**EGTOP/2018**

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

# Expert Group for Technical Advice on Organic Production
# EGTOP

## Feed III/Food V Report

The EGTOP adopted this technical advice at the plenary meeting of 26 to 28 November 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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All declarations of interest of permanent Group members are available at the following webpage:
http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2522&NewSearch=1&NewSearch=1

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## EXECUTIVE SUMMARY


The Group made the following conclusions:
For the substances requested in the mandate, the Group discussed whether their use is in line with the objectives and principles of organic production, and whether they should therefore be included in Annex VI or VIII of Commission Regulation (EC) No 889/2008. It concluded the following:

**Guar gum** should be included in Annex VI without restrictions.

**Sweet chestnut extract** was considered by the group (provided that can be considered as an agricultural product from a legal point of view) in line with the Commission Regulation (EC) No 889/2008, Annex VI.2 (sensory additive) as a flavouring compound. On the contrary, sweet chestnut extract can neither be assessed nor listed in Annex VI.4 as a zootechnical additive because it is not categorised as such in the horizontal legislation.

**Betaine anhydrous** should be included in Annex VI with the following restrictions "only betaine anhydrous from natural origin and when available from organic production and only for monogastric animals".

**Sodium propionate and calcium propionate** should not be included in Annex VI.

**Dimanganese chloride trihydroxide** should not be included in Annex VI.

**L-selenomethionin** should not be included in Annex VI.

**Hop extract** should be included in Annex VIII with the following recommendation "only for antimicrobial purposes in production of sugar" and when available from organic production.

**Pine rosin extract** should be included in Annex VIII with the following recommendation "only for antimicrobial purposes in production of sugar" and when available from organic production.

**Activated Carbon** was not assessed since all the documentation was only in German language.

**Vegetable Carbon** was not assessed since all the documentation was only in German language.

**Clean smoke** is not in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007.

## 1. TERMS OF REFERENCE

In light of the most recent technical and scientific information available to the experts, the Group is requested:
To answer if the use of the below listed substances 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:
Feed additives
1. ES Dossier: Guar gum;
2. SI Dossier: Sweet chestnut powder;
3. FR Dossier: Betaine;
4. IT Dossier: Sodium propionate and calcium propionate;
5. BE Dossier: Dimanganese chloride trihydroxide;
6. BE Dossier: L-selenomethionine (BE).

Food additives
7. AT Dossier: Hop extract
8. AT Dossier: Pine tree extracts containing natural rosin acids (in form of potassium salts);
9. DE Dossier: Activated Carbon;
10. DE Dossier: Vegetable Carbon;
11. DE Dossier: Clean smoke.

# 2. CONSIDERATIONS AND CONCLUSIONS

## 2.1. Guar gum

### Introduction, scope of this chapter

The assessment of Guar gum relates to the request for inclusion of this substance as a feed additive in Annex VI (feed additives used in animal nutrition) – 1. Feed additives, 1.3 Technological additives, (c) binders and anti-caking agents. Assessment of Guar gum as a thickening agent, stabiliser and binder.
The dossier was submitted by Spain.

### Authorisation in general production and in organic production

Guar gum (E412) is authorised by Regulation (EC) No 1831/2003 List of feed additives (OJ L245 of 12/09/1985).
Guar gum is authorised by Commission Regulation (EC) No 889/2008 as food additive (Annex VIII; Section A – Food additives, including carriers) in organic farming.

### Agronomic use, technological or physiological functionality for the intended use

Guar gum is produced in India that ranks first in the production of guar grown in the northwest of the country. Other main countries are Pakistan, USA and Brazil.
Guar gum is a thickening agent and stabiliser with binding effects at low dose, in the 0.1 – 1% range in feed processing. In feed processing, binding agents are necessary to produce e.g. pellets or mineral blocks. The products should retain a stable shape. Crumbling or falling apart should be avoided so that feed and mineral losses are prevented and the integrity of its physical structure during transport, storage and administration to the animals is maintained.
Guar gum can be used as a feed and faeces binder in aquaculture (Mudgil et al., 2014).

### Necessity for intended use, known alternatives

The currently authorised binders do not give sufficient consistency to the feed blocks with which farmers supplement the feed of organic cattle in Andalusia. As a result, the usual practice of distributing granulated feed on the soil of farms has a high degree of decline, as it breaks down, which increases feed costs. Successful agglutination with guar gum has been tested.
According to the descriptive report of the requesting company the manufacturing process of concentrated feedstuffs under the form of granulates means there is a need for certain auxiliary products facilitating the pressing process and also improving the quality of the final product. Formerly these substances needed to be used in very high quantities (up to 3% in weight of the final product), eventually causing negative effects on the livestock, and always decreasing the nutritional value of the feedstuff.
Among the modern agents favouring granulation, with low incorporation rate (0.1–0.2%) are cellulose derivate such as carboxymethyl cellulose and different natural gums (guar gum, xanthan gum, etc.). These are frequently also used for elaborating foods for human consumption.
One of the main advantages of low incorporation of organic binding agents is that they do not dilute the diet. Hence, they play a very important role in the making of feedstuffs for early life stages, where highly nutritional diets are requested, that are difficult to granulate (high fat and lactose and low fibre contents), and where a perfectly presented pellet with adequate flexibility and texture is essential.
Alternative substance but not allowed by the Commission Regulation (EC) No 889/2008 for feed is locust bean gum (E410).

### Origin of raw materials, methods of manufacture

Guar gum is obtained from the seeds of the guar bean (*Cyamopsis tetragonoloba*) by removing outer layers and seedling and then grinding the remaining parts. Besides guaran, which is the main component, guar gum contains 10 to 15 % water, 5 % protein, 2.5 % crude fibre and less than 1 % ash. The endosperm called part of the seed of the guar plant contains predominantly long-chain carbohydrates, which are composed in a characteristic way of the simple sugars mannose and galactose. Grounding this part of the seed guar gum is obtained. Its long-chain compounds can bind very large amounts of water.
There are different manufacture methods; mechanically or with chlorinated solvents or alkali or acid treatment.

### Environmental issues, use of resources, recycling

No significant issues of environmental impact are expected.
Using guar gum in aquaculture feeding could have positive environmental impact due to reduced losses of ammonia and phosphorus. The faeces is bound and can be filtered out of the water.

### Animal welfare issues

No significant issues of animal welfare impact are expected.

### Human health issues

Guar gum is already allowed in organic food production and there is no limitation on the daily consumption quantity.

### Food quality and authenticity

Guar gum is also allowed in food production (EFSA, 2017).

### Traditional use and precedents in organic production

There is no traditional use or precedents of guar gum in organic production of feed. But it is used in organic food production
Since there is organic production of guar beans, guar gum should be available in organic quality.

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

Guar gum is listed in USDA National Organic Program as a food ingredient at §205.606 *Nonorganically produced agricultural products allowed as ingredients in or on processed products labelled as "organic*." (g) Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).
Guar gum is not listed in USDA National Organic Program as prohibited additive at §205.604 *Nonsynthetic substances prohibited for use in organic livestock production.*
Guar Gum is listed in IFOAM Norms as permitted in Appendix 4 *List of approved additives and processing/post-harvest handling aids*.

