has the advantage over metatartaric acid in that KPA's effectiveness does not decline with age of the wine.

Animal welfare issues

None.

Human health issues
The EFSA safety Panel concluded that there was no safety concern from the proposed use and use levels of potassium polyaspartate as a stabiliser in wine (19).

Food quality and authenticity
KPA positively improves wine quality by preventing formation of tartaric acid crystals. It does not remove flavour or aroma compounds in the way that other tartrate proofing chemicals do.
KPA is not a traditional additive to wine, so is not truly authentic. There is no indication that its use would be detectable by the consumer. In due course it is expected that additives to wine will need to be labelled. This would be a positive step forward to enable clarity on the additives used in alcoholic drinks, as in other food & drink.

Traditional use and precedents in organic production
This is not a traditional compound, and it has no direct precedent in organic wine. Significant research has been done into finding new additives that will stabilise wine against tartrate crystal formation, so this is a modern, scientific development.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
No current authorisation in any known organic standards.

Other relevant issues
The dossier has been developed with the help of the Stabiwine project, which includes organic stakeholders. They have selected KPA as the preferred new additive for use in organic wine.

Reflections of the Group / Balancing of arguments in the light of organic production principles
The group is aware of the growing concern from consumers regarding the amount of ingredients/processing aids in organic wines. Therefore, the group recommends a thorough review of the list of additives for wine.

Conclusions
As there are viable alternatives, more in line with organic production, that can be used for stabilization of organic wine against precipitation of tartaric acid crystals (e.g. temperature control, bentonite that is of mineral origin, meta-tartaric acid), the group is inclined to consider not essential the use of KPA. As a consequence, the group does not recommends KPA for addition to Annex VIIIa of 889/2008.

2.12. Hydrochloric acide (for the production of pyrodextrines)

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

Authorisation in general production and in organic production
Hydrochloric acid (HCl) is accepted as a food additive "E 507" according to Commission Regulations (EU) no. 1130/2011 and (EU) No 1129/2011 (applicable from 01/06/2013) and is in the list of Group 1 additives generally authorised in foodstuffs (including starches) to be used in accordance with the *quantum satis* principle. In addition, hydrochloric acid is authorised to be used only for pH adjustment in accordance with the *quantum satis* principle for:
1) Processed cereal based foods and baby foods as defined by Directive 2006/125/EC (13.1.3);
2) Other foods for young children (13.1.4);
3) Dietary foods for infants for special medical purposes and special formulae for infants (13.1.5.1).

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

Necessity for intended use, known alternatives
Weaker acids such as acetic acid, lactic acid and citric acid can be used for adjustment of pH, but they might influence the products as larger amounts of acids are needed for the pH adjustment.
Enzymatic processes may be used to produce dextrins. The new dossier clearly explains that enzymatic processes cannot be used to produce pyrodextrins & that maltodextrins produced by enzymic hydrolysis clearly do not have the same properties such as glazing, gluing etc. that pyrodextrins do.
Hydrochloric acid is intended to be used as a processing aid in the processing of organic pyrodextrin from potato starch. The acids split the glycoside bonds in the starch so smaller molecules are formed. Citric acid and sulphuric acid are now authorised as processing aids for preparation of organic foodstuffs of plant origin, and they have been tested for the purpose of dextrin formation from starch; however, they are not good for this purpose.
The dossier maintains that the only way to produce pyrodextrins suitable for coating in deep-fat frying, improving workability of the dough on bakery production lines (reducing stickiness), as a final film coating for confectionery, for final treatment and decorating bakery products (shiny glaze, adhering spices or seeds) and as a substitute for glucose syrup for gluing of muesli bars.

Origin of raw materials, methods of manufacture
The dossier maintains that organic pyrodextrin produced using hydrochloric acid can be produced from organic potatoes if hydrochloric acid is permitted.

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

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

Animal welfare issues
None.

