EUROPEAN COMMISSION

Directorate-General for Agriculture
and Rural Development

Expert Group for Technical Advice on Organic Production

EGTOP

FINAL REPORT

On

Fertilisers IV and Plant Protection Products VI

The EGTOP adopted this technical advice at the plenary meeting of 10th to 12th of March 2021.

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

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

EGTOP

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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https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2522&NewSearch=1&NewSearch=1

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EXECUTIVE SUMMARY

For the substances requested, the Permanent Group discussed whether their use is in line with the objectives and principles of organic production according to Regulation (EC) No 834/2007, and whether they should be included in Annex I respectively Annex II of Regulation (EC) No 889/2008. It concluded the following:

- ABE IT-56 is recommended to be included in Annex II, section 4, provided neither the strain nor the growing media are of GMO origin.
- Burnt shale, is not recommended to be included in Annex I.
- Selenium is recommended for inclusion to Annex I of Regulation (EC) No 889/2008, with the restrictions that deficiency must be proven on the soils and the use should be limited only to soils relevant for animal rearing and/or grazing
- Sodium nitrate is recommended to be included in Annex I with the restriction of use only for algae production on land in closed systems.
- Talc (E553b) is recommended be included in Annex II, section 4.

1. BACKGROUND

Several Member States have submitted dossiers under Article 16(3)(b) of Council Regulation (EC) No 834/2007 concerning the possible inclusion of a number of substances in Annex I and Annex II to Commission Regulation (EC) No 889/2008 and in general, on their compliance with the above mentioned legislation.

France introduced requests on ABE IT-56 and Talc (E553b) as plant protection products. Estonia introduced a request on Burnt shale as a soil conditioner/neutraliser. Austria introduced a request on Selenium as a fertiliser with effects on animal feeding. Moreover, Italy introduces a request on Sodium Nitrate as fertiliser/nutrient for algae production. Therefore, the Group is requested to prepare a report with technical advice on the matters included in the terms of reference.

2. TERMS OF REFERENCE

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 authorised to be used in organic production under the EU organic legislation.

Substances:

- **ABE IT-56**
- **Burnt shale**
- **Selenium**
- **Sodium nitrate**
- **Talc (E553b)**

3. CONSIDERATIONS AND CONCLUSIONS

3.1 ABE-IT 56

Introduction, scope of this chapter

The request from France pertains the inclusion of ABE-IT 56 (a fractionation product of the lysate of *S. Cerevisiae* strain DDSF623 originating from Lallemand Yeast Culture Collection, Canada) in Annex II, Pesticides — Plant protection products, section 4 as an elicitor of plant defence, mainly against downy mildew in grapevine but also on other crops.

Authorisation in general production and in organic production

ABE-IT 56 is authorised in EU for conventional agriculture under RCE1107/2009 (since April 29, 2019). It is classified as a 'low-risk active substance (EFSA, 2018).

A similar product, Cerevisane, is also authorized and was subject of EGTOP preliminary evaluation in EGTOP Report PPP IV (EGTOP, 2018) with an outcome declaring it to be in line with the principles of organic farming.

There is no traditional use in organic agriculture but by-products from *Saccaromices cerevisiae*, whose cells have been inactivated or killed, are allowed as feed additive (Annex V).

Saccaromices cerevisiae (active organism) is also allowed in processing (bread and bakery products as well as wine) with no limitations of strain type, providing they are not GMO, and it should be produced organically for bakery and organic origin should be preferred for wine-making.

There is no evidence of authorization for use in organic farming outside EU or in private standards nor in IFOAM Basic standards or Codex Alimentarius.

Agronomic use, technological or physiological functionality for the intended use

ABE-IT 56 is to be used as spray, as elicitor of plant defensive reaction against several pathogens, but especially downy mildew on grape, with a declared efficacy of 54%. It seems to have effect also on powdery mildew and botrytis. It can be complementary to copper use (reducing its used amount) and potentially replace it in case of low infection rates, but it cannot totally replace copper in normal climatic conditions.

Mostly useful on:

- **Grapevine**, *Vitis vinifera*, against black mildew, powdery mildew and bothrytis
- **vegetables**
- **cereals**
- **fruit production**

Necessity for intended use, known alternatives

In the strategies for copper reduction (no replacement), it can be useful on tree crops, vegetables, and cereals. Several alternatives, agronomic methods, and direct control are into place but any further tool to reduce and potentially avoid copper use is to be considered.

Origin of raw materials, methods of manufacture

The yeast strain (Saccharomyces cerevisiae DDSF623) has been selected on cereals in Europe and now is managed by Lallemand Canada. It is non-GM. The yeast is cultivated on growing media and processed in France. The process is basically a lysis by endogenous enzymes, followed by physical operations. No additives or coadjuvants are used.

