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

Date: April 27, 2018

Subject: Sodium Dodecylbenzene Sulfonate (SDBS) - petitioned

NOSB Chair: Tom Chapman

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: None

Statement of the Recommendation:

At this time, the NOSB does not recommend sodium dodecylbenzene sulfonate (SDBS) be added to the National List at §205.605(b)

Rationale Supporting Recommendation (including consistency with OFPA and Organic Regulations):

The NOSB notes the availability of allowed natural and synthetic alternatives to this substance. However, the Board also recognizes the importance of having the ability to rotate among several materials in an antimicrobial regime to reduce the incidence of microbial resistance. In the absence of public comment advocating for the addition of SDBS to the National List and the availability of alternatives, the NOSB does not see it as essential to organic production.

NOSB Vote:

Classification Motion:

Motion to classify sodium dodecylbenzene sulfonate (SDBS) as nonagricultural, synthetic Motion by: Scott Rice Seconded by: A-dae Romero Briones Yes: 13 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Listing Motion:

Motion to list/accept sodium dodecylbenzene sulfonate (SDBS) at §205.605(b) Motion by: Joelle Mosso Seconded by: Steve Ela Yes: 0 No: 13 Abstain: 0 Absent: 0 Recuse: 0

Motion Failed

National Organic Standards Board Handling Subcommittee Petitioned Material Proposal Sodium Dodecylbenzene Sulfonate (SDBS) January 16, 2018

Summary of Petition (October 2015 petition):

Sodium dodecylbenzene sulfonate (SDBS) is petitioned by Ecolab, Inc. for addition to the National List at §205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))", (b) Synthetics Allowed. SDBS is one of two active ingredients (the second is lactic acid) in an antimicrobial formulation for use in treating fruits and vegetables in the premises of organic food retail establishments. The Ecolab, Inc. branded formulated antimicrobial material is labeled as Antimicrobial Fruit & Vegetable Treatment (AFVT). AFVT is used in food retail environments such as restaurants, cafeterias, food service operations, commissaries and kitchens. The petitioner states their product would help to provide the organic users a new reliable antimicrobial.

AFVT is used via a sink-mounted dispensing system, which controls the concentration released into wash water. The proposed use is for raw and processed fruits and vegetables and involves a minimum 90 second immersion in the antimicrobial wash water, followed by a draining stage prior to further processing and/or serving. When used at suggested label rates, the concentration of SDBS is 76-111 ppm. SDBS remains on the produce at produce species dependent levels up to 10 ppm.

SDBS is currently approved for use as an antimicrobial agent in produce wash water by the Food and Drug Administration (FDA) under 21 CFR 173.405. It is not listed as FDA Generally Recognized as Safe (GRAS). SDBS has been reviewed by the Environmental Protection Agency's (EPA) Safer Choice Program and is included in the Safer Chemical Ingredients List (SCIL).

SDBS is an anionic surfactant used in industrial, institutional and chemical detergents & cleaners, specialty cleaners, sanitization products, emulsifiers, suspension or wetting agents, absorbents in pesticide and other agricultural chemicals, along with numerous other uses (TOXNET – Toxicology Data Network, 2014).

Summary of Review:

On October 13, 2015 the NOP received a petition from Ecolab, Inc. to add SDBS (CAS #25155-30-0) to the National List at §205.605. The petition was forwarded to the Handling Subcommittee on November 2, 2015 for review. At the time of initial review on December 1, 2015, the Handling Subcommittee deemed the petition sufficient and did not request a technical review (TR).

A proposal was brought to the 2016 Spring NOSB meeting and included several questions for the public to better inform the Board's deliberation:

- 1. What are retailers currently using to address food safety concerns?
- 2. Are any of the alternatives mentioned in the petition currently used at the retail level and if so are they effective in addressing these areas of food safety concerns?
- 3. What is the level (if any) of impurities as mentioned in this (2016) document found in SDBS?