Human health issues
Gastric acid is one of the main secretions of the stomach of human and animals, and it consists mainly of hydrochloric acid and acidifies the stomach content to a pH of 1 to 2. The stomach itself is protected from the strong acid by the secretion of a thick mucus layer, and by secretin induced buffering with sodium bicarbonate.
Hydrochloric acid is corrosive to the eyes, skin, and mucous membranes. Acute (short-term) inhalation exposure may cause eye, nose, and respiratory tract irritation and inflammation and pulmonary oedema in humans. Acute oral exposure may cause corrosion of the mucous membranes, oesophagus, and stomach and dermal contact may produce severe burns, ulceration, and scarring in humans. Chronic (long-term) occupational exposure to hydrochloric acid has been reported to cause gastritis, chronic bronchitis, dermatitis, and photosensitization in workers. Prolonged exposure to low concentrations may also cause dental discoloration and erosion. EPA has not classified hydrochloric acid for carcinogenicity (20).
Personal protective equipment such as rubber or PVC gloves, protective eye goggles, and chemical-resistant clothing and shoes are used to minimise risks when handling hydrochloric acid.
Hydrochloric acid is required for the production of pyrodextrins. There is no indication that pyrodextrins are in any way injurious to health. They are regarded as foods, rather than additives. They may be used to reduce acrylamide production in the coating of fried foods.

Food quality and authenticity
Pyrodextrins could be used to hide food quality deficits & cannot be considered to be authentic. The hydrochloric acid use would not be expected to be mentioned on the label as its use is as a processing aid.

Traditional use and precedents in organic production
Hydrochloric acid is authorised in Annex VIII B of regulation 889/2008 as a processing aid for preparation of organic foodstuff of animal origin, specified as use for gelatine production, and for the regulation of the pH of the brine bath in the processing of cheeses Gouda, Edam, Massdammer, Boerenkaas, Friese and Leidse Nagelkaas, only.

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

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

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

Not permitted in Japanese Organic Standards. JAS

Other relevant issues

The key question in considering this application is not whether hydrochloric acid is permissible. Concentrations used are low (c2%) and there is no residual acid in the finished pyrodextrin.

The key question is whether it is desirable to add a new use for HCl in order to have organic pyrodextrins in organic food products. On the positive side they may be used to reduce acrylamide production in fried foods. However, they may also be used for non-traditional techniques such as glazing which has previously been done using organic milk, egg white etc.

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

HCl has been permitted for use, specifically to allow production of organic gelatine. There are some positive uses for pyrodextrin which would be opened for the organic sector, by the enabling of production of organic pyrodextrin. There is also an argument that the use of any chemical to produce an organic ingredient is against the principles of the regulation. Furthermore, the group consider that there are alternatives to the use of pyrodextrin (e.g. different recipes, different products, etc.) based on agricultural ingredients and the acrylamide risk can be managed differently.

Conclusions

The group considers the use of Hydrochloric Acid to produce organic pyrodextrin not in line with the objectives, criteria & principles of Regulation 834/2007.

2.13. Maltitol & maltitol syrup for bakery products

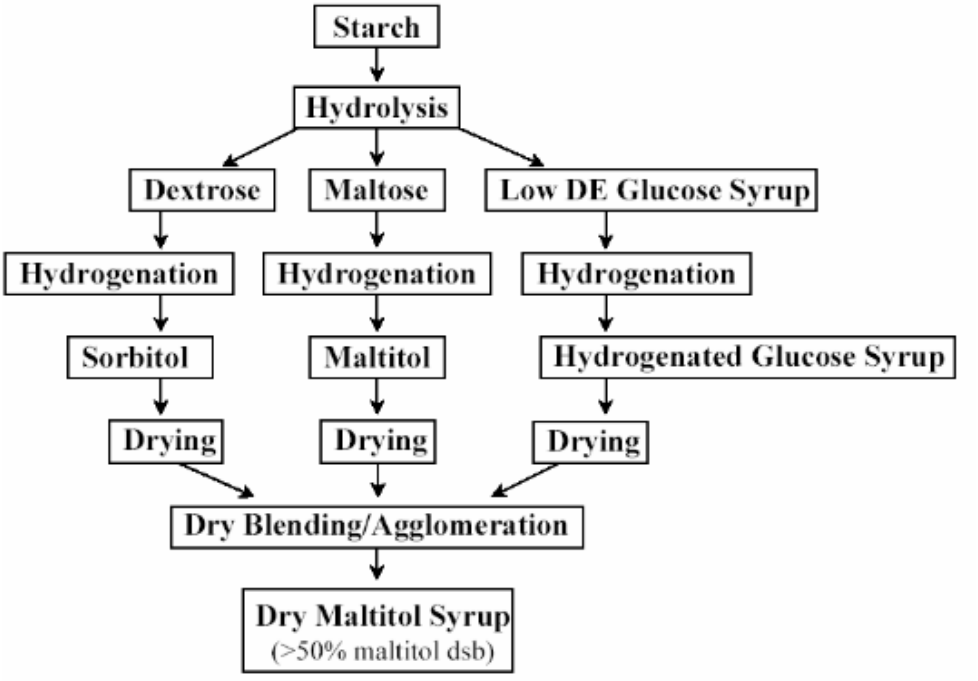
Introduction, scope of this chapter
The following report is based on the request of IT for the addition of conventional maltitol (E 965 i) and maltitol syrup (E 965 ii) as a food additive in organic food processing as a low-calorie sweetener for bakery products.