The formulated product (JDE01) contains 325.6g/l of active ingredients. The producers recommend eight application per year of 3l/ha of formulated product.

Environmental issues, use of resources, recycling

The yeasts are ubiquitous in the environment. It has low persistence except for sediments.
Residues are the same as other strains, difficult to monitor them specifically. There is no evidence of detriment on non-target organisms.

Animal welfare issues

No issue, it is ubiquitous.

Human health issues

Similarly, to Cerevisane, yeast has low acute toxicity on rats and no concern are reported on eyes irritation. Skin sensitization leads the product to Cat. 1, there is potential sensitization hazard by inhalation. Such risks are more of concern on other uses of yeas, i.e. bakery workers, than on farmers using the product for plant protection.

No concern for consumer health.

Food quality and authenticity

No concern. No MRL required.

Traditional use and precedents in organic production

The product is similar to Cerevisane (allowed in organic as PPP by Commission Implementing Reg. 2019/2164 after EGTOP preliminary assessment). Both products have no traditional use in organic farming in EU nor in other areas.

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

ABEIT65, as Cerevisane, is not mentioned in the Codex Alimentarius guidelines for the production, processing, labelling and marketing of organically produced food (edition 2013), nor in the IFOAM Norms for Organic Production and Processing (edition 2014). However, both standards allow 'microorganisms'. In the USA, ABEIT65 and Cerevisane would probably be classified as 'non-synthetic' and would be allowed under the National Organic Program (NOP).

Other relevant issues

none

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

The expert group considers the product in line with the principles of organic farming, similar to already allowed product. The only concern is the origin of growing media where the yeast is grown, due to potential GM presence/contamination.

Conclusions

Provided neither the strain nor the growing media are of GMO origin, the use of ABE-IT 56 as plant protection product is in line with the objectives, criteria, and principles of organic Regulation (EC) No 834/2007. The addition of ABE-IT56 to Annex II, section 4 of Regulation (EC) No 889/2008 is recommended.

References

EFSA, 2018, Peer review of the pesticide risk assessment of the active substance ABE-IT 56 (components of lysate of *Saccharomyces cerevisiae* strain DDSF623).
https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5400

EGTOP, 2018 PPP IV.
https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeetingDoc&docid=29318

3.2 Burnt shale

Introduction, scope of this chapter

On the basis of the information provided by the dossier delivered by Estonia, the group is requested to assess if the use of burnt shale can be authorized as soil conditioner/soil neutralizer, according to art. 3(1) of the Regulation (EC) No 889/2008 and, therefore, can be added in the Annex I. Burnt shale is also known as "burnt oil shale", the commercial name is Enefix/Enefix +, the CAS code is 93685-99-5.

Noticeable part, up to 40% of Estonian and Latvian (Kreimane et al., 2016) agricultural soils, need lowering of acidity (acidic soils are regional specificity of Estonia) and eco-friendly enrichment with nutrients on a regular basis. Burnt shale is a fast-acting soil conditioner with a low sowing rate, which helps to reduce expenses related to the soil conditioning and soil acidity reducing in the agricultural sector.

Authorization in general production and in organic production

Burnt shale is not covered by the EU fertiliser legislation 2003/2003.

In Estonia, burnt shale is subject to the national fertiliser law (Väetiseseadus, 2003; https://www.riigiteataja.ee/en/). Under this, burnt shale with the minimum acid neutralizing capacity of 30% as calcium, is classified as lime fertiliser. Burnt shale is registered in Estonian National Register of Fertilisers as an ameliorant, registration n° 026. The authorisation is given for unlimited time if the self-control obligation regarding the composition of the fertiliser is fulfilled after every 6 months.

Burnt shale is not authorized for organic production.

Agronomic use, technological or physiological functionality for the intended use

Burnt shale has been used in Estonia since long time as a soil conditioner in the domestic agricultural sector and it has proven to be an eco-friendly, nutrient rich and efficient soil conditioner through decades. Burnt shale is a fast-acting soil conditioner with a low sowing rate, which helps to reduce expenses related to the soil conditioning and soil acidity reducing in the agricultural sector.

Due to high content of valuable trace elements and nutrients, the use of burnt shale has a wider purpose than simply balancing the soil pH. Burnt shale can also be used for balancing soil mineral composition, which prevents leaching of valuable nutrients from the soil. In this way, the use of burnt shale contributes to balancing the mineral composition of the whole soil and prevents its imbalance.

