



April 4, 2019

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2642-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-18-0071

RE: Materials Subcommittee –Assessing Cleaning and Sanitation Materials Used in Organic Crop, Livestock and Handling (Discussion)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Materials Subcommittee’s Discussion Document on Assessing Cleaning and Sanitation Materials Used in Organic Crop, Livestock and Handling. The subcommittee is inviting discussion on a new system for reviewing sanitation and disinfection materials in organic production and processing.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Summary

- ✓ We support the Subcommittee’s intended outcomes for this work agenda item: to enable consistent reviews of these materials and to provide a comprehensive toolbox of food safety options for organic producers.
- ✓ We have questions about how a new “system” or “framework” for reviewing sanitizers fits in to the larger existing context and process for NOSB to evaluate substances under OFPA and NOP requirements.
- ✓ We ask that NOSB withdraw its request for the Technical Review because the scope of work is unclear and stakeholders have not yet had an opportunity to weigh in on this new concept of sanitizer review.
- ✓ Grouping sanitizers by active ingredient and/or function could be a helpful exercise in assessing whether alternatives are available, and will support the Subcommittee’s stated goal to “identify materials needed to fill potential gaps in organic crop production, livestock health, and food safety.”

We offer the following more detailed comments:

Background

Substances for cleaning, sanitation, and disinfection are listed on the National List across the crop, livestock, and handling scopes, and are reviewed by NOSB when these substances are petitioned and/or are undergoing Sunset Review. Public commenters and NOSB members have expressed continued interest in learning more about antimicrobials and the range of available products that are both effective and most appropriate for use in organic production and handling. The Organic Trade Association agrees.

It is critical that organic producers and handlers have a tool kit of antimicrobials that will allow them to fully comply with all food safety requirements and have the ability to rotate among several materials to reduce the incidence of microbial resistance. It is also critical that the National List continues to represent the best and least-toxic technology our food system has developed. For this reason, the Organic Trade Association continues to be supportive of NOSB's work agenda item to develop questions to assess the essentiality of sanitizer (antimicrobial) materials.

Intended outcomes of NOSB's "system" for reviewing sanitizers

The discussion document¹ presented at this spring 2019 meeting describes the Subcommittee's intent to develop "a **system to assess sanitizers for essentiality** as well as evaluate them under the OFPA and NOP regulatory criteria for the National List." According to the discussion document, this work agenda item is intended to "assist the NOSB Crops, Livestock, and Handling Subcommittee to **generate consistent reviews** when addressing the possible placement of sanitation materials on the National List." The subcommittee also states that, "**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.**"

The discussion document also acknowledges that NOSB has requested a Technical Review to provide "information on the essentiality and appropriateness for these types of materials in a variety of situation;" "reference and information to develop a framework and questions for reviewing sanitation and disinfection materials;" and "a broad scope of questions to consider for such materials." The Technical Review is intended to be used as a reference for NOSB members to "**enable consistent reviews of these materials and provide a comprehensive toolbox of food safety options for organic producers.**"

We support the intended outcomes of this effort: collecting information and references; enabling more consistent reviews; and filling gaps in food safety tools. These outcomes will support continuous improvement in the regulatory approval of more effective and less toxic sanitizers that are needed to ensure safe production and processing of organic foods. However, we have questions about how this new "system" (which is also referred to as a "framework" or "methodology" in the document) for reviewing sanitizers fits in to the larger existing context and process for NOSB to evaluate substances under the Organic Foods Production Act (OFPA) and National Organic Program (NOP) requirements. The Subcommittee has not described how the system will work or how it will impact existing NOSB policies and procedures.

Furthermore, we are concerned that NOSB moved to request a Technical Review for a work agenda item that is in such an early conceptual stage and without first receiving public comment on the concept itself.

¹<https://www.ams.usda.gov/sites/default/files/media/MSAssessSanitizerFoodLivestockWebApril2019.pdf>

The scope of work for the Technical Review, as described in the discussion document, is unclear. It also appears to defer to the third party technical reviewers to develop evaluation criteria on behalf of the Board which would not be appropriate. **For these reasons, we ask that NOSB withdraw its request for the Technical Review described in the discussion document.** We believe that more clarity is needed from NOSB on several aspects of this new concept of sanitizer review, and stakeholders need the opportunity to weigh in on the concept details. This information exchange is essential to ensuring that a future Technical Review will address a clear and appropriate scope of work, resulting in a better technical resource for current and future NOSB members.

“Evaluation criteria” for reviewing sanitizer materials

The Subcommittee’s discussion document identifies a list of 16 “evaluation criteria” that could be included in the new system/framework for reviewing sanitizers. It is not explained how these criteria will fit in to the Subcommittee’s vision for a system of reviewing sanitizers, nor how these criteria align with the existing requirements of OFPA or the NOP.