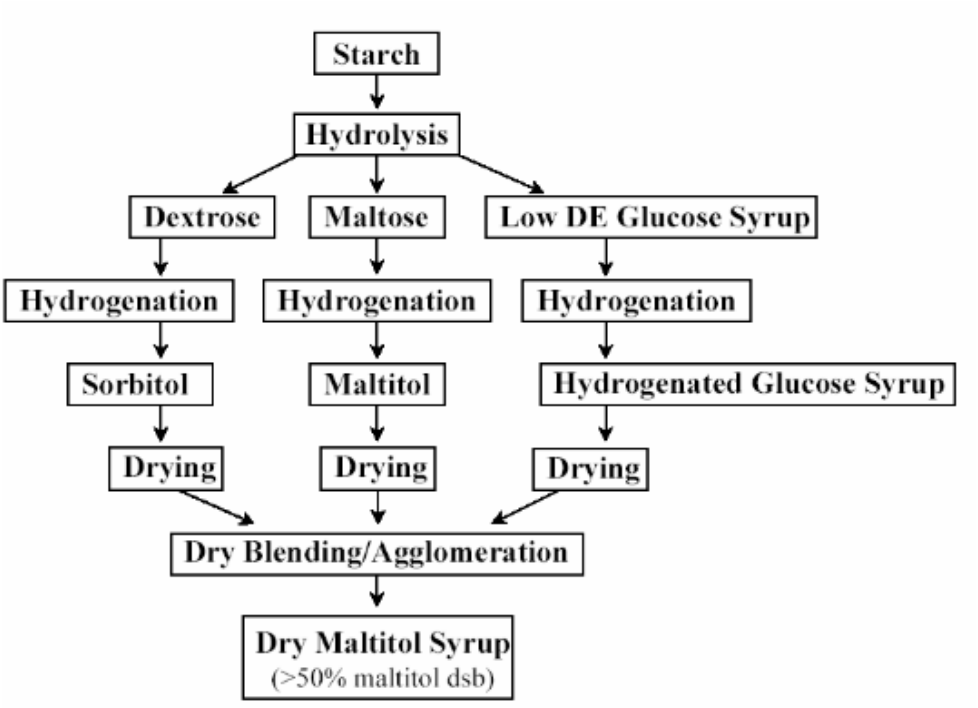
Authorisation in general production and in organic production
Maltitols (E 965 i) and maltitol syrup (E 965 ii) are listed as polyols in the Commission Regulation (EC) No 1129/2011 on additive and are useable for bakery ware only energy-reduced or with no added sugar.

Agronomic use, technological or physiological functionality for the intended use
The intended use is to obtain no calorie or energy reduced bakery products.

Necessity for intended use, known alternatives
The necessity for this sweetener is not clearly demonstrated. So far erythritol is authorised in organic production and may be used instead.

Origin of raw materials, methods of manufacture
Maltitol & maltitol syrup are produced from starch which is hydrolysed and hydrogenated (see process below).