Positive effects of burnt shale usage to soil quality, fertilisation efficiency and crop productivity has been proven by several studies (Turbas, Hiis, 1969; Turbas, 1996; Järvan, Põldma 1998).

Burnt shale is spread on the field using lime spreader. During the wintertime, the thickness of the snow layer should be taken into account when spreading. The application dosage recommended by the dossier is 3–4 tons per hectare. Burnt shale should be mixed with the soil before sowing and crop emergence.

Burnt shale includes following relevant nutrients and trace elements: calcium, magnesium, phosphorus, potassium, zinc, cobalt, manganese, molybdenum, copper, iron, selenium, sulfur, boron, silicone.

Basic physical properties are: fine powder with greyish to slightly brownish colour, odourless, non-flammable; relative density (20°C): 2.7–2.9 g/cm3; humidity 0.1–0.2%; pH (t=20 °C, suspension in water): 11–13.5; low solubility in water (20°C)=(<1 g/l).

Necessity for intended use, known alternatives

Ground limestone and dolomite are currently authorised alternatives. However, ground limestone and dolomite have a significantly slower speed of reaction with the soil and lower neutralising capacity compared to burnt shale. Burnt shale has a lower sowing rate, which increases savings from the soil conditioning and enrichment of the soil with many plant nutrients.

Areas limed and amounts applied are well below what is necessary for maintaining recommended soil pH values in many European regions (Goulding, 2016), including in Estonia (Loide, 2010).

Origin of raw materials, methods of manufacture

The use of burnt shale in agriculture in larger quantities began in the 1960s when the first large oil shale powered thermal power plant in Estonia was commissioned. Indeed, burnt shale is a by-product of electricity production. Oil shale (mineral rock), mined in open and underground mine, is used as a raw material. Pure grounded oil shale without any chemical additives is combusted under t=1500 °C and/or t=900 °C. Thereafter, by means of cyclones and filters, fine calcareous material is separated out from flue gases. The dossier reports that in Estonia quality control of the burnt shale is carried out on a daily basis. Consistency of nutrients is measured at least twice a year. After separation and quality control, fine material as a product is stored in dry silos (8 silos with the capacity of 2100 tonnes each) in a stable environment.

The following content of the heavy metals in burnt shale-oil shale fly ash is reported in the dossier: Zn 26.6 mg/kg; Cu < 0.5 mg/kg; As 7.45 mg/kg; Hg <0.01 mg/kg; Cd 0.2 mg/kg; Cr 16.8 mg/kg; Ni 9.8 mg/kg; Pb 19.7 mg/kg.

The following content of the PCB, PAH and dioxines in burnt shale (test protocol is added below) is reported in the dossier: Sum PAH (EPA) content less than the limit of determination (n.d.); Sum dioxines, PCDD/DF content less than the limit of determination (n.d.); Sum WHO-PCB 0.00000195 µg/kg DW (ca 2 picograms/kg).

Neutralizing capacity: 52.9% (Ca); 94.5% (CaCO3). Reactivity: 97.2%.

Environmental issues, use of resources, recycling

The use of burnt shale lowers soil acidity, enriches soil with nutrients, prevents soil erosion, nourishes plants primarily through the improvement of the living environment and the quality of the soil.

Burnt shale is a by- product of energy production. Therefore, its use would reduce the negative impact due to mining and production processes to obtain other soil conditioners (e.g. dolomite and limestone gravel production).

However, it is very important to consider that the use of burnt shale in agriculture, in larger quantities, began in the 1960s when the first large oil shale powered thermal power plant in Estonia was commissioned. Therefore, Estonia has adopted a national development plan that limits the annual mining of oil shale to 20 million tonnes. At this rate, mineable reserves will last for 25–30 years. The Estonian National Audit Office audited whether the goals set in the National Development Plan for Oil Shale Use to reduce the environmental impact of oil shale mining and processing has been achieved, concluded that, on the basis of the audit, "The state has not achieved the goals set in the National Development Plan for Oil Shale Use", which are to reduce the environmental impact of oil shale mining and use and to increase the efficiency of mining and use. The state has not carried out a comprehensive assessment of the environmental, health or socioeconomic impact of the use of new oil shale reserves in the preparation of the new development plan". More details can be found in the Audit Report at: https://www.eurosai.org/en/databases/audits/Actions-of-the-state-in-directing-the-use-of-oil-shale/.

Animal welfare issues

No issues.

Human health issues

The burnt shale is produced from natural material (mineral rock) and production process runs without any chemical or synthetic additives (simple combustion of mineral material at high temperature). According to the dossier, the content of heavy metals, PCB, PAH and dioxines in burnt shale is within the maximum residue levels established at European level.

Food quality and authenticity

No issues.