### Other relevant issues

None identified

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

Already other substances for binding and anti-caking purposes are available and permitted in the organic regulation. Since guar gum is more efficient at lower application quantities than the

currently permitted binding agents, less product quantity is required. This is positive for the formulation of feed since less percentage of the binding additive in the product is needed. In this way the diet is not diluted.
The group is aware that feed additives in Annex VI do not have the request of being of organic origin. But since guar beans are an agricultural product and available in organic quality the group recommend that guar gum should be considered to be of organic origin. This is in line with the conclusion in the Final report on Food IV concerning tara gum.
The group considers furthermore that the specific conditions for food and feed additives should be harmonised. When the substance is available in organic form it should be a condition for both food and feed additives.

### Conclusions

The use of the feed additive guar gum as a binder and anti-caking agent is in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007. The addition to Annex VI 1.3 of Commission Regulation (EC) No 889/2008 is recommended, preferably from organic production.

### References


- EFSA, 2017. Re-evaluation of guar gum (E 412) as a food additive. EFSA Journal 2017; 15(2):4669. doi.10.2903/j.efsa.2017.4669
- Final report on Food IV : https://ec.europa.eu/agriculture/organic/sites/orgfarming/files/docs/body/final-report-etop-food-iv_en.pdf
- Mudgil D, Barak S, Khatkar B, S. 2014. Guar gum: processing, properties and food applications—A Review. J Food Sci Technol. 51(3): 409–418. https://doi.10.1007/s13197-011-0522-x


## 2.2. Sweet Chestnut Extract

### Introduction, scope of this chapter

Assessment of sweet chestnut extract (*Castanea sativa Mill*) respectively as a sensory and zootechnical feed additive in Annex VI (Feed additives used in animal nutrition). The dossier was submitted by Slovenia.
However, the group cannot asses the requested additive as a zootechnical additive since it is not listed as such in the horizontal legislation. Slovenia has submitted a dossier to the European Commission (DG Santé) for the inclusion of sweet chestnut extract in the horizontal legislation also as a zootechnical additive, both as a substance that favourably affects the environment (4c) and as a substance that enhances animal welfare (4e, new functional group they want to add in the legislation).

### Authorisation in general production and in organic production

Sweet Chestnut extract is authorised by Regulation (EC) No 1831/2003 List of feed additives as a sensory feed additive, 2b Flavouring compounds (2004/C 50/01) OJ C 50, 25.02.2004).
According to the Commission Regulation (EC) No 889/2008 feed additives for sensory purpose are allowed to be used but “only extracts from agricultural products”. As zootechnical additives only enzymes and microorganisms are allowed.
Tannic acid is an additive listed in the horizontal legislation as flavouring compound and is also listed in as a food processing aid (filtration aid) in annex VIII B of the Reg. (EC) No 889/2008.

## Agronomic use, technological or physiological functionality for the intended use

Sweet chestnut extract contains a high amount of tannins (> 70%). Tannins are widely found in plant material and normally extracted from wood from Sweet Chestnut, Oak and Quebracho. Tannins are water-soluble polyphenolic compounds, also including tannic acids, which is a synonym for hydrolysable tannins. The term tannin refers to the use of wood tannins from oak in turning animal hides into leather. They are used mainly as tanning agents for vegetable leather tanning but tannins have also found their way into human food and animal nutrition. In animal nutrition it has been used mainly as a sensory feed additive but studies have also shown beneficial effects on animal performance and health when feeding chestnut tannins. The use of chestnut tannins is also associated with better environmental resources for the animals since the increasing dry matter content leads to drier litter (Schiavone et al., 2008).

## Necessity for intended use, known alternatives

For its function as flavouring additive there are other alternatives. But not for the zootechnical purposes, especially if the functional group of animal welfare (4e) is added into the zootechnical purposes in Regulation (EC) No 1831/2003, as requested by SI.

## Origin of raw materials, methods of manufacture

Tannic acid is extracted with water, acetone or ethyl acetate from a variety of botanical sources after grinding into a fine. After grinding, the solvents are evaporated. After the evaporation steps, the powder is washed and dried. (EFSA, 2014)
In conclusion, it is possible to only use water to extract the Chestnut powder. Chestnut wood is crushed into particles of certain dimensions and extracted by means of hot soft water without any additives (T=116°C, pressure = 1,2 bar, t = 8 h). The solution obtained by extraction is condensed in the systems of vacuum evaporators (from 4 % - 50 %), the 50 % solution is further dehydrated in a spray dryer (T=220°C) to the final market powder form.

## Environmental issues, use of resources, recycling

According to EFSA, tannic acids are not considered hazardous to the environment.
Favourably effects on the environment by better litter conditions since studies shows effects of lower moisture due to less ammonia and methane (Huang et al., 2018).

## Animal welfare issues

Chestnut extract as well as tannic acid are recognised as food flavouring agents and are included in the European Union list of food flavourings.
A better respiratory conditions and greater growth performance, which enhance animal welfare, have been reported by Schiavone et al., 2008. Tannins have traditionally been regarded as "anti-nutritional factor" for monogastric animals and poultry, but recent researches have revealed some of them, when applied in appropriate manner, improved intestinal microbial ecosystem, enhanced gut health and hence increased productive performance (Huang et al., 2018).

## Human health issues

According to EFSA, the use of tannic acid as a feed additive presents no safety risk to consumers.

## Food quality and authenticity

Some authors reported better meat quality by introducing chestnut extract in the animals diet, but there is not enough elements to make a sound assessment on this issue.

## Traditional use and precedents in organic production

These wood extract have been traditionally used as tanning agents for vegetable tanning leather. As a natural wood extract it has a long term of use in organic farming (in animal husbandry).

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

Sweet chestnut extract is not listed in USDA National Organic Program as prohibited additive at §205.604 *Nonsynthetic substances prohibited for use in organic livestock production.*
Sweet chestnut extract is not listed in IFOAM Norms as permitted in Appendix 4 *List of approved additives and processing/post-harvest handling aids*.

## Other relevant issues

The group consider sweet chestnut extract (provided that can be considered as an agricultural product from a legal point of view) in line with the Commission Regulation (EC) No 889/2008, Annex VI.2 (sensory additive) as a flavouring compound. Feed additives do not have to be organically produced to be used in organic feed.

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

Sweet chestnut extract is only categorised in the horizontal law as a feed additive for sensory purposes. Therefore, the group cannot consider it as zootechnical additive as long as it is not in the horizontal legislation.
The group considers, furthermore, sweet chestnut extract as an agricultural product and, therefore, in line with the Commission Regulation (EC) No 889/2008, Annex VI.2 (sensory additive) as a flavouring compound.
The group is aware that feed additives in Annex VI do not need of being of organic origin but, in case is available in organic quality, the group recommend that it should be preferably of organic origin. This is in line with the conclusion in the Final report on Food IV concerning e.g. tara gum.
The group considers furthermore that the specific conditions for food and feed additives should be harmonised. When the substance is available in organic form it should be a condition for both food and feed additives.

## Conclusions

Sweet chestnut extract (provided that can be considered as an agricultural product from a legal point of view) is in line with the Commission Regulation (EC) No 889/2008, Annex VI.2 (sensory additive) as a flavouring compound. The group considers it should be preferably from organic production, if available. On the contrary, sweet chestnut extract can neither be assessed nor be listed in Annex VI.4 (zootechnical additive) because it is not categorised as such in the horizontal legislation.