Maltitol is commercially also one of the largest produced polyols with an approximate volume of 160 000 MT including hydrogenated starch hydrolysates. A survey of products shows that maltitol is used in food mostly in the sweet food categories such cakes, pastries, sugar confectionery, chocolate, chewing gum and snack bars as well as a tablet sweetener, as it has a similar sweetness to sugar (sucrose). Maltitol is made through the hydrogenation of maltose, which is obtained from enzyme conversion of starch to maltose. Maltitol is non-cariogenic and resistant to metabolism by oral bacteria which break down sugars and starches to release acids that may lead to cavities or erode tooth enamel (21).

Environmental issues, use of resources, recycling
No adverse information was found regarding environmental issues on maltitol or maltitol syrup.

Animal welfare issues
None.

Human health issues
Maltitol has been evaluated by Scientific Committee on Food in 1984 and 1999 (SCF 1985 and 1999) and then in 2005 for maltitol syrup. This committee considered its use as acceptable provided that limitations due to laxative action were kept in mind (22).

Food quality and authenticity
Maltitol syrup contain mainly maltitol but also many others oses and polyols: sorbitol, maltitol and hydrogenated glucose syrup.
The use of E 965 (ii) maltitol syrup might lead to misleading of the consumer, due to its mixed nature.

Traditional use and precedents in organic production
There is no precedent for use of these compound organic production.

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

Not permitted in US NOP Standards
Not permitted in Japanese JAS standards
Not listed in the IFOAM NORMS for Organic Production and Processing (version 2014).

Other relevant issues

There is insufficient information in the dossier on the production methods of maltitol, in particular whether maltitol is produced by processes such as ion exchange.
The group is clear that it would be preferable if the maltitol or maltitol syrup could be produced in organic form. There is insufficient information in the dossier to assess whether this is possible.

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

The group understands that production is partially from an enzymatic process. Erythritol is already permitted as a sweetener for use in organic production. In the reflections of the EGTOP III there was a suggestion that erythritol should only be allowed for specific diets in case of obesity or diabetic concerns.
The group perceives that need for these compounds is very limited. The fact that maltitol syrup is a mixture of compounds also makes it difficult to decide on individual components of the syrup.
The Group reiterated the opinion (expressed in EGTOP Food III), that there is not a general need for sweetened low calorie organic products, but there may be a need for specific nutritional purposes especially for diets in cases of obesity. The group considered that the current entry for Erythritol in Annex VIII A of regulation 889/2008 is incomplete in that EGTOP Food III recommended that this sweetener should be listed "for specific nutritional purposes especially for diets in cases of obesity".

Conclusions

The group is not able to recommend the adoption of maltitol and maltitol syrup as sweeteners listed in Annex VIII A of regulation 889/2008 for bakery wares as the dossier does not contain sufficient information to completely inform this assessment.

2.14. Tara Gum for thickening

Introduction, scope of this chapter
The request refers to the possible use of Tara gum powder E 417 as a food additive (thickener, stabiliser) in Annex VIII A to Commission Regulation (EC) No 889/2008.

Authorisation in general production and in organic production
Tara gum is approved as a food additive by the Food Chemicals Codex and functions mainly as a thickener and stabiliser.
Regulatory status (EU, national, others) (including expiry dates of authorisation if applicable):

- JECFA (1986), published in FNP 37 (1986) and in FNP 52 (1992). Metals and arsenic specifications revised at the 57th JECFA (2001). An ADI 'not specified' was established at the 30th JECFA (1986).
- CODEX ALIMENTARIUS - GSFA - FOOD ADDITIVES Updated up to the 37th Session of the Codex Alimentarius Commission (2014).
- DIGESA (Dirección General de Salud Ambiental / General Direction of Enviromental Health) every 6 months.
- Current version Regulation (EC) No 1333/2008 on food additives.

Agronomic use, technological or physiological functionality for the intended use
Tara gum, also called Peruvian carob, is a white to yellowish powder which is soluble in hot water and partially soluble in cold water. Chemically, tara gum is comprised of polysaccharides, mainly galactomannans, of high molecular weight.
Mostly in combination with other thickeners or stabilisers tara gum is used to stabilise products as ice cream, sorbet, sauces, desserts, bakery products, etc.

