# Formal Recommendation From: National Organic Standards Board (NOSB) To: National Organic Program (NOP)

Date: October 26, 2018

Subject: Sodium citrate - petitioned

**NOSB Chair:** Tom Chapman

# The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

**Statement of the Recommendation:** The NOSB received a petition to approve sodium citrate as an aid used to prevent coagulation of blood in the manufacture of dried blood meal. The NOSB determined sodium citrate to be synthetic. The Board voted to allow this annotated use of sodium citrate and place it on the National List of approved synthetics for crop production.

# **Rationale Supporting Recommendation**

The attached recommendation is made with some reticence by the Board, since it has not previously reviewed and approved synthetic materials for placement on the National List that are used in the processing of a generic crop production material, such as blood meal. The Board was compelled to complete its review of the petition, despite the fact that there is no place on the National List for "processing aids" for crop production materials. There is concern that in reviewing this material it could create the assumption that every input into any previously approved crop production material will also have to be reviewed. Finally, the NOSB does not wish to create uncertainty in the classification of commonly accepted natural materials if it is found there might be a synthetic sub-ingredient used as a processing aid.

The NOSB would like the NOP to review sodium citrate and decide if a material, used in this manner to process a crop production material, needs to be placed on the National List or not. The Board does not consider the use of sodium citrate in the manufacture of blood meal an issue, and therefore unanimously approved this material. However, there is concern that there may be other synthetic aids used in the production of approved natural or synthetic materials. There is concern that listing sodium citrate may cause unwanted consequences, such as Materials Review Organizations ceasing approval of currently allowed materials, until these other synthetic production aids are placed on the National List, as well as the ambiguity of where this material should be listed.

# **NOSB Vote:**

**Classification Motion:** Motion to classify sodium citrate as a synthetic substance.

Motion by: Harriet Behar Seconded by: Emily Oakley

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Listing Motion: Motion to add sodium citrate at §205.601 with the annotation "For use as an

anticoagulant in the production of blood meal."

Motion by: Harriet Behar Seconded by: Steve Ela

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse:0

**Outcome:** Motion Passed

# National Organic Standards Board Crops Subcommittee Petitioned Material Proposal Sodium Citrate June 19, 2018

# Summary of **Petition**:

A petition was received in July 2016 for the use of sodium citrate as an anticoagulant when drying blood into blood meal which is then used as a crop fertility input in organic production. The petition specifically describes the sodium citrate as a processing aid in the production of dried blood meal.

#### **Summary of Review:**

Sodium citrate, a salt derivative of citric acid, currently appears on the National List of approved synthetic substances at §205.605(b), allowed as an ingredient in or on processed products labeled as organic or made with organic. There is no restrictive annotation for its use in organic handling. It is produced microbially typically from a molasses fermentation process and then neutralized with sodium hydroxide and crystallized into sodium citrate. It can also be produced microbiologically directly from the culture of a specific strain of yeast.

To date, the NOSB has not routinely been asked to review processing aids used in the production of crop fertility inputs. To our knowledge (according to a spring 2017 OMRI newsletter), sodium citrate is currently being used to produce blood meal used in organic production (i.e., the products are OMRI listed).

It is unclear if listing this material will instigate review and NOSB approval of more crop input processing aids. Would some materials currently in use and present on the National List no longer be allowed due to the presence of non-approved processing aids? In its spring 2017 newsletter, OMRI (a materials review organization which aids organic producers in determining allowed and prohibited materials in organic production) noted that if sodium citrate is approved as an anticoagulant processing aid for blood meal, they may feel compelled to review other anticoagulants. If other synthetic anticoagulants not present on the National List are used, OMRI may decide to not approve those brand name blood meal products as OMRI listed. It is unclear if the approval of sodium citrate as a processing aid in the drying of blood into blood meal as a crop fertility input would result in more processing aids being brought forth or disrupt the availability of other crop inputs due to the use of processing aids that are not present on the National List.

In discussions with the National Organic Program staff, it is still unclear where this material would specifically be listed on the National List, since there is no dedicated section for crop input processing aids and the term *processing aid* is not defined in the context of crop input production. It is also unclear if the use of sodium citrate, a synthetic, as a processing aid in the production of blood meal, would change blood meal from its current status as a nonsynthetic substance to a synthetic one, and therefore blood meal (made using sodium citrate) should be placed on the National List (similar to liquid fish products pH adjusted with synthetic acids). The NOSB Crops Subcommittee is bringing the sodium citrate proposal forward for full NOSB discussion, review, and vote, and will continue to work with the NOP to address the issues listed above.

# **Specific Uses of the Substance:**

Sodium citrate is routinely used to aid in the processing of blood meal to prevent coagulation. Blood will begin to clot soon after slaughter, making the drying of the blood into blood meal difficult to impossible. Keeping the blood chilled and continually agitated are mechanical methods used to slow or prevent the rapid clotting of the blood, but this is impractical in a commercial sense when spray drying liquid blood into blood meal. Canada, Codex, the European Union, Japan and IFOAM allow sodium citrate in use of organic processed foods, but do not specifically approve its use in organic crop production as a crop input manufacturing processing aid.