## References

- EFSA, 2014. EFSA Scientific opinion. Scientific Opinion on the safety and efficacy of tannic acid when used as feed flavouring for all animal species. EFSA Journal 2014;12(10):3828, 1-18. https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2014.3828
- Huang Q, Xiu L, Zhao G , Huc T, Wang Y, 2018. Potential and challenges of tannins as an alternative to in-feed antibiotics for farm animal production. Animal Nutrition 4(2): 137-150. https://doi.org/10.1016/j.aninu.2017.09.004

- Redondo LM, Chacana P A, Dominguez J E, Fernandez Miyakawa M E, 2014. Perspectives in the use of tannins as alternative to antimicrobial growth promoter factors in poultry. Front. Microbiol., 27 March 2014 | https://doi.org/10.3389/fmicb.2014.00118
- Schiavone A, Guo K, Tassone S, Gasco L, Hernandez E, Denti R, Zoccarato I, 2008, Effects of a Natural Extract of Chestnut Wood on Digestibility, Performance Traits, and Nitrogen Balance of Broiler Chicks. Poultry Science, Volume 87 (3): 521–527.

## 2.3. Betaine

### Introduction, scope of this chapter

The assessment of Betaine anhydrous relates to the request for inclusion of the substance as a feed additive in the Annex VI (feed additives used in animal nutrition) - 3. Nutritional additives, (a) Vitamins, pro-vitamins and chemically well-defined substances having similar effect. The dossier was submitted by France.

### Authorisation in general production and in organic production

Betaine anhydrous is authorised by Regulation (EC) No 1831/2003 List of feed additives for ten years (until 23 July 2025) (OJ of EU L174 of 3 July 2015) as a “nutritional additive” under the functional group “vitamins, pro-vitamins and chemically well-defined substances having a similar effect”, under the identification number 3a920.

### Agronomic use, technological or physiological functionality for the intended use

Betaine is used in feed for monogastric animals to promote beneficial effects on the intestinal tract preventing osmotic stress occurring during diarrhoea or coccidiosis. There is also some evidence that betaine may improve the digestibility of specific nutrients. As a product of choline oxidation, betaine is involved in transmethylation reactions of the organism. Betaine as a methyl donor provides its labile methyl groups for the synthesis of several metabolically active substances such as creatine and carnitine. Supplementation with betaine may decrease the requirement for other methyl donors such as methionine and choline. There is also some evidence for enhanced methionine availability after dietary supplementation of betaine resulting in improved animal performance. Alterations in the distribution pattern of protein and fat in the body have been reported following betaine supplementation. A more efficient use of dietary protein may result from a methionine-sparing effect of betaine, but also direct interactions of betaine with metabolism-regulating factors have to be considered. Though the mode of action of betaine as a carcass modifier remains open, there is, however, growing evidence that betaine could have a positive impact on both animal performance and carcass quality (Dhama et al., 2014, Eklund et al., 2005, Kalmar et al., 2014**).**

### Necessity for intended use, known alternatives

No alternatives known. Betaine improves availability of methionine from feeding components. Methionine is a limiting amino acid in the diet of poultry, pigs and fish.

### Origin of raw materials, methods of manufacture

Betaine is extracted from sugar beet molasses or vinasses, by-products of sugar production, and concentrated to high purity. It is also synthetically accessible by nucleophilic substitution of trimethylamine with chloroacetic acid.

### Environmental issues, use of resources, recycling

Betaine is widely distributed in nature as an endogenous metabolite in most organisms including microorganisms, plants and animals. The betaine content of crops ranges from below the detection limit of 150 mg/kg in maize and soybean products to about 4 000–5 000 mg/kg in wheat and wheat middlings. The use of betaine as a feed additive is not expected to substantially increase its concentration in the excreta and the environment. Consequently, the supplementation of feed with betaine anhydrous does not pose a risk to the environment. (EFSA, 2013)

### Animal welfare issues

The proposed highest use level of betaine (2000 mg supplemented betaine/kg complete feed) is considered safe for piglets with a margin of safety below 5. This conclusion is extended to all pigs and extrapolated to all animal species and categories (EFSA, 2013).

### Human health issues

Betaine anhydrous should be considered irritant to skin, eyes and mucous membranes and a skin sensitizer. It is likely to cause skin sensitisation (EFSA, 2013).

### Food quality and authenticity

The process from raw materials to delivery is controlled by quality control procedure based on the Hazard Analysis and Critical Control Point (HACCP) principle.

### Traditional use and precedents in organic production

Betaine is already used in organic poultry feed in some members states.

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

Betaine anhydrous is not listed as permitted in USDA National Organic Program.
Betaine anhydrous is not listed in IFOAM Norms as permitted in Appendix 4 *List of approved additives and processing/post-harvest handling aids*.

### Other relevant issues

Be aware that betaine anhydrous can be produced from GM beets.

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

Methionine is a limiting amino acid in the diet of poultry, pigs and fish. Betaine improves availability of methionine from feeding components.
The group recommends restricting the use of betaine anhydrous only to monogastric animals. The group also proposes to restrict the substance “chemically well-defined substances having similar effects” to just include betaine anhydrous. The group consider this is crucial to avoid opening the category for all known chemically substances, but is aware that this could lead to more substances needed to be assessed, especially if substances are already used under this definition in some member states. Since the additive of betaine anhydrous produced from GM beets also is allowed by the horizontal law it is important to exclude this source when using it as additive in organic production. Furthermore the group recommends that only betaine derived from sugar beet production and not synthetic one should be allowed and, if available, only from organic sugar beet production.

### Conclusions

The use of the feed additive betaine anhydrous as nutritional additive, is in line with the

objectives, criteria and principles of Council Regulation (EC) No 834/2007.
The addition to Annex VI 3.a of Commission Regulation (EC) No 889/2008 is recommended. The table should be amended with Substance: "chemically well-defined substances having similar effects" and Description/condition of use:

- "only betaine anhydrous from natural origin; when available from organic production; only for monogastric animals"

## References


- Dhama K, Tiwari R, Khan R U, Chakraborty S, Gopi M, Karthik K, Saminathan M, Arumugam D P, Tulasi S L, 2014. Growth Promoters and Novel Feed Additives Improving Poultry Production and Health, Bioactive Principles and Beneficial Applications: The Trends and Advances-A Review. DOI: 10.3923/ijp.2014.129.159.
- EFSA, 2013. Scientific Opinion on the safety and efficacy of betaine anhydrous as a feed additive for all animal species based on a dossier submitted by Danisco Animal Nutrition. EFSA Journal 2013;11(5), 3209. https://doi.org/10.2903/j.efsa.2013.3209
- Eklund M, Bauer E, Wamatu J, Mosenthin R, 2005. Potential nutritional and physiological functions of betaine in livestock. Nutr Res Rev. 18(1):31-48. DOI:10.1079/NRR200493
- Kalmar, ID, Verstegen MWA, Vanrompay D, Maenner K, Zentek J, Iben C, Leitgeb R, Schiavone A, Prola L, Janssens GPJ, 2014. Efficacy of dimethylglycine as a feed additive to improve broiler production. Livest Sci 164: 81-86. https://doi.org/10.1016/j.livsci.2014.03.003


## 2.4. Sodium propionate and calcium propionate as feed additive

### Introduction, scope of this chapter

The assessment of sodium propionate (E281) and calcium propionate (E282) relates to the inclusion of the substances as feed additives in Annex VI 1.(a) Preservatives. The request is limited to ruminants. The dossier was submitted by Italy.