Necessity for intended use, known alternatives
Tara gum can replace other allowed thickeners as Guar, locust bean gum (LBG), probably in a lower concentration. As a stabilisers e.g. for ice cream it is frequently used in a stabilising system with LBG, guar and starch from tapioca. Tara can also be used together with LBG, pectin and others, depending upon the recipe.
Tara gum is part of the same chemical family as Guar gum. Both have a molecular structure known as galactomannans. Tara has similar cold-water solubility & thickening characteristics to Guar gum, but has some advantages:

- The flow of tara gum is smooth and more natural whereas guar's flow characteristic is more pseudo-plastic. Guar gum tends to lead to stringy drips and doesn't flow smoothly.
- The structure of tara gum is smooth and soft. Guar gum can have a slimy texture in some applications.
- Tara gum in combination with Xanthan gum or carrageenan can form a very soft gel structure.
- Tara gum is odourless and tasteless while guar gum has an unpleasant odour and taste.
- The flavour release of tara gum is better than guar gum.
- Tara gum when added to a gel can increase the gel elasticity and retain water within the structure. This improves the shelf stability of the gel.
- Tara gum provides freeze-thaw stability by preventing the formation of ice crystals in ice creams.

Origin of raw materials, methods of manufacture

Caesalpinia spinosa (Molina) Kuntze, commonly known as tara, is a tree species native to Peru, Bolivia, Chile, Ecuador, Colombia, Venezuela and Cuba.
Tara gum is produced by separating and grinding the endosperm of the tree's seeds. It is a white or beige, nearly odourless powder. It consists of polysaccharides of high molecular weight composed mainly of galactomannans. Tara gum is used as a thickening agent and stabiliser in the food industry, where it is sometimes referred to as Peruvian carob, its E-number is E 417. The properties of tara gum are similar to that of carob beans and guar gum, widely used in the EU.

Environmental issues, use of resources, recycling
None.

Animal welfare issues
None.

Human health issues
EFSA re-evaluated 2017 the guar gum, locust bean gum, tara and other gums used as food additive. In the request it's written that the alternatives for tara is locust bean gum and guar gum. Therefore, the three were compared with Tara gum.
Tara. The EFSA Panel concluded that there is no need for a numerical ADI for tara gum (E 417 and that there is no safety concern for the general population at the refined exposure assessment of tara gum (E 417) as a food additive at the reported uses and use levels.
Guar gum. The EFSA Panel concluded that there is no need for a numerical ADI for guar gum (E 412), and there is no safety concern for the general population in their fined exposure assessment of guar gum (E 412) as a food additive. But for infants and young children the Panel concluded that the available data do not allow an adequate assessment of the safety of guar gum (E 412) for consuming these foods for special medical purposes(food categories 13.1.5.1 and 13.1.5.2: Baby).
Locust bean gum. The EFSA Panel concluded that there is no need for a numerical ADI for locust bean gum (E 410), and that there is no safety concern for the general population at the refined exposure assessment for its reported uses as a food additive. The Panel concluded that the available data do not allow an adequate assessment of the safety of locust bean gum (E 410) in these foods for infants and young children.

Food quality and authenticity
None identified.

Traditional use and precedents in organic production
Traditional used in Peru.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards
Tara gum is not listed at JAS, NOP, Codex alimentarius for organic, Canadian and Australian regulation for organic products.

Other relevant issues
Food grade organic tara gum powder is available certified organic (NOP) for cosmetics and as well for bakery.

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

The dossier included certification evidence only for the exporter, not for the producer. No producer is listed in the certifiers lists as a producer.
It is clear that it does exist in organic state & is imported to the EU.
The group recommend that it should be added only in organic quality. This stipulation should be extended to locust bean gum, gellan gum, arabic gum, & guar gum, in the same way as suggested for lecithin above.

Conclusions

The group considers that use of Tara gum powder as a food additive (thickener) is in line with the objectives, criteria & principles in Regulation 834/2007 for addition to Annex VIII A of 889/2008.

2.15. Carnauba vax

On Monday June 4 a request of evaluating a change of disposition for Carnauba vax was delivered by the Secretariat to the permanent group. Although the group did not have the possibility to evaluate the dossier according to the appropriate methods and times, the following considerations are exceptionally expressed.
In principle the group is not in favour of the use of carnauba wax for the proposed use, as it impacts the natural and physiological development of fruit ripeness. Nevertheless, the group considers it could be exceptionally allowed in areas and for productions where mandatory low temperature treatments exist, and only for the time the quarantine measures are into force, and no alternatives are available. The groups recommends as well that carnauba was use is reported on the label.