Public comment in advance of and during the Spring 2016 meeting did not sufficiently address the above questions. Several comments, including from the petitioner, generally supported the addition of SDBS to the National List. One commenter noted while SDBS has advantages over other antimicrobials, they

believe the NOSB should first conduct a thorough review of all antimicrobials and available products and favor those with fewer health impacts on workers and consumers. Several commenters noted the need for more data regarding potential harm to human health and the environment. Several commenters noted the availability of several alternative, already allowed antimicrobials and felt SDBS did not meet the essentiality criteria of OFPA. One commenter requested a TR be provided any time an antimicrobial material is petitioned.

Based on the comments received and its determination that more data was necessary to make a decision, the Board voted to refer the proposal back to the Handling Subcommittee. On May 18, 2016, the Handling Subcommittee requested a TR be commissioned to review SDBS. On May 30, 2017, the Program provided the TR to the Subcommittee, which deemed it sufficient on August 1, 2017. During its August 1, 2017 meeting, the Subcommittee also reviewed and found sufficient a petition addendum submitted by the petitioner.

The TR provided additional information on the manufacture of SDBS, alternatives to its use, and potential impact on human health and the environment. The petition addendum and comments from the petitioner submitted during the Spring 2017 public comment period also address these points. See below for further discussion on these criteria.

Allowance under other Organic Standards

- Canadian General Standards Board Permitted Substances List SDBS is not listed in the CAN/CGSB-32.311-2015 - Organic production systems - Permitted substances lists.
- CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
 SDBS is not listed in Codex Alimentarius GL 32-1999.
- European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 SDBS is not listed in EC No. 834/2007 or 889/2008.
- Japan Agricultural Standard (JAS) for Organic Production SDBS is not listed in the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) standards for organic production.
- International Federation of Organic Agriculture Movements (IFOAM) SDBS is not listed in the IFOAM norms for organic production.

Category 1: Classification

1. Substance is for: _____ Livestock X Handling

2. For HANDLING and LIVESTOCK use:

a. Is the substance _____ Agricultural or ____ Non-Agricultural Describe reasoning for this decision using NOP 5033-2 as a guide:

SDBS is not a mineral or bacterial culture, is not a microorganism or enzyme, and is not a crop or livestock product nor derived from crops or livestock. There is no agricultural source or feedstock for the production of SDBS.

b. If the substance is **Non-agricultural**, 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 guide:

SDBS is not manufactured, produced or extracted from a natural source. It has undergone a chemical change so that it is chemically/structurally different than its source material. The chemical change is not created by a naturally occurring biological process, or by heating or burning biological matter.

The petitioner does not manufacture SDBS, but uses it as 1 of 2 active ingredients in their formulated product AFVT. The petition lists 3 manufacturers of SDBS:

- 1. Pilot Chemical Company Santa Fe Springs, CA
- 2. Stepan Company Northfield, IL
- 3. Unger Fabrikker A.S. Fredrikstad, Norway

SDBS is manufactured from linear alkylbenzenesulfonate (LAS) produced from linear alkylbenzene (LAB). SDBS is the sodium salt of LAS. The manufacturing process determines SDBS's composition and specific application performance level.

SDBS manufacture is based on a chemical synthesis production scheme from petroleum feedstocks: dehydrogenation, alkylation and sulfonation with potentially halogenated intermediates. There is no natural process for producing SDBS. SDBS is produced from kerosene or paraffin, and benzene from crude oil feedstocks. Sulfonation requires the use of sulfuric acids or burning elemental sulfur also from fossil fuel feedstocks. There is no agricultural source or feedstock for the production of SDBS.

Current manufacturing practice for LAS requires chemical catalysis which depending on the specific catalyst used can produce environmental pollution and equipment corrosion. The use of homogeneous zeolite catalysis can reduce much of the pollution associated with current catalytic methods, but the zeolite method is still in the developmental stages and there is still much work ahead in improving the manufacturing process (Aitani et al., 2014).