### Authorisation in general production and in organic production

Sodium propionate (E281) and calcium propionate (E282) are authorised by Regulation (EC) No 1831/2003 List of feed additives as 1a Preservatives and sodium propionate also as 1k Silage additives.
(E281--1a: OJ L 245,12.09.1985, p.1 respectively 1k: OJ L 320, 30.11.2013, p.16) (E282--1a: OJ L 245,12.09.1985, p.1)
Sodium propionate is allowed, with restriction on the quantity, according to Regulation No 1222/2013, for pigs and poultry
Both substances are also permitted as food additive (used especially for bread).

### Agronomic use, technological or physiological functionality for the intended use

Sodium and calcium propionate can be added to silage, seeds (wet seeds for conservation) and feed as a preservative to reduce mould and mycotoxins.
A reduction of mould and mycotoxins improves the quality of feed. Feed intake, health and fertility of animals is improved.

### Necessity for intended use, known alternatives

In principle, the use of preservative may be considered necessary for silage (bad weather), cereals (too wet for storing) and feed (storing for a longer time). The main intended use is a preservative against mould.
There are many alternatives for different feed and silage products. Propionic acid (E280) is the most important alternative, but also other acids like sorbic acid (E200), formic acid (E236),

acetic acid (E260), lactic acid (E270) and sodium formate (E237) are allowed by Reg. (EC) No 889/2008, Annex VI 1. (a), although only products based on propionic acid seem to be currently on the market.
Organic molasses can be used in feed as a source for energy and increased feed intake. The use of molasses of conventional origin is also permitted by Reg. (EC) No 889/2008 art. 22, in processing organic feed and feeding (up to 1%), when the organic form is not available.
Enzymes and bacteria (mainly lactic acid bacteria) are allowed, as silage additives, by Reg. (EC) No 889/2008 Annex VI 1e, when the weather conditions do not allow for adequate fermentation.
It also common to mix molasses and lactic acid bacteria.

### Origin of raw materials, methods of manufacture

Sodium and calcium propionate can occur naturally in cheese, fish and algae.
Sodium propionate is produced in a reaction between propionic acid and sodium carbonate. The process of neutralisation is obtained by mixing propionic acid and sodium hydroxide or sodium carbonate. Calcium propionate is produced in a reaction between propionic acid and calcium hydroxide or calcium oxide.

### Environmental issues, use of resources, recycling

Not relevant.

### Animal welfare issues

No negative effects.

### Human health issues

EFSA mentions sodium propionate and calcium propionate as harmless.
Sodium and calcium propionate are not corrosive for equipment and not irritant for workers.

### Food quality and authenticity

In general, the use of feed preservatives may improve both quality and safety of the feed, as well as the food products (e.g. milk).

### Traditional use and precedents in organic production

No traditional use.

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

Sodium propionate and calcium propionate are not listed as permitted in USDA National Organic Program.
Sodium propionate and calcium propionate are not listed in IFOAM Norms as permitted in Appendix 4 *List of approved additives and processing/post-harvest handling aids*.

### Other relevant issues

If too much propionate is added at ensiling time, lactic acid fermentation may be depressed.

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

The dossier claims for the use of sodium and calcium propionate as a preservative of feed. However, the group is not aware of the presence on the market of sodium propionate and calcium propionate as preservatives of feed. They seem only sold as products to prevent ketosis.

Furthermore, such products are usually mixed with benzoate, formate or propionic acid.

The group is aware of one scientific study (Haus Riswick, 2011) comparing acids, salts and bacteria in silage, in which bacteria was found the most effective. Other scientific papers only compare acids and bacteria.
On the light of the above considerations, the group considers that a) suitable alternative additives are already allowed by the organic regulation, both for the preservation of seeds, feed and for silage; b) including salts, besides acids, on the annex VI 1a. would pave the way for many other application (e.g. benzoate, formate, sorbat).

### Conclusions
The use of sodium propionate and calcium propionate as feed additives is not in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007. The addition to Annex VI 1a of Commission Regulation (EC) No 889/2008 is not recommended.

### References

- www.riswick.de/pdf/silieren_von_gras_unter_schwierigen_Bedingungen.pdf
- https://www.schaumann.de/fe_haus_riswick_2011_ccm_konservieren_mit_bonsilage.html
- www.milkproduction.com/library/scientific-articles/nutrition/silage-additives/


## 2.5. Dimanganese chloride trihydroxide - $Mn_2(OH)_3Cl$

### Introduction, scope of this chapter
The assessment of Dimanganese Chloride Trihydroxide relates to the request of the substance as a feed additive in Annex VI (feed additives used in animal nutrition) - 3. Nutritional additives, (b) compounds of trace elements.
The dossier was submitted by Belgium.

### Authorisation in general production and in organic production
Dimanganese Chloride Trihydroxide (3b507) is authorised by Regulation (EC) No 1831/2003 (OJ L 216, 22.08.1970, p.1) until 11/09/2027 as feed additives in animal nutrition.
For organic production, other sources of Manganese are authorised in the Commission Regulation (EC) No 889/2008 as manganous (II) carbonate, manganous oxide and manganic oxide, manganous (II) sulfate, mono- and/or tetrahydrate.

### Agronomic use, technological or physiological functionality for the intended use
Manganese is a naturally occurring element found in rock, soil, water, and food. In humans and animals, manganese is an essential nutrient that plays a role in bone mineralisation, protein and energy metabolism, metabolic regulation, cellular protection from damaging free radical species, and formation of glycosaminoglycans (Nys et al, 2018).
Manganese can exist in both inorganic and organic forms (Hilal *et al.*, 2016):
The inorganic forms include manganese chloride ($MnCl_2$), manganese sulfate ($MnSO_4$), manganese acetate (MnOAc), manganese phosphate ($MnPO_4$), manganese dioxide ($MnO_2$), manganese tetroxide ($Mn_3O_4$), and manganese carbonate (MnCO3), Dimanganese Chloride Trihydroxide ($Mn_2(OH)_3Cl$).
The organic compounds are complexed manganese using peptides or amino acids from hydrolysed protein or specific, individual amino acids as the organic molecules to which manganese is complexed.

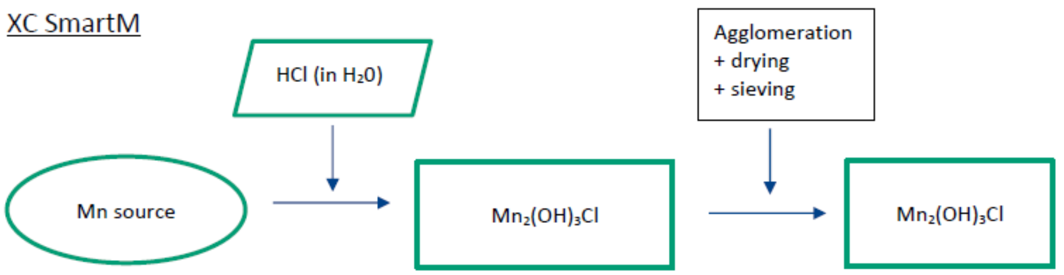
Only one scientific paper assessed the bioavailability of Dimanganese Chloride Trihydroxide. In fact, Conly *et al.* (2012) compared the relative bioavailability and tolerance of Dimanganese Chloride Trihydroxide and manganese sulfate ($MnSO_4$) for growing broiler chickens. They showed that the calculated bioavailability of these two sources of Manganese did not differ significantly ($P > 0.20$).