# **Approved Legal Uses of the Substance:**

Sodium citrate is present on the EPA Safer Chemical Ingredient list (SCIL) and described in the <u>Technical Report</u> as a material of low concern. Sodium citrate is not currently allowed as a synthetic in organic crop production as a stand-alone material, and the Crops Subcommittee is presenting this proposal to limit its use in organic crop production to use as an anticoagulant in the production of blood meal. It is currently allowed as an ingredient in organic foods, typically used as a pH control, buffering agent, and stabilizer. Sodium citrate is present on the National List as an approved synthetic in organic processed foods, with no restrictions.

#### **Action of the Substance:**

Sodium citrate acts as a chelation agent that removes the available calcium present in the blood. The naturally present calcium acts to allow the fibrinogen in freshly harvested blood to convert to fibrin which causes clotting or coagulation. Even with the use of this anticoagulant, blood must be dried fairly quickly after harvest. The sodium citrate is added directly to blood as it is collected in the meat slaughtering facility.

#### Manufacture:

Sodium citrate, the sodium salt derivative of citric acid, is a crystalline white powder with a melting point of >300°C. Its molecular formulae are: anhydrous:  $C_6H_5O_7Na_3$ ; hydrated:  $C_6H_5O_7Na_3$ ·nH<sub>2</sub>O (n = 2 or 5) or  $C_6H_5Na_3O_7$  or  $C_6H_5O_7$ . 3Na. It has a molecular weight of 258.08 grams/mole. A two-dimensional structure of sodium citrate is provided in Figure 1. Previous technical reviews for citric acid and sodium citrate are available on the NOP website (NOP, 2015). Sodium citrate is the sodium salt of citric acid. It is prepared by neutralizing citric acid with sodium hydroxide or sodium carbonate and subsequent crystallization. It is most commonly in the anhydrous or dihydrate forms.

Figure 1 2D Sodium Citrate Structure (PubChem, 2017)

# Category 1: Classification

1. For CROP use: Is the substance \_\_\_\_\_ Non-synthetic or \_\_x\_ Synthetic?

Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a quide.

Sodium citrate is produced through a chemical process, introducing sodium hydroxide or other synthetics to a naturally fermented citric acid.

# 2. For CROPS: Reference to appropriate OFPA category:

Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

Sodium citrate may fall within the OFPA production aid category. Sodium citrate is not a synthetic inert ingredient of toxicological concern.

# **Category 2: Adverse Impacts**

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

The technical report (TR) does not identify any detrimental chemical interactions with other materials used in organic farming systems. It is currently approved for use with no restrictions as an ingredient in organic foods.

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

The TR states "Sodium citrate is of low acute toxicity to freshwater fish, daphnia, algae and marine species. Similarly, sodium citrate has no obvious toxic potential against protozoans and many species or strains of bacteria including activated sludge micro-organisms (EPA, 1992; OECD, 2001)."

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

The production of sodium citrate (biological fermentation process) results in waste byproducts. The agricultural byproducts can be composted, and the acidic wastewater can be treated through a variety of wastewater treatment systems. No toxic environmental contamination was noted in the TR. 4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

As petitioned, there are no effects expected on human health, the TR states any remainder of the sodium citrate in the blood meal is expected to become a metabolite of soil bacteria. Organic farmers or consumers would not be in contact with sodium citrate. Workers in processing facilities might experience irritation to the eyes and skin when handling sodium citrate.

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

The TR did not note any negative effects associated with the low concentration of sodium citrate found in blood meal used as a fertility input in organic production. The many benefits of blood meal as a crop fertilizer were noted.

6. Are there any adverse impacts on biodiversity? (§205.200)

The TR states citric acid is found naturally in soil and water, and sodium citrate readily degrades when in contact with soil microorganisms. There is low toxicity to aquatic environments, and no negative effects upon terrestrial ecosystems and animals.

# Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

The Crops Subcommittee asked for further detail to explore alternatives to the use of this synthetic in the production of blood meal. The TR notes that none of the mechanical methods were practical for spray drying since this process involves spraying a fine, uniform mist and any coagulation interferes with the process. However, there are blood meal products that do not use sodium citrate, but they may not have the same uniformity or other beneficial characteristics of products that are spray dried.

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

The Crops Subcommittee discussed this issue in detail and found sodium citrate to be compatible with a system of sustainable agriculture. It is currently approved for use with no restrictions as an ingredient in organic foods. The TR states citric acid is found naturally in soil and water, and sodium citrate readily degrades when in contact with soil microorganisms. The TR did not note any negative effects associated with the low concentration of sodium citrate found in blood meal used as a fertility input in organic production. The many benefits of blood meal as a crop fertilizer were noted and sodium citrate is an important aid in the manufacture of blood meal.

# **Classification Motion:**

Motion to classify sodium citrate as a synthetic substance.

Motion by: Harriet Behar Seconded by: Emily Oakley

Yes: 6 No: 0 Abstain: 1 Absent: 1 Recuse: 0

# **National List Motion:**

Motion to add sodium citrate to  $\S 205.601$  with the annotation "For use as an anticoagulant in the

production of blood meal." Motion by: Harriet Behar Seconded by: Emily Oakley

Yes: 6 No: 0 Abstain: 1 Absent: 1 Recuse: 0

Approved by Steve Ela, Crops Subcommittee Chair, to transmit to NOP August 22, 2018