One of the questions posed to the public during the review of the first proposal requested information regarding the level of impurities in SDBS. SDBS may contain impurities that include neutral oil (unsulfonated materials), arsenic (As), iron (Fe), and lead (Pb). These impurities are not due to the manufacturing process but occur in the substance in background levels. The TR notes commercially prepared SDBS is usually greater than 96% pure. In the petition addendum, the petitioner states the SDBS used in their product is 91% pure. SDBS in the form and purity used in produce wash water does not normally contain toxic levels of the heavy metals or contaminants listed by the FDA in its list of chemical contaminants, metals, natural toxins and pesticide guidance documents and regulations, e.g. aflatoxins, acrylamides, dioxins, PCBs, melamine or radionuclides.

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)]

SDBS is an ingredient in a formulated product for use as an antimicrobial in the preparation and

processing of raw fruit and vegetables. Used as directed, there is little potential for detrimental chemical interactions with other materials.

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)]

Mode of Action

SDBS acts as a surfactant that disrupts bacterial membranes, subsequently changing their structure, attachability, and permeability. It denatures some bacterial proteins and inactivates some bacterial enzymes on the bacterial outer membrane involved in ionic transport.

Studies of the efficacy of various commercial detergent formulations in reducing human pathogens on inoculated fruits and vegetables and comparisons with other treatments have been reported for apples, strawberries, cantaloupe, tomatoes, and lettuce. Results from these studies indicate that detergent washes sometimes can achieve bacterial population reductions of 100 to 1000 fold, equaling or surpassing sodium hypochlorite, but in other cases showed no greater efficacy than water (Sapers, 2014). For example, a 0.2% (200 ppm) solution of SDBS had the same efficacy as a water wash in reducing Escherichia coli O157:H7 bacterial load on romaine lettuce (Keskinen 144 and Annous, 2011).

Other studies show that SDBS can be used in combination with phosphoric acid to reduce *Escherichia coli* O157:H7 on apples (Wright et al., 2000). Treatments with phosphoric acid and SDBS have an antimicrobial effect reducing bacterial populations by 10 to 100 fold (Sapers et al., 2001). Phosphoric acid is allowed in organic production for use as an equipment cleaner, cleaning of food contact surfaces only and to adjust the pH of liquid fish fertilizer [7 CFR 205.605(b), (j)(7)].

Effect on the Environment

The process of manufacture may determine the degree of negative impact on the environment, with alternative methods aimed at improving the manufacturing process. After use, surfactants are mainly discharged into sewage treatment systems and dispersed into the environment as effluent discharge into surface waters and sludge disposal on agricultural land (Ying, 2006). LAS, the progenitor of SDBS, is not acutely toxic to organisms at environmental concentrations. Concentrations of LAS found in municipal wastewater treatment systems is 1-10 mg/L (Manousaki et al., 2004). Aquatic chronic toxicity of surfactants occurs at concentrations usually greater than 0.1 mg/L (Ying, 2006).

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

The TR notes the preferred method for disposal of sewage sludge is as a soil fertilizer and so it is important to consider that LAS is slow to biodegrade under anaerobic conditions where oxygen is limited. Biodegrability may be improved through the use of low frequency ultrasound. However, several government public safety evaluators have concluded that LAS does not represent an environmental problem (HERA, 2013; OECD, 2005; EPA, 2006).

 Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

The TR provides references to studies of LAS exposure, noting LAS is readily absorbed from the

gastrointestinal tract. However, the TR also notes most of the absorbed dose is eliminated in the urine. Further, at the concentrations used, LAS is not a sensitizer or an irritant and is not carcinogenic. Exposure to concentrations of LAS higher than label use has shown to be an irritant to the skin and eyes.

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)]

See information in question 3.

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

See information in question 2. For further data, refer to the TR, lines 308-329.

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)]

Preventive practices are an essential aspect of organic production. As noted in the TR, keeping fresh produce free of soil and reducing the potential for bacterial contamination of produce during pre and postharvest is a FDA requirement. The addition of SDBS to produce wash water aids in the removal of bacteria from produce surfaces, however it is easier to prevent contamination than to remove it later (Sapers, 2003).