## Necessity for intended use, known alternatives

For organic production, other sources of Mn are authorised in the Commission Regulation (EC) 889/2008 as manganous (II) carbonate, manganous oxide and manganic oxide, manganous (II) sulfate, mono- and/or tetrahydrate.

## Origin of raw materials, methods of manufacture

The chemical reactions required to produce Dimanganese Chloride Trihydroxide crystals are described below. The process involves a reaction between a manganese source with free hydrochloric acid.




## Environmental issues, use of resources, recycling

No significant issues of environmental impact would be raised by permitting the use of Dimanganese Chloride Trihydroxide. Furthermore, Manganese is widely present in nature.

## Animal welfare issues

Manganese is an essential nutrient that plays a role in several biological functions.

## Human health issues

Manganese is an essential nutrient that plays a role in several biological functions.
There is no specific data about the use of Dimanganese Chloride Trihydroxide and the human health and without information, EFSA could not conclude on the safety for the user when handling dimanganese chloride trihydroxide.

## Food quality and authenticity

None identified

## Traditional use and precedents in organic production

There is no precedent for use of this type of manganese source in organic production.
Other sources of manganese are used, essentially in premix of animal feed.

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

Dimanganese Chloride Trihydroxide is not listed as permitted in USDA National Organic Program.

Dimanganese Chloride Trihydroxide is not listed in IFOAM Norms as permitted in Appendix 4 *List of approved additives and processing/post-harvest handling aids*.

### Other relevant issues

None identified

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

Other sources of manganese are already available and permitted in organic production. The group is not aware of scientific evidence proofing that the assessed substance would permit more bioavailability in feed than the already permitted manganese additives. Neither the group is aware of scientific documents confirming the positive affects described by the request.

### Conclusions

The use of the feed additive Dimanganese chloride trihydroxide is not in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007. The addition to Annex VI 3b of Commission Regulation (EC) No 889/2008 is not recommended.

### References


- Hilal, E.Y., Elkhairey, M.A.E. and Osman, A.O.A. (2016) The Role of Zinc, Manganse and Copper in Rumen Metabolism and Immune Function: A Review Article. Open Journal of Anima Sciences , 6, 304-324.
- Nys, Y., Schlegel, P., Durosoy, S., Jondreville, C., and Narcy, A. (2018). Adapting trace mineral nutrition of birds for optimising the environment and poultry product quality. *World's Poultry Science Journal, 74*(2), 225-238. doi:10.1017/S0043933918000016
- Commission Implementing Regulation (EU) 2017/1490 of 21 August 2017 concerning the authorisation of manganous chloride tetrahydrate, manganese (II) oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of protein hydrolysates, manganese chelate of glycine hydrate and dimanganese chloride trihydroxide as feed additives for all animal species. OJ L 216, 22.8.2017, p. 1–14. http://data.europa.eu/eli/reg_impl/2017/1490/oj
- Conly A K, Poureslami R, Koutsos EA, Batal A B, Jung B, Beckstead R, Peterson D G, Tolerance and efficacy of tribasic manganese chloride in growing broiler chickens. Poultry Science 91 (7): 1633–1640. https://doi.org/10.3382/ps.2011-02056.


## 2.6. L-Selenomethionine - $C_5H_{11}NO_2Se$

### Introduction, scope of this chapter

The assessment of L-Selenomethionine - $C_5H_{11}NO_2Se$ (3b815) relates to the request for inclusion of the substance as feed additive in the Commission Regulation (EC) 889/2008, Annex VI (feed additives used in animal nutrition) - 3. Nutritional additives, (b) Compounds of trace elements. The dossier was submitted by Belgium.

### Authorisation in general production and in organic production

L-Selenomethionine (3b815) is authorised by Regulation (EC) No 1831/2003 List of feed additives (until 28 February 2024) (OJ L 39, 08.02.2014, p.53) as a “nutritional additive” under the functional group “compounds of trace elements”.
L-Selenomethionine is also authorised in Europe as food supplement EC 1170/2009 (EFSA, 2009).

### Agronomic use, technological or physiological functionality for the intended use

Selenium is a key component for animal and human nutrition as its plays a major role in the immune system. However, in most case, balanced diet is sufficient to fulfil the needs. Selenium is a natural component of the diet, and is present in fish (0.32 mg/kg), offal (0.42 mg/kg), brazil nuts (0.25 mg/kg), eggs (0.16 mg/kg) and cereals (0.02 mg/kg) (EFSA, 2009).
L-selenomethionine accounts for 50 to over 80 % of total selenium in plants such as cereals and legumes including soybean grown on selenium-rich soil (Rayman et al., 2008).
Burk et al. (2006) concluded that selenium in the form of L-selenomethionine was better absorbed than selenium in the form of sodium selenite.

### Necessity for intended use, known alternatives

The necessity for selenium supplementation for livestock is not essential in case of balanced diet. By the way, for nutritional purpose in specific condition selenium should be used to supplement the diet.
Known alternatives of L-Selenomethionine, permitted in organic farming, are selenite, selenate and selenised yeast.

### Origin of raw materials, methods of manufacture

The process is not well described and it is only specified that L-selenomethionine is chemically synthetized. The raw material is not specified.
The dossier claims that the manufacturing process is low dust guarantee, which brings an added marketing value.

### Environmental issues, use of resources, recycling

The manufacturing process with no selenium rich waste compound is more environmentally friendly than selenised yeast production which waste contain high amount of selenium.

### Animal welfare issues

Selenium is an essential nutrient often lacking in organic diets, but selenium compounds can also be acutely and chronically toxic. The toxicity of L-selenomethionine is comparable to other forms of selenium, in terms of equivalent amounts of bioavailable selenium (EFSA, 2009).

### Human health issues

Given the product guarantee of a maximum dust value of 0,2 mg/m³ in the manufacturing process, the respiratory risk is limited.

### Food quality and authenticity

The proposed product shows high amount of Selenium (39%) with quite high quality grade (97% L-selenomethionine pure).

### Traditional use and precedents in organic production

No use is reported in the dossier, nor is the group aware of uses in organic production.

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

L-Selenomethionine is not listed as permitted in USDA National Organic Program.
L-Selenomethionine is not listed in IFOAM Norms as permitted in Appendix 4 *List of approved additives and processing/post-harvest handling aids*.

### Other relevant issues

None

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

L-Selenomethionine is categorised as a compound of trace element in the horizontal law (list of feed additives), but it is also an amino acid chemically synthesised, while Selenomethionine. without "L" is produced by *Saccharomyces cerevisiae*. Because alternative sources of selenium are already allowed by the organic regulation, the group does not consider necessary to include L-Selenomethionine in Annex VI.