Traditional use and precedents in organic production

Since Estonia is situated in the year-round changing climatic conditions, it is a challenge for the entire local agricultural sector to operate and maintain its effectiveness. In addition, a large part of Estonian agricultural soils, need lowering of acidity (Truu et al., 2008). Burnt shale is the only fast-acting soil conditioner that is produced in Estonia locally.

Indeed, burnt shale has been used as a soil conditioner in traditional Estonian agriculture since the middle of the 20th century. However, the area where burnt shale has been used as an agricultural soil conditioner cover Baltic states, Ukraine, Poland and Belarus.

In the period between November 2016 and October 2018, the union of the leading Estonian organic farmers carried out field trials with burnt shale on 20 hectares of arable land. The results confirmed the positive effect of burnt shale – rapid neutralization of the soil pH and higher yield. The union stated that burnt shale is a material with a unique combination of valuable nutrients and trace elements content and fast pH neutralization effect. Those characteristics are with key importance in all the geographical regions similar to Estonia to ensure sustainable development of the local organic farming sector.

However, although calcium carbonate of other origin is traditionally used in organic farming, burnt shale has no traditional use in organic production.

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

Burnt shale is not explicitly mentioned in the major international organic farming standards (Codex Alimentarius guideline for the production, processing, labelling and marketing of organically produced food; IFOAM Norms for Organic Production and Processing; National Organic Program (NOP).

Other relevant issues

None.

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

In the previous EGTOP final report Fertiliser III, is stated that: "*The Group had very limited time to evaluate the oil shale ash dossier and could therefore produce only a preliminary evaluation. Considering the lack of knowledge on possible contaminants, the Group does not recommend its use now. In case that the applicant can demonstrate that oil shale ash is safe, the Group may assess application of shale ash again*".

At the light of the evaluation of the new dossier provided by Estonia, burnt shale results, more than other currently authorised alternatives (e.g. ground limestone and dolomite), a nutrient rich and efficient soil conditioner. It is effective not only for balancing the soil pH, but also for balancing soil mineral composition, which prevents leaching of valuable nutrients from the soil.

However, although the dossier reported contents of heavy metals, PCB, PAH and dioxins in burnt shale within the norm limits, the group is concerned that due the high recommended dosage, repeated year by year, a contaminant accumulation in the soil may occur.

In addition, what creates great concern, in the opinion of the group, is the Estonian National Audit Office assessment of the environmental impact of oil shale mining and use, according to which the mineable reserves will last for 25–30 years at the current rate. In light of this, the statement reported in the dossier that burnt shale "*contributes to reducing the ecological footprint and helps to preserve and save the environment*" appears totally unfounded.

Conclusions

The use of burnt shale as soil conditioner/soil neutralizer, is not in line with the objectives, criteria, and principles of organic Regulation (EC) No 834/2007. The addition of burnt shale to Annex I of Regulation (EC) No 889/2008 is not recommended.

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3.3 Selenium

Introduction, scope of this chapter

Based on the information provided by the dossier delivered by Austria, the group is requested to assess if the use of Selenium can be authorized as fertiliser (soil conditioner), according to art. 3(1) of the Regulation (EC) No 889/2008 and, therefore, can be added in the Annex I. Selenium is sold as a complex mixture, the commercial names Selcotec, Calciprill 105, the CAS code are 7787-41-9; 13410-01-0.

Mineral liming fertiliser with selenium is requested, by Austria, for field crops and field vegetable with 1% Se as Barium Selenate, Sodium Selenate, Sodium and/or Barium Selenite + 88% $CaCO_3$ Calcium carbonate, 5 % $MgCO_3$ Magnesium carbonate. This is the formulation of the fertilizer of mines origin.

Authorization in general production

Selenium, as other micro-nutrients, is not regulated at European level (not included in EC Reg. 2003/2003) but can be allowed at national level for specific needs and purposes. For example, it is allowed in Austria and Germany on pasture and in Italy for specific crops. In all cases, it is allowed in limited amounts and for defined purposes and time-frame.

Authorization in organic production

There is no traditional use in organic farming as fertiliser, but it is allowed as micro-nutrient as feed additive (Regulation (EC) No 889/2008, annex VI. 3b NUTRITIONAL ADDITIVES, Compounds of trace elements, in the form of Sodium selenite, Sodium selenate and inactivated Selenised yeast inactivated.

Agronomic use, technological or physiological functionality for the intended use

Selenium is a trace element that plays an important role in the health and performance of animals. Selenium deficiencies have significant impacts such as reduced fertility, placental retentions, and the incidence of mastitis and metritis. The response to selenium supplementation depends on the current selenium status (low or adequate) in animals. The selenium content in the forages and grass depends directly on the selenium content in the soil. This creates a difference in the levels of selenium in animal meat according to breeding areas. The selenium content in the meat also varies among species because of the morphology of the digestive organs and the metabolism of selenium (Mehdi and Dufrasne, 2016).

