National Organic Standards Board Materials Subcommittee Discussion Document Assessing Cleaning and Sanitation Materials Used in Organic Crop, Livestock and Handling February 21, 2019

I SUMMARY

Sanitizers and disinfectants are used in all areas of organic crop/livestock production and food processing. These materials are present on the National List of Allowed and Prohibited Substances (National List) at Sections 206.601, 205.603, and 205.605 of the USDA organic regulations. Based upon this work agenda item, the NOSB Materials Subcommittee will assist the NOSB Crops, Livestock, and Handling Subcommittees to generate consistent reviews when addressing the possible placement of sanitation materials on the National List that have direct contact with organic crops, livestock, and foods.

II INTRODUCTION

For a number of years, there has been public comment and discussion asking the NOSB to develop a system to assess sanitizers for essentiality as well as evaluate them under the OFPA and NOP regulatory criteria for inclusion on the National List. Commenters, including advocacy organizations, certifiers, and handlers, referred to this as a "comprehensive review of sanitation materials". The NOP and NOSB agree that a technical review and reference materials used by the NOSB, need to focus on the current regulatory requirements for materials review, as well as providing practical evaluation guidelines for this unique set of materials. The NOSB evaluates materials for inclusion on the National List when the materials are newly petitioned, as well as when listed materials come up for their sunset review.

One of the aspects the NOSB reviews when assessing a material for inclusion on the National List is essentiality to organic production. In determining if a material is currently essential to organic production, the NOSB considers the availability of either approved synthetic or natural alternatives to the current or proposed National List material. Materials used to clean or sanitize may have a wide range of actions and effectiveness in many situations, or they may be narrowly targeted for specific needs or circumstances. Since NOSB membership rotates, and with it the expertise and knowledge about sanitizer use, it is important to have a reference document for current and future members to use when evaluating these materials. Reference materials and evaluation guidelines will promote consistency

Background information on how to assess these materials by category, as well as a list of viable alternatives, would be useful information for both the NOSB and organic producers. There is universal support among NOSB members to provide materials to organic producers in order to meet food safety requirements. Our goal is not to limit these tools. This review could help identify materials needed to fill potential gaps in organic crop production, livestock health, and food safety.

To support the NOSB in their review of such materials (new petitions and sunset reviews), the NOSB has requested a technical review to provide information on the essentiality and appropriateness for these types of materials in a variety of situations. The Materials Subcommittee acknowledges that any changes to the National List is beyond the scope of any technical review; such changes can only be pursued by the National List petition process.

III BACKGROUND

A technical review has been requested to provide the following information:

- References and information to develop a framework and questions for review of sanitation and disinfection materials in all areas of crop/livestock production or during food handling. The framework/methodology could be used as guide for both sanitizer/disinfectant petitioners to address in their petition and for the NOSB and associated subcommittees to consider when they are in the material sunset review process.
- A broad scope of questions to consider for such material reviews. This could include mode of action in various environmental conditions (i.e. hot/cold; wet/dry), target microorganisms (i.e. bacterial, fungal, viral), other regulatory considerations (e.g. Food Safety Modernization Act requirements), and other questions/considerations that would provide the subcommittees with scientific information to make informed decisions.
- A consideration of how other international organic regulatory organizations address this unique area of materials review for possible improvement to the NOP's National List.

This document can be used as reference for current and future NOSB members, as well as the public, to enable consistent reviews of these materials and provide a comprehensive toolbox of food safety options for organic producers.

- Evaluation criteria could include:
 - 1. Level of toxicity on human health in its manufacture, use, and disposal
 - 2. Consideration of how the materials meet the current requirements to be on the Safer's Choice list of sanitizers
 - 3. Corrosive nature
 - 4. Presence of harmful odors
 - 5. Length of time residue remains after application
 - 6. Compatibility or incompatibility with other chemicals
 - 7. Persistence and effect on the environment in its manufacture, use, and disposal
 - 8. Ancillary ingredients found in commercial formulations, especially those of toxicological concern
 - 9. Use of nanotechnology in its manufacture and/or presence in final product
 - 10. Susceptibility of resistance by its target organism when material is used over time
 - 11. Ease of application and use
 - 12. Whether the product is broad spectrum or narrow spectrum
 - 13. Its effectiveness on gram-positive/gram-negative bacteria, fungi, algae, viruses, and other pathogens.
 - 14. Its effectiveness in various environmental situations, i.e. cold/hot, wet/dry
 - 15. Is it required to be used under federal or state statutes in specific situations?
 - 16. For what specific type of use is it commercially approved: crops, livestock, handling?

The technical review could aid the NOSB by categorizing these materials by use so there can be a comparison of materials by function, which will help in determining which are unique. As new products are petitioned, manufacturers can identify where their products should be classified.

Materials classified by their active ingredients:

- A. Chlorine compounds (both calcium and sodium hypochlorite)
- B. Bromide
- C. Alcohols: Ethanol, isopropanol
- D. Peroxide and peroxyacid compounds
- E. Hydrogen peroxide
- F. Acid anionic compounds (sulfuric, hydrochloric)
- G. Ionic compounds (trisodium phosphate, sodium bisulfate)
- H. Fatty acid compounds (glycerin)
- I. Acetic, citric, lactic, phosphoric, carboxylic, and other acids
- J. Quaternary ammonium compounds
- K. Iodophor compounds
- L. Soap-based compounds
- M. Ozone, ethylene oxide, hydrochlorofluorocarbons, chlorine dioxide, and other gasbased sanitizers
- N. UV light, infrared light
- O. Essential oils: natural or synthetic compounds based upon their chemical makeup
- P. Microorganism-based products (example brand names: Bio-Save, Nexy)
- Q. pH adjusters or surfactants used in concert with the above materials
- R. Silver and other elements

IV RELEVANT AREAS OF THE STATUTE, RULE, and RELATED DOCUMENTS

§ 205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

(a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

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

(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;

(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;

(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;

(5) The substance is listed as generally recognized as safe (GRAS) by 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; and

(6) The substance is essential for the handling of organically produced agricultural products. (c) Nonsynthetics used in organic processing will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

Organic Foods Production Act (U.S.C. 6518)

(m) Evaluation- In evaluating substances for inclusion in the proposed National List or proposed amendment to the National List, the Board shall consider-

(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

(2) 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;

(3) the probability of environmental contamination during manufacture, use, misuse, or disposal of such substance;

(4) the effect of the substance on human health;

(5) the effects of the substance 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;

(6) the alternatives to using the substance in terms of practices or other available materials; and

(7) its compatibility with a system of sustainable agriculture.

V DISCUSSION QUESTIONS

Please answer the questions below to assist the Board in creating a framework to help future NOSB members evaluate sanitizers both on the National List and those newly petitioned.

- 1. Should the "evaluation criteria" list noted above be modified, consolidated, or shortened; are there additional items needed?
- 2. Should the "materials classified by their active ingredients" noted above be modified, consolidated, or shortened; are there additional items needed?
- 3. Do you have additional suggestions for the development of this framework?

SUBCOMMITTEE VOTE

Motion to accept the "Assessing Cleaning and Sanitation Materials Used in Organic Crop, Livestock and Handling" Discussion Document Motion by: Harriet Behar Seconded by: Dan Seitz Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Emily Oakley, Subcommittee Chair to transmit to NOSB, February 21, 2019