### Conclusions

The use of L-selenomethionin as feed additive is not in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007. The addition to Annex VI 3b of Commission Regulation (EC) No 889/2008 is not recommended.

### References


- EFSA, 2009. L-selenomethionine as a source of selenium added for nutritional purposes to food supplements. Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food. The EFSA Journal (2009) 1082, 1-39.
- Raymond F. Burk, Brooke K. Norsworthy, Kristina E. Hill, Amy K. Motley and Daniel W. Byrne, 2006. Effects of Chemical Form of Selenium on Plasma Biomarkers in a High-Dose Human Supplementation Trial. Cancer Epidemiol Biomarkers Prev (15) (4) 804-810; DOI: 10.1158/1055-9965.EPI-05-0950
- Rayman, M., Infante, H., and Sargent, M. (2008). Food-chain selenium and human health: Spotlight on speciation. British Journal of Nutrition, 100(2), 238-253. doi:10.1017/S0007114508922522


## 2.7. Hop extracts containing natural hop alpha acids, hop beta acids and their derivatives (in form of potassium salts)

### Introduction, scope of this chapter

Assessment of Hop extracts containing natural hop alpha acids, hop beta acids and their derivatives (in form of potassium salts) for sugar production. The assessment relates to the request for inclusion of the substance as a food processing aid in the Commission Regulation (EC) No 889/2008, in Annex VIII B.
The dossier was submitted by Austria. (Note, submitted in parallel with a similar application for pine resins for the same use.)

### Authorisation in general production and in organic production

Organic hops are widely used as organic ingredients in organic beers. However, there are acknowledged shortages of specific varieties of hops in organic form so derogations for use of specific varieties of non-organic hops are widely issued throughout the EU.
Certified organic hop extracts could in theory be made using organic hops as the extraction method described in the dossier does not require any non-permitted solvents, as the extraction is with liquid Carbon Dioxide. However, the group is unaware on any production of organic hop extracts.
Hop extracts are considered food ingredients when used in beer, while for the function described in the dossier they are considered as processing aids as they fulfil the definition in Reg (EC) No 1333/2008, (Ref: 1. Regulation (EC) No 1333/2008 of the European Parliament

and of the Council of 16 December 2008 on food additives) in that they are not consumed as food in themselves and are intentionally used in sugar beet processing to suppress growth of bacteria.

### Agronomic use, technological or physiological functionality for the intended use

Hops and hop extracts of various types are used widely in the production of beer, where they predominantly provide bitterness. Other components of the extracts may provide hop aroma to beers. They also traditionally provided some antibacterial effect in beers, particularly before the widespread use of pasteurisation.

The active ingredients in hops – natural hop alpha acids (humulones), hop beta acids (lupulones) and their derivatives – are particularly effective against Gram-positive bacteria such as lactic acid bacteria, bacilli, clostridia, listeria but also other microorganisms (e.g. *M. tuberculosis*).

Hop acids were also tested in a range of different other fields of application apart from brewing industry (e.g. animal dietary supplements, pharmaceuticals, veterinary hygiene, dental hygiene, silage production and others) but did not become commercially feasible so far. Parallel to that, hop acids (termed "natural antibacterial") were introduced to the sugar industry at the beginning of the 1990s as an alternative to formaldehyde and dithiocarbamates (and other conventional chemical products) in order to control bacterial growth in the extraction area.

### Necessity for intended use, known alternatives

Formaldehyde and dithiocarbamates were compounds previously used for suppression of bacterial growth in sugar production. Arvanitis et al. (2004) indicated that quaternary ammonium compounds may also be used, but of this and those listed above, formaldehyde is preferred for cost reasons. Also beet pomace includes some antimicrobial compounds, but it is clear that there remains a significant microbial problem with beet sugar processing without antimicrobials (Čanadanović-Brunet et al., 2011).

Hop extracts are not specifically needed for production of organic sugar from organically grown sugar beet in that the process is currently undertaken without them in Germany, Austria, Switzerland and Romania. Production of organic sugar from organic cane is also carried out in several countries without the use of hop extracts.

The advantages of using hop extracts appear to be that the processing of organic beet can be extended as the problems associated with microbial growth are exacerbated by long storage of the beet before processing, therefore enabling production of more organic sugar from more organic sugar beet. The hop extracts reduce the production of acids which can hydrolyse sucrose, reducing yields. They also reduce production of gasses by bacteria during processing which in turn cause foam production, increased energy use and potential for explosive hydrogen mixtures.

### Technological function in food;

The hop extracts have no function in food. They are solely processing aids of relevance during the early phases of extraction of sugar from sugar beet.

### Origin of raw materials, methods of manufacture

The extraction is made with supercritical Carbon Dioxide and the extracts obtained contain a high proportion of beta acids (lupulones), which are the most effective antimicrobial compounds in hops. Beta acids have a lower value in the brewing process than the alpha acids, which provide bitterness in beer.

Pollach et al. (2002) mention that the beta acid resin extract of hops specifically designed for use in the sugar industry is prepared as an alkaline solution, presumably using potassium hydroxide, to produce the potassium salts of the beta acids.

### Environmental issues, use of resources, recycling

No significant issues.

### Animal welfare issues

None. Plant derived material only. Note that the by-product of the organic sugar production (sugar beet pulp) might be used as animal feed. No welfare issues are expected.

### Human health issues

Hop extracts are GRAS (US Code of Federal Regulations, 2012).
No residues of the hop extracts would be transferred into the sugar, so no human health effects are expected. Similarly, no effects on operators in production plants are expected.
As an alternative to formaldehyde and dithiocarbamates they represent the possibility to reduce health concerns for workers in the industry.

### Food quality and authenticity

No effect on food quality or authenticity is expected.

### Traditional use and precedents in organic production

They are currently not used in organic sugar production because not listed in Annex VIII Section B of Reg. (EC) No 889/2008.

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

Hop extracts containing natural hop alpha acids, hop beta acids and their derivatives is not listed as permitted in USDA National Organic Program.
Hop extracts containing natural hop alpha acids, hop beta acids and their derivatives is not listed in IFOAM Norms as permitted.

### Other relevant issues

No GM concerns as hops are currently not being genetically modified, as far as the group is aware.

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

Note that the dossier was submitted with a parallel one for pine resin extracts for use in sugar production. Both dossiers identify that both hop extracts and pine resin extracts may be used alternately to reduce risk of bacterial strains resistant to one or the other developing due to overuse of a single antimicrobial preparation.
In the group opinion, the use non-organic hop extracts in brewing would not help the development of the organic brewing sector. Therefore, the use of non-organic hop extracts should be restricted to only antimicrobial purposes in the processing of sugar production.
The group is aware of the limited availability of organic hops that makes difficult today to limit the use of hope extract for sugar production to organic origin. Nevertheless, in the future when availability is on place it should be restricted to organic production.

### Conclusions

The group considers hop extract as a food processing aid in line with the objectives, criteria and principles of Council Regulation (EC) No. 834/2007.

The addition of hop extract as a processing aid to Annex VIII B of the Reg. (EC) No. 834/2007 is recommended with the restriction of use “only for antimicrobial purposes in production of sugar” and, when available, with the restriction of “from organic production”.