As a consequence, selenium salts can be used as fertiliser (applied as spread fertiliser) at a dosage of 250 kg per ha and year, but with a limitation of 1 kg Se/ha/year). It is most efficient to spread the selenium salts at the beginning of the vegetation period with the first fertilisation.

Selenium is absorbed by plants with a fast initial effect and a long-term effect over the growing season. The plant picks up the selenium and stores it as protein. Selenium in form of protein is optimally available for living organism.

Necessity for intended use, known alternatives

Selenium (Se) is not essential for plants but is required for many physiological functions in humans and animals. The scope of its use is to supply sufficient amounts of selenium to animals grazing (pasturing/rearing on the fertilised areas). So, the alternative is to add selenium to feed but the dossier, as well as bibliography, reports lower efficiency and, as a consequence, higher amounts needed. As reported above, Selenium can be added to organic feed as Sodium selenite, Sodium selenate and Selenised yeast inactivated (as from annex VI.3 of Regulation (EC) No 889/2008).

The use of carefully regulated amounts of supplemental selenium in areas with Selenium deficiency in soils, and subsequently in crops has been effective in improving productive performance of domestic food-producing animals. Coincidentally, there have been instances reported of situations where selenium toxicity has resulted from a combination of naturally-high environmental levels, enhanced by agricultural, environmental practices, so a continued animal supplementation may contribute to selenium toxicity (Oldfield, 1992).

Origin of raw materials, methods of manufacture

Seleniun is found in metal sulphyde ores, where it partially replaces the sulphur. Commercially, selenium is obtained as a by-product in the refining of the ores, most often during production. Minerals that are pure selenide or selenate compounds are known but rare.

The ore by-products are mechanically processed into fertilisers components.

Environmental issues, use of resources, recycling

The selenium rich materials are sourced from mining as a by-product. There is no evidence on environmental impact in the areas pertained.

The use of mining by-products can be considered a form of recycling, but the amounts used as fertiliser are minimal compared to other uses.

Animal welfare issues

The use of selenium on soil is reported to improve animal health on deficient locations. There are significantly fewer stillbirths due to healthier animals.
It seems that the intake through the plant material improves efficiency (Mehdi and Dufrasne, 2016), compared to addition to feed.

Selenium deficient status was associated with most studied disorders in cows, and both deficient and marginal herd status were strongly associated with poor health of calves, particularly with increased risks of myopathy and infectious diseases (Enjalbert et al. 2006).

Herbage selenium concentration is generally low in some areas in Scandinavian countries where Se and vitamin E supplementation to ruminants on organic farms have been recommended (Govasmark et al. 2005) to protect animals from infectious diseases (Blanco-Penedo et al. 2014).

Human health issues

The effect of selenium enrichment on humans is analogous to the effect on other animals. In areas with selenium deficiencies, it has been used for more than 30 years in the Scandinavian countries via functional food to improve physical and mental health.

Food quality and authenticity

In case of areas with deficiencies it improves feed and feed nutritional quality.

Traditional use and precedents in organic production

None

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

It is allowed by NOP in use in crop production, as micronutrient, upon documented deficiency.

Other relevant issues

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

Selenium is the requested substance, as from the expert group assessment. Following, Barium Selenate, Sodium Selenate, Sodium/ Barium Selenite are the corresponding requested salts.
Selenium should not be way for allowing the use of the other components of the preparation/product although $CaCO_3$ calcium carbonate, $MgCO_3$ magnesium carbonate and CaO basic active ingredients are already allowed in organic production. The group's opinion only pertains Selenium (or corresponding salts).

Barium Selenate, Sodium Selenate, Sodium/ Barium Selenite are not neutral compounds. ECHA (European Chemical Agency), according to the harmonised classification and labelling (ATP01) approved by the European Union, classifies the substances as toxic if swallowed, toxic if inhaled, very toxic to aquatic life, very toxic to aquatic life with long lasting effects and may cause damage to organs through prolonged or repeated exposure.

Bio-fortification of crops (for food or feed use) is considered not in line with the principles of organic farming that prefers to prevent nutrient deficiencies through diversification of foods and feeds.

The group considers that selenium salts from natural origin can be allowed for use on soils where deficiencies of selenium are analytically proven and secondly, only allowed for soils used for animal rearing or grazing.