3. REFERENCES

1. Ref: SIDS Initial Assessment Report For SIAM 14. Paris, France, 26-28 March 2002
2. https://pubchem.ncbi.nlm.nih.gov/compound/glycerol#section=Formulations-Preparations
2bis. https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2017.4720
3. http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5088/epdf
4. Ref: Swanson, B.G., Pea and lentil protein extraction and functionality, J Am Oil Chem Soc (1990) 67: 276. https://doi.org/10.1007/BF02539676
5. http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-247.pdf
6. Cooke, Twiddy, & Reilly, 1987 in Wessel et al., The lactic acid bacteria, the food chain, and their regulation, trends in food science and tech, 2004
7. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4743
7bis. Wilson, R,. van Schie, B. J., & Howes, D. 1998. Overview of the preparation use & biological studies on polyglycerol polyricinoleate (PGPR). Food Chem Toxicol, 36, 711-718
8. https://www.hindawi.com/journals/isrn/2013/124767/
8bis. Tenore RR, 2012. Process for the direct manufacture of polyglycerol polyricinoleate. Patent No. US8,101,707 B2
9. Gomez JL, Bastida J, Maximo MF, Montiel MC, Murcia MD and Ortega S, 2011. Solvent-free polyglycerol polyricinoleate synthesis mediated by lipase from Rhizopus arrhizus. Biochemical engineering journal, 54, 111–116
10. Ortega S, Gomez JL, Bastida J, Maximo MF, Montiel MC and Gomez M, 2013. Biocathalytic synthesis of polyglycerol polyricinoleate: a comparison of different commercial lipases. Chemical and Biochemical Engineering Quarterly Journal, 27, 439–448
10bis. Ortega-Requena S, Bodalo-Santoyo A, Bastida-Rodrıguez J, Maximo-Martın MF, Montiel-Morte MC and Gomez-Gomez M, 2014. Optimized enzymatic synthesis of the food additive polyglycerol polyricinoleate (PGPR) using Novozym® 435 in a solvent free system. Biochemical Engineering Journal, 84, 91–97
11. http://chemicaloftheday.squarespace.com/todays-chemical/2009/8/5/castor-oil.html
12. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5015816/
13. https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=grasnotices&id=266
14. EFSA: 2017: Re-evaluation of polyglycerol polyricinoleate (E 476) as a food additive. https://www.efsa.europa.eu/en/efsajournal/pub/4743
15. Ref:https://fr.openfoodfacts.org/cgi/search.pl?search_terms=cigarette&search_simple=1&action=process
16. Ozdemir Y, Guven E, Ozturk A (2014) Understanding the Characteristics of Oleuropein for Table Olive Processing. J Food Process Technol 5:328. doi:10.4172/2157-7110.1000328
17. Enzymatic Hydrolysis of Oleuropein from Olea europea (Olive) Leaf Extract and Antioxidant Activities, Jiao-Jiao Yuan, Molecules 2015, 20, 2903-2921; doi:10.3390/molecules20022903
18. http://www.efsa.europa.eu/en/efsajournal/pub/2592
19. http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4435/epdf
20. https://www.epa.gov/sites/production/files/2016-09/documents/hydrochloric-acid.pdf
21. https://www.sciencedirect.com/topics/agricultural-and-biological-sciences/maltitol
22. http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/354.pdf

Regulations

Codex Alimentarius : *"Guidelines for the production, processing, labelling and marketing of organically produced foods (revision 201)*

USDA National Organic Program 7 CFR Part 2015
Japanese agricultural Standard for Organic Processed Foods (last revision March 27, 2017)
IFOAM Norms for Organic Production and Processing (version 2014)
National Standard of Canada: Organic production systems, Permitted substances lists (2015)
Australian Certified Organic: Standard 2017 V.1
National Standard for Organic and Bio-Dynamic Produce Edition 3.7 Last updated - 1 September 2016, Australian Government