### References


- Arvanitis N, Kotzamanidis C Z, Skaracis G N, Karagouni A D, 2004. The effectiveness of commercial antimicrobial compounds against saccharolytic microorganisms isolated from a beet sugar production line. World J Microbiol Biotechnol 20 (3): 291–296.
- Čanadanović-Brunet J M, Savatović S S, Ćetković G S, Vulić J J, Djilas S M, Markov S L, Cvetković D D, 2011. Antioxidant and Antimicrobial Activities of Beet Root Pomace Extracts. Czech J. Food Sci Vol. 29(6): 575–585. https://www.agriculturejournals.cz/publicFiles/210_2010-CJFS.pdf
- Pollach G, Hein W, Beddie D, 2002. Application of hop β-acids and rosin acids in the sugar industry. Zuckerindustrie 127(12): 921–930. https://betatec.com/wp-content/uploads/2015/09/Application_acids_sugar_industry.pdf.
- Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives
- US Code of Federal Regulations, 2012. Food and Drugs, PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE, Subpart A—General Provisions, §182.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates). https://www.gpo.gov/fdsys/granule/CFR-2012-title21-vol3/CFR-2012-title21-vol3-sec182-20


## 2.8. Pine tree extracts containing natural rosin acids (in form of potassium salts)

### Introduction, scope of this chapter

Assessment of Pine tree extracts containing natural rosin acids (in form of potassium salts) for sugar production. The assessment relates to the request for inclusion of the substance as a food processing aid in the Commission Regulation (EC) No 889/2008, in Annex VIII B.
The dossier was submitted by Austria. (Note, submitted in parallel with a similar application for hop extracts for the same use).

### Authorisation in general production and in organic production

Natural Aleppo Pine resins are used in the production of traditional Greek wines, (retsina) where they predominantly provide some antibacterial effect. They are also used as a base for chewing gum (Coppen and Hone, 1995).
Pine rosin extracts are considered food ingredients when used in wine. For the function described in the dossier they are considered as processing aids, as they fulfil the definition in the Regulation (EC) No 1333/2008 in that they are not consumed as food in themselves and are intentionally used in sugar beet processing to suppress growth of bacteria.
Not currently allowed for any uses in organic production.

### Agronomic use, technological or physiological functionality for the intended use

Pine tree extracts use within the sugar industry can be considered an alternative to formaldehyde to control bacterial growth in the extraction area. This was done in particular as use of the alternative, hop extracts, alone resulted in adaption by the bacteria.
They are also used in areas such as veterinary hygiene, silage production etc.

The active ingredients in pine resin (natural rosin acids) are effective against Gram-positive bacteria such as lactic acid bacteria, bacilli, clostridia, listeria but also other microorganisms (e.g. *M. tuberculosis*).
Nowadays, most rosin is used in a chemically modified form, rather than in the raw state in which it is obtained. It consists primarily of a mixture of abietic- and pimaric-type acids with smaller amounts of neutral compounds.

### Necessity for intended use, known alternatives

Formaldehyde and dithiocarbamates were compounds previously used for suppression of bacterial growth in sugar production. Arvanitis et al. (2004) indicated that quaternary ammonium compounds may also be used, but of this and those listed above, formaldehyde is preferred for cost reasons. Also beet pomace includes some antimicrobial compounds, but it is clear that there remains a significant microbial problem with beet sugar processing without antimicrobials (Čanadanović-Brunet et al., 2011).
Pine resin extracts are not specifically needed for production of organic sugar from organically grown sugar beet in that the process is currently undertaken without them in Germany, Austria, Switzerland and Romania. Production of organic sugar from organic cane is also carried out in several countries without the use of pine extracts.
The advantages of using pine extracts appear to be that the processing of organic beet can be extended as the problems associated with microbial growth are exacerbated by long storage of the beet before processing, therefore enabling production of more organic sugar from more organic sugar beet. The pine extracts reduce the microbial production of acids which can hydrolyse sucrose, reducing yields. They also reduce production of gasses by bacteria during processing which in turn cause foam production, increased energy use and potential for explosive hydrogen mixtures.

### Technological function in food

The pine extracts have no function in food. They are solely processing aids of relevance during the early phases of extraction of sugar from sugar beet.

### Origin of raw materials, methods of manufacture

The extracts are made from conventional pine resin by extraction with steam. Rosin can be also a by-product of turpentine extraction from pine resin. Some additions such as diatomaceous earth and oxalic acid may be made during the extraction (Coppen and Hone, 1995).

### Environmental issues, use of resources, recycling

No significant issues of environmental impact would be raised by permitting the use of pine extracts in sugar production.

### Animal welfare issues

None. Plant derived material only. Note that the by-product of the organic sugar production (sugar beet pulp) might be used as animal feed. No welfare issues are expected.

### Human health issues

Pine resin extracts are permitted under US Federal code of regulations (2018).
No residues of the pine extracts would be transferred into the sugar, so no human health effects are expected. Similarly no effects on operators in production plants are expected.
As an alternative to formaldehyde and dithiocarbamates they represent the possibility to reduce health concerns for workers in the industry.

Pollach et al. (2002) highlight that pine rosin production is a by-product of the production of turpentine oil, which is harmful to the skin and if swallowed neat. It is included in the European Biocide list. Pollach et al. (2002) also report that rosin acids are toxic to fish.

## Food quality and authenticity

No effect on food quality or authenticity is expected.

## Traditional use and precedents in organic production

Pine tree resins have been used as a flavouring and microbial stabiliser in wine for a very long time. Resin extracts are not traditionally used. Steam distilled resin extracts are more recent and have no tradition in food production.
They are currently not used in organic sugar production as they are currently not listed in Annex VIII Section B of 889/2008.

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

Pine extract containing natural rosin acids, is not listed as permitted in USDA National Organic Program.
Pine extract containing natural rosin acids, is not listed as permitted in IFOAM Norms.

## Other relevant issues

No GM concerns as pine trees are currently not being genetically modified as far as the group is aware.

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

Note that the dossier was submitted with a parallel one for hop extracts for use in sugar production. Both dossiers identify that both hop extracts and pine resin extracts may be used alternately to reduce risk of bacterial strains resistant to one or the other developing due to overuse of a single antimicrobial preparation.
Pine rosin extracts using steam can clearly be organic, providing that the farming and processing are both certified organic.
If pine resin extracts is used for organic chewing gum production, it should be considered an organic ingredient, rather than an additive or processing aid, therefore it should be certified organic.
The use of non-organic pine resin extracts should be restricted to use only for antimicrobial purposes in the processing of sugar production.
The group is aware of the limited availability of organic pine that makes difficult today to limit the use of pine extract for sugar production to organic origin. Nevertheless, in the future when availability is on place it should be restricted to organic production.

## Conclusions

The group considers pine rosin extract to be in line with the objectives, criteria and principles of Council Regulation (EC) No. 834/2007.
The addition of pine rosin extract as a processing aid to Annex VIII B of the Reg. (EC) No. 834/2007 is recommended with the restriction of use “only for antimicrobial purposes in production of sugar” and, when available, with the restriction of “from organic production”.