Conclusions

The use of selenium salts of natural origin, as fertiliser, is in line with the objectives, criteria, and principles of organic Regulation (EC) No 834/2007. The addition of selenium salts is recommended for inclusion to Annex I of Regulation (EC) No 889/2008, with the restrictions that deficiency must be proven on the soils and the use should be limited only to soils relevant for animal rearing and/or grazing.

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3.4 Sodium Nitrate

Introduction, scope of this chapter

The application for Sodium Nitrate is made exclusively for algae production on land in closed systems. The substance is known under the following terms: Mineral sodium nitrate, also known as: Chilean nitrate, Nitratine, Chile saltpetre, Chile sodium nitrate. The possibility of using mineral sodium nitrate will be of interest to all algae (seaweeds, microalgae and cyanobacteria) producers and distributors, since sources of soluble nutrients are essential for growth and production of these organisms at industrial scale.

Authorization in general production and in organic production

Authorized as fertiliser in Reg. (EC) No 2003/2003. Sodium Nitrate was allowed before in (EEG) No 2092/91 but drown back because high solubility. According to art. 42 of Regulation (EC) No 834/2007, the Italian Ministry of agriculture, food and forestry (MIPAAF), with document N. 5931 13 March 2012, confirmed the authorization of mineral sodium nitrate (Chilean nitrate) as nutrient for production of organic spirulina. Document N.5931 was in force since 2017 as the reference regulatory instrument in Italy for companies that intended to certify spirulina as organic. However, the EU Reg. 673/2016 established that detailed production rules for seaweed should also apply to the production of microalgae for further use as food. Chilean nitrate is no longer allowed since it is not included in Annex I of Regulation (EC) No 889/2008consolidated.

Agronomic use, technological or physiological functionality for the intended use

Natural Chilean nitrate is a natural fertiliser derived from “caliche” ore, a nitrogenous rock found in the Atacama Desert in Northern Chile and Southern Perú. It contains 16% nitrogen as its main nutrient and a series of secondary and trace nutrients (Opdebeeck et al. 2019). Natural sodium nitrate fertiliser, in its raw form, is a layer of mineral several centimetres thick (caliche). Caliche deposits are crude mineral conglomerates of salts, possibly formed from nitrogen fixation by microorganisms in playa lakes and associated soils approximately 10 to 15 million years ago (USDA, 2002). It is one of the few natural source of nitrate and it was historically used as a nitrogen fertiliser in agriculture and industry before the advent of chemical derived nitrogen fertilisers.

Relevant nutrients and trace elements content:

Potassium K % 1.0 - 1.4

Arsenic As ppm < 1

Cadmium Cd ppm < 1

Chromium Cr ppm < 1

Iron Fe ppm < 5

Lead Pb ppm < 5

Mercury Hg ppm < 0,1)

Necessity for intended use, known alternatives

The possibility of using mineral sodium nitrate will be of interest to all algae (seaweeds, microalgae and cyanobacteria) producers and distributors, since sources of soluble nutrients are essential for growth and production of these organisms at industrial scale.

Complex organic nitrogen sources, listed in Annex I, cannot be metabolized by algae if not previously mineralized. Some algae strains are able to grow on organic nitrogen source such as urea, but this is not allowed in organic production.

In the final report of Aquaculture IV, the group discussed if stripped nitrogen should be allowed for production of microalgae and/or seaweed. The group concluded that *Ammonium sulfate originating from N-Stripping has a high solubility which is not in line with the organic principles for crop production (as highlighted in EGTOP report Fertilisers III). In order to avoid any misunderstanding, the use shall be restricted to macro-/microalgae production* *in closed and land-based systems.* However, the substance is not yet added to the organic regulation and therefore not allowed at the moment.

In some closed aquaculture farms in Europe it seems that vinasse or other by-products from sugar and potato starch industry are used for a similar purpose.

Origin of raw materials, methods of manufacture

Formation of the Chilean nitrate deposits date backs 200,000 years. Natural sodium nitrate fertiliser, in its raw form, is a layer of mineral several centimetres thick (caliche). Caliche deposits are crude mineral conglomerates of salts, possibly formed from nitrogen fixation by microorganisms in playa lakes and associated soils approximately 10 to 15 million years ago. In addition to sodium nitrate, caliche contains sulphates, chlorides of sodium, calcium, potassium, magnesium and various micronutrients including borate, iodate, and perchlorate (USDA, 2002).

Because caliche is located close to the surface, it is recovered by open-pit mining.

Chilean nitrate remains the primary source (greater than 90%) of the worlds mined sodium nitrate, and the United States (US) is the leading consumer (Wisnkiak and Garces, 2019).

Environmental issues, use of resources

No information about impact of open-pit mining in Chile. In 1990, Chilean nitrate accounted only for less than 1% of the world fixed nitrogen market.