Aside from preventive practices during the pre and postharvest stages, there are a number of synthetic and non-synthetic materials available for use as an alternative to SDBS. Electrolyzed water, sodium and calcium hypochlorite and peroxyacetic acid are synthetic alternatives. Non-synthetic alternatives include organic acids (ascorbic acid, citric acid, lactic acid, lactates, tartaric acid, malic acid and organic vinegar (acetic acid)); essential oils such as cinnamon, rosemary, oregano and others; grapefruit seed extract; and egg white lysosome. Each has been shown to reduce microbial levels of *Listeria monocytogenes, Salmonella typhimurium, Escherichia coli* O157:H7, *Shigella dysenteria, Bacillus cereus* and *Staphylococcus aureus*.

In the petition addendum, the petitioner includes some drawbacks to these alternatives. For peracetic acids, these products are less suitable or manageable in retail and foodservice settings: concerns for worker exposure, impractically large quantities in which they are sold, short storage life. For chlorine dioxide and ozone, the material must be generated onsite, there are concerns regarding worker exposure and use is limited to trained employees. For chlorine, sodium hypochlorite is easy to use, inexpensive and convenient. However, both the petitioner and TR note the corrosive properties of chlorine solutions as having the potential to shorten the life of stainless steel equipment used in produce processing.

 For Livestock substances, and Nonsynthetic substances used in Handling: In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

Not applicable

Category 4: Additional criteria for synthetic substances used in Handling (does not apply to nonsynthetic or agricultural substances used in organic handling).

Describe how the petitioned substance meets or fails to meet each numbered criterion.

 The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1))

SDBS cannot be manufactured from a natural source. Its manufacture is based on a chemical synthesis production scheme from petroleum feedstocks: dehydrogenation, alkylation and sulfonation with potentially halogenated intermediates. There is no natural process for producing SDBS.

Non-synthetic alternatives/substitutes include organic acids. See Category 3, question 1 above.

(2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2))

As noted above, SDBS's adverse effects can be minimized in the manner in which it is manufactured and the method of its disposal.

(3) The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3)

SDBS is introduced into wash water service to improve the removal of soil and bacteria attached to the surface of produce. If used according to the FDA instructions it does not penetrate into the produce being washed and subsequently its application does not affect the nutritional quality of the food (Sapers, 2014). Adverse effect on health is addressed in Category 2, question 4, above.

(4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law; (§205.600(b)(4))

SDBS is added to fresh produce wash-water as an aid in the removal of surface bacteria. Except for residual SDBS remaining on the produce at produce species dependent levels up to 10 ppm, SDBS does not contribute to the flavor, color, texture or nutritive value of the product (Watanabe et al., 1972).

(5) The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5))

SDBS is included in the <u>FDA Food Additive Status list</u>. It is a substance that has a miscellaneous technical effect and is a food additive for which a petition has been filed and a regulation issued. It is specified in this list for < 0.2% in wash water as a surface active agent in commercial detergents used in washing fruits & vegetables, or to assist in lye peeling these products, 21 CFR 173.315. However, SDBS is not GRAS. SDBS has been reviewed by the Environmental Protection Agency's (EPA) Safer Choice Program and is included in the Safer Chemical Ingredients List (SCIL).

(6) The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))

SDBS is not essential. There are alternatives available. See Category 3, question 1, above.

(7) In balancing the responses to the criteria in Category 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, <u>Compatibility with Organic Production and Handling</u>, <u>April 2004</u>)

The subcommittee notes the availability of allowed natural and synthetic alternatives to this substance. However, the subcommittee also recognizes the importance of having the ability to rotate among several materials in an antimicrobial regime to reduce the incidence of microbial resistance. In the absence of significant public comment advocating for the addition of SDBS to the National List and the availability of alternatives, the subcommittee does not see it as essential to organic production.

Classification Motion:

Motion to classify sodium dodecylbenzene sulfonate as petitioned as nonagricultural, synthetic. Motion by: Scott Rice Seconded by: A-dae Romero Briones Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0

National List Motion:

Motion to add sodium dodecylbenzene sulfonate as petitioned at 205.605(b). Motion by: Joelle Mosso Seconded by: Steve Ela Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

References

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Approved by Lisa de Lima, Handling Subcommittee Chair, to transmit to NOSB February 21, 2018