## References

- Arvanitis N, Kotzamanidis C Z, Skaracis G N, Karagouni A D, 2004. The effectiveness of commercial antimicrobial compounds against saccharolytic microorganisms isolated from a beet sugar production line. World J Microbiol Biotechnol 20 (3): 291–296. https://link.springer.com/article/10.1023/B:WIBI.0000023837.73558.35
- Čanadanović-Brunet J M, Savatović S S, Ćetković G S, Vulić J J, Djilas S M, Markov S L, Cvetković D D, 2011. Antioxidant and Antimicrobial Activities of Beet Root Pomace Extracts. Czech J. Food Sci Vol. 29(6): 575–585. https://www.agriculturejournals.cz/publicFiles/210_2010-CJFS.pdf
- Coppen J.J.W. and Hone G.A., 1995. Gum naval stores: Turpentine and rosin from pine resin. Natural Resources Institute. Food and Agriculture Organization of the United Nations. http://www.fao.org/docrep/v6460e/v6460e08.htm
- Pollach G, Hein W, Beddie D, 2002. Application of hop β-acids and rosin acids in the sugar industry. Zuckerindustrie 127(12): 921–930. https://betatec.com/wp-content/uploads/2015/09/Application_acids_sugar_industry.pdf
- US Code of Federal Regulations, 2018. Food and Drugs, PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE, Subpart A—General Provisions, §182.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.20


## 2.9. Activated Carbon

The documentation was only in German language, therefore the subgroup was not able to assess the substance.

## 2.10. Vegetable Carbon

The dossier was only in German therefore the subgroup was not able to assess the substance. (It is noted that the food additive vegetable carbon was assessed in Final report Food IV).

## 2.11. Clean Smoke

### Introduction, scope of this chapter

The proposed amendment to the already authorised usual smoking technologies in Article 26 of Reg. (EC) No 889/2008 asks for the authorisation of smoke generated from primary products (pure smoke condensate) applied to organic foods like meat products (e.g. ham), cheese, tofu or fish. The dossier was submitted by Germany.

### Authorisation in general production and in organic production

Smoke condensates generated from primary products are permitted in conventional food according to Article 3 (3) of Reg. (EC) No 2065/2003.
The Reg. (EC) No 1321/2013 authorise 10 specific primary products (smoke condensates) that comply with the requirements in 2065/2003.
These flavours are not currently allowed by the Reg. (EC) No 889/2008. Indeed, article 26 of the Reg. (EC) No 889/2008 specifically mentions smoking as an allowed process, which

requires that shall be respected principles of good manufacturing practice, but does not mention smoke flavours.

### Agronomic use, technological or physiological functionality for the intended use

The dossier provides an alternative to traditional smoking, imparting smoke flavours to products that may be more difficult to smoke. It is claimed that the levels of toxic compounds, such as polycyclic aromatic hydrocarbons in food are reduced by the process.
The dossier describes the production of smoke containing the pure smoke condensate and the use of this smoke to impart smoke flavour directly to foods, but does not apply for that process to be allowed in the organic regulation. It provides support for the claim that the generation of smoke from primary pure smoke condensate is analogous to smoking and therefore should be permitted. However, it appears that the process of generating smoke from smoke condensate is a proprietary process. It is for this reason that the dossier requests amendment of Article 26 of Reg. (EC) No 889/2008 to include smoke condensates, rather than requesting a separate mention of smoke condensates as permitted flavour additives not covered by 1334/2008 or 388/1988.

### Necessity for intended use, known alternatives

The claims in the dossier are that this process minimises contaminants which are present in traditional smoking methods. It also claims a positive overall environmental impact due to reduced environmental emissions (see below).

### Origin of raw materials, methods of manufacture

According Reg. (EC) No 1321/2013, the production of smoke condensates must be done using non treated timber, and the type of timber used must be declared. Smoke is generated by heating in a continuous process and the smoke is condensed and dissolved in water, leaving tar phases that contain the majority of the PAH.
The dossier requests addition of a process whereby the smoke condensate is used to generate smoke by forcing through a nozzle with air. It is this smoke, which is used to treat the foods. The dossier claims that the process is identical to conventional smoking, without the tars and charcoal.

### Environmental issues, use of resources, recycling

Reduction of production of tar fraction and reduced need for cleaning of smoking rooms, etc. is claimed. Also reductions in CO2 emission of 83%, and water usage of 100% are claimed.

### Animal welfare issues

None.

### Human health issues

The dossier identifies papers demonstrating reduced levels of PAH associated with the use of smoke condensates compared with traditional smoking (Ziefenhals, 2008). However, such paper is in German language, therefore the group was not able to read it.
Other processes, particularly the use of friction generated smoke appear to produce similarly lower levels of PAH in the foods. It can be argued that the use of friction generated smoke is more close to true smoking than the process applied for.
There is no information available in the dossier to assess the microbiological stability of foods treated using the applied for process, compared with traditional smoking.

## Food quality and authenticity

A clever process of generating smoke from the primary smoke product (condensate) is used to cover the fact that this process is not strictly smoking, but is the application of a smoke derived flavour as an aerosol. There is therefore some doubt as to the authenticity of the resulting food as "smoked".

## Traditional use and precedents in organic production

Although smoking is a traditional process, the process applied for is not a traditional process and has not been traditionally used for foods. The dossier claims that smoke condensates have been used for 50 years.

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

Smoke flavours are permitted in the US under USDA NOP standards para 205.605 Flavours, using only non-synthetic sources and not be produced using synthetic solvents and carrier systems or any artificial preservative.

## Other relevant issues

The group is concerned that if products treated with smoke generated from primary products is labelled with wording such as smoked, it would be misleading. Furthermore, it appears that the process of generating smoke from smoke condensate is a proprietary process.

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

In the EGTOP report on Food II - 2014 is reported the following Reflections of the Group:

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

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

The current proposed amendment to the article 26 of Reg. (EC) No 889/2008 is the following: "Additives, processing aids and other substances and ingredients used for processing food or feed and any processing practice applied, such as smoking <u>and the smoking with smoke generated from primary products</u> ..."

On one hand, the group recognize the environmental and human health benefit claimed by the dossier. On the other hand, the group fully agree with the previous assessment delivered by EGTOP, as well as is concerned over authenticity of food treated with this process, particularly if it is described as smoked. Furthermore, it appears that the process of generating smoke from smoke condensate is a proprietary process.

## Conclusions

The proposed amendment to the article 26 of the Reg. (EC) No 889/2008, asking to consider the smoking with smoke generated from primary products (pure smoke condensate) analogous to smoking, and therefore allowed, is not in line with the objectives, criteria and principles of Council Regulation (EC) No 834/2007.

## References

EFSA 2008; European Food Safety Authority, "Polycyclic Aromatic Hydrocarbons in Food, Scientific Opinion of the Panel on Contaminants in the Food Chain" (Question N° EFSA-Q-2007-136) Adopted on 9 June 2008, p.15, 27, 43, 48

EFSA 2007; European Food Safety Authority," Findings of the EFSA Data Collection on Polycyclic Aromatic Hydrocarbons in Food" Issued on 29 June 2007

Ziegenhals K. 2008 „Bestimmung der 16 von der EU als prioritär eingestuften Polyzyklischen Kohlenwasserstoffe (PAH) in verschiedenen Lebensmittelgruppen" Dissertation Fakultät Mathematik und Naturwissenschaften der Universität Dresden.