Chilean nitrate remains the primary source (greater than 90%) of the worlds mined sodium nitrate, and the United States (US) is the leading consumer (Wisnkiak and Garces, 2019). However, non-synthetic sodium nitrate accounts for a very small amount of the nitrogen fertiliser used in US agriculture. In 2001, 75,000 tons of Chilean nitrate were sold to farmers in US and constituted only the 0.14% of the total US fertiliser application (Urbansky, et al. 2001). The resource is not on the verge of total exploitation.

Animal welfare issues

No issues.

Human health issues

No issues.

Food quality and authenticity

Since sodium nitrate is comparable to the natural nutrient of algae, it is not expected to affect the end product.

Traditional use and precedents in organic production

Sodium Nitrate was allowed before in (EEG) No 2092/91 but drown back because high solubility. According to art. 42 of Regulation (EC) No 834/2007, the Italian Ministry of agriculture, food and forestry (MIPAAF), with document N. 5931 13 March 2012, confirmed the authorization of mineral sodium nitrate (Chilean nitrate) as nutrient for production of organic spirulina. Document N.5931 was in force since 2017 as the reference regulatory instrument in Italy for companies that intended to certify spirulina as organic. However, the EU Reg. 673/2016 established that detailed production rules for seaweed should also apply to the production of microalgae for further use as food. Chilean nitrate is no longer allowed since it is not included in Annex I of Regulation (EC) No 889/2008 consolidated.

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

US:

Natural Chilean nitrate currently is authorized (on a regulated status) in organic agriculture in the NOP (National Organic Program), National List of Allowed and Prohibited Substances. The NOP published Notice 12-1 on September 11, 2012 to explain how operations using natural sodium nitrate should proceed [2].

While listed on the National List as prohibited non-synthetic substance, sodium nitrate can be used in organic production in accordance with its annotations (e.g. unrestricted for spirulina).

Australia:

All synthetic products including Chilean nitrate are prohibited by Annex 1 (Products for use as Fertilisers and Conditioners) (NASAA, 2019).

International Certifiers:

According to International Federation of Organic Agriculture Movements (IFOAM), Chilean nitrate is prohibited for plant production (Urbansky, et al. 2001). However, neither Australian regulation nor IFOAM consider algae, but only traditional crops.

Other relevant issues

None.

Reflections on organic principles

Requirement that mineral fertilisers must be of low solubility (see Art. 4(b)(iii) of Regulation (EC) No 834/2007). One of the key distinctions between organic and conventional farming is that organic farming uses nitrogen fertilisers of low solubility, while conventional farming uses high solubility nitrogen fertilisers.

In micro-algae production, it is not accurate to use the term "fertilisation". "nutrition" is a more correct wording. Spirulines should be nourished with soluble nutrients. Therefore, the principle that only low solubility mineral fertilisers may be used in organic production, cannot be applied to micro-algae (EGTOP, 2018).

For cultivation of macroalgae/microalgae/cyanobacteria, nutrients from terrestrial animal origin should be permitted, with the restriction reported in the Annex I of the Regulation (EC) No 889/2008 and provided that any microbial contamination of the final product can be avoided. The use shall be restricted to macro-/microalgae production in closed and land-based systems.

The question of the potential depletion of sodium nitrate resources in Chile was discussed. Due to the very low demand with use limited to macro-/microalgae production in closed and land-based systems, depletion is not expected.

Conclusions

The use of sodium nitrate, also known as Chilean nitrate, Nitratine, Chile saltpetre, Chile sodium nitrate, only for algae production on land in closed systems, is in line with the objectives, criteria, and principles of organic Regulation (EC) No 834/2007. The addition of sodium nitrate (also known as Chilean nitrate, Nitratine, Chile saltpetre, Chile sodium nitrate) to Annex I of Regulation (EC) No 889/2008 is recommended with the following restriction: only for algae production on land in closed systems.

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3.5 Talc (E553b)

Introduction, scope of this chapter

The assessment of the food additive Talc (E553b) (Magnesium silicate-$Mg_3Si_4O_{10}$(OH)2, (CAS no.: 14807-96-6) relates to the request for inclusion of this substance as a plant protection product in Annex II, Pesticides - Plant protection products, section 4. The dossier was provided by France.

Authorisation in general production and in organic production

Talc (E553b) is authorised as food additive and as a feed additive according to the European Commission's Final review report (SANTE/11639/2017 rev.4. 2018) for Talc as basic substance. This is according to the horizontal legislation and not to the organic one.

In organic Talc can be used as a fertiliser according to annex I in Regulation (EC) No 889/2008 as included in compound product *Stone meal and clays*.

Since 2018 Talc (E553b) is allowed as a basic substance by horizontal law (EU pesticides database. 2018) In the annex II in Regulation (EC) No 889/2008, basic substances are allowed but with the condition of use: "Only those basic substances as defined by Article 23 of Regulation (EC) No 1107/2009 (2) which are food as defined in Article 2 of Regulation (EC) No 178/ 2002 and have plant or animal origin". Talc a whitish raw material of mineral origin and therefore could not be allowed in organic as a basic substance but can, if allowed be added in annex II in section 4, *Substances other than those mentioned in Sections 1, 2 and 3*.

Agronomic use, technological or physiological functionality for the intended use

Talc is a clay mineral, not soluble in water, composed of hydrated magnesium silicate with the chemical formula Mg3Si4O10(OH)2. Talc (E553b) is a powdered natural hydrous magnesium silicate containing varying proportion of such associated materials as alpha quartz, calcite, chlorite, dolomite, magnesite and phlogopite.

Intended to be use as spray (water dispersible powder) on fruit trees and grapevines as physical and thermal barrier, as repellent to insects and fungi.

As repellent against insects like *Cacopsylla pyri, Bactrocera oleae, Hyalesthes obsoletus, Scaphoideus titanus, Rhagoletis completa*, and *Capcopsylla pruni*. And as repellent to foliar fungi like mildews: *Venturia inaequalis, Plasmopara viticola*, and *Botrytis cinerea*.

Necessity for intended use, known alternatives

There are already alternatives allowed in the regulation with similar use and effects, as Kaolin or stone meals and clays. The allowance of Talc (E 553b) would provide yet another tool to be used in the strategy to protect plant health, that is not a biocidal substance.

Origin of raw materials, methods of manufacture

Talc (E 553b) is a white mineral powder produced after grinding talc that has been mined. Talc is naturally occurring. Deposits of talc are found in several countries, including China, United States, India, Brazil and France. Different types of deposit occur depending on the way in which the talc was formed, and each type contains a different group of associated minerals (EFSA, 2018).

Environmental issues, use of resources, recycling

According to EFSA's conclusion, no residues or unacceptable effects on the environment are expected given the conditions of use and its degradation pathway (EFSA, 2016).

Animal welfare issues

According to EFSA's report, the substance has neither an immediate nor a delayed harmful effect on human or animal health (EFSA, 2016). Talc is also used as feed additive as anti-caking mixture in feed.

Human health issues

According to EFSA's report, the substance has neither an immediate nor a delayed harmful effect on human or animal health (EFSA, 2016). EFSA's did also a re-evaluation of a number of related feed additives, among them, talc (E 553b) as late as 2018 with some recommendations e.g. better definitions and characterizations of the substances, but it is still a feed additive (EFSA, 2018).

Food quality and authenticity

It is a food and feed additive.

Traditional use and precedents in organic production

Talc is used for many purposes and provides specific functions in many industries. This is thanks to its properties such as platyness, softness, hydrophobicity, organophilicity and inertness. It is for example used in agriculture as fertiliser, in food industry as anti-caking agent, in ceramics, for personal care in cosmetics and baby powders etc. (IMA, 2011).
In organic Talc can be used as a as fertiliser according to annex I in Regulation (EC) No 889/2008 as included in compound product *Stone meal and clays*.

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

It is not listed as prohibited in the NOP list of non-synthetic prohibited substances.

Other relevant issues

None

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

Considering the widespread use of talc for many purposes as food, feed, human products etc. and considering the outcome of EFSA's assessment as the product as a basic substance for use in plant production the group do not see any major obstacles for addition of talc (E553b) as a plant protection product in the organic regulation. However, it is important to emphasize that the assessment and the allowance of the substance should be only for Talc (E553b), the food additive, and not for any product of Magnesium silicate though the purity of the product is crucial to secure that the use do not contribute to spread or accumulation of pollutants.

Conclusions

The use of talc (E553b) as plant protection product is in line with the objectives, criteria, and principles of organic Regulation (EC) No 834/2007. The addition of talc (E553b) to Annex II, section 4 of Regulation (EC) No 889/2008 is recommended.

References

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Other issues

It could be useful for further evaluation of PPP product of microbial origin to differentiate, in the dossier and in the annex where they are listed, between the use of active microorganism and the use of their metabolites or parts of microorganisms or inactivated microorganisms. Those specifications may clarify the mode of action and potential side effects on environment, non-target organisms and on the risk to cause resistance to the substance.

MINORITY OPINIONS

None.

LIST OF ABBREVIATIONS / GLOSSARY

None.