Regardless of the type of material (sanitizer or not), NOSB must conduct its evaluation of substances for National List in accordance with OFPA (7 USC 6517 and 6518). Part 6517 includes the guidelines for the National List. Under these guidelines, the National List may provide for the *allowance of a synthetic substance only if* use of the substance “(i) would not be harmful to human health or the environment; (ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; and (iii) is consistent with organic farming and handling”, and the National List may provide for the *prohibition of a non-synthetic substance only if* use of the substance “(i) would be harmful to human health or the environment; and (ii) is inconsistent with organic farming or handling, and the purposes of this chapter (7 USC 6517(c).” In Part 6518, OFPA identifies seven criteria that the NOSB must consider in its evaluation of substances: “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.” In developing recommendations for substances on the National List, NOSB is statutorily required to evaluate substances based on the evaluation criteria and the guidelines specified in OFPA. Processing aids or adjuvants are subject to additional criteria set out in the NOP regulations 7 CFR 205.600(b).

In applying the statutory and regulatory criteria to specific substances undergoing review by NOSB, it is reasonable to expect that NOSB may need to develop more specific questions to be asked of petitioners and/or of technical reports to ensure that NOSB has sufficient information to conduct its review and develop its recommendation. Such internal evaluation tools can have a role in supporting consistency in the depth of analysis, technical information, and application of the OFPA requirements. However, it is critical that any such internal evaluation tools align with the existing statutory requirements of OFPA and regulatory requirements of NOP, and do not conflict or distract from these requirements.

As the Subcommittee continues to develop its new concept of reviewing sanitizers, it must make clear and concerted efforts to frame the system within the context of OFPA and the NOP regulations. Actions to support this effort may include:

- Develop a purpose statement that identifies evaluation criteria as an internal tool to support review under OFPA and NOP.
- For each evaluation criteria, identify the specific OFPA statues and/or 7 CFR 205.600 regulation for which the evaluation criteria is intended to help address. Any criterion that does not help determine compliance with OFPA or 7 CFR 205.600 should be eliminated.
- Develop a disclaimer statement that acknowledges that the Subcommittee’s list of evaluation criteria is not a substitute for OFPA or NOP. NOSB members must be free to interpret the statutory and regulatory criteria, and should not be limited to only the questions/criteria included in the internal evaluation tool.
- Consider choosing a different name other than “evaluation criteria.” That phrase is used in the heading of 7 CFR 205.600 and refers to specific regulatory and statutory requirements. NOSB must avoid any confusion between the Subcommittee’s concepts and the requirements of OFPA and NOP.

The Subcommittee should consider whether the evaluation criteria described in this discussion document should be applicable for all materials, and not just for sanitation materials. Neither OFPA nor the NOP regulations include any criteria unique to sanitizers. Therefore, it may not be appropriate to impose a unique set of evaluation tools for these materials when *all* materials must be evaluated under the same set of statutory and regulatory criteria. If the Subcommittee’s list of evaluation criteria is only used for sanitizer materials, it could actually contribute to *inconsistency* in review of sanitizers compared to other materials. This would upend the ultimate goal of NOSB to bring more consistency to the review of materials. Furthermore, if this evaluation system is limited only to sanitizers, NOSB would need to develop clear definitions for the terms (cleaner, sanitizer, and disinfectant) and be able to parse out which materials are reviewed under this system. This could be difficult especially when certain sanitizers are classified as pesticides within certain regulatory schemes.

“Classification” of sanitation materials by active ingredients

The Subcommittee’s document includes a list of 18 active ingredients under which petitioned or sunset materials could be classified. The Subcommittee would use these classifications to compare materials by function, which will “help in determining which are unique.”

Grouping sanitizers by active ingredient and/or function, and conducting a gap analysis of materials within and among each group could be a helpful exercise to support NOSB’s evaluation of “the alternatives to using the substance in terms of practices or other available materials (7 USC 6518(m)(6))” and whether the substance “is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products (7 USC 6517(c)(2)(a)).” This exercise will support NOSB’s stated goal of this evaluation framework to “help identify materials needed to fill potential gaps in organic crop production, livestock health, and food safety.”

The Subcommittee may want to consider choosing a different term for this list of active ingredients other than “classification.” That term is used to refer to the determination of a substance as synthetic or non-synthetic, and/or agricultural or non-agricultural, and NOSB must avoid any confusion between this internal tool and the regulatory definitions.

Discussion Questions

1. *Should the “evaluation criteria” list noted above be modified, consolidated, or shortened; are there additional items needed?*

Please see above for comments regarding the “evaluation criteria” for reviewing sanitizer materials

2. *Should the “materials classified by their active ingredients” list noted above be modified, consolidated, or shortened; are there additional items needed?*

Please see above for comments regarding the “classification” of sanitizer materials by active ingredient

3. *Do you have additional suggestions for the development of this framework?*

Please see above for comments regarding additional suggestions for developing this framework.

Conclusion

Although the Organic Trade Association continues to be supportive of NOSB’s work agenda item to develop questions to assess the essentiality of sanitizer (antimicrobial) materials, it is essential that such internal evaluation tools are clearly aligned with the statutory and regulatory requirements of OFPA and the NOP. Additional clarifications from NOSB are needed to ensure that these type of internal evaluation tools do not distract from OFPA and NOP requirements, and that consistency is maintained across NOSB’s review of substances for the National List. We also ask that NOSB withdraw its request for the Technical Review because the scope of work is unclear and stakeholders have not yet had an opportunity to weigh in on this new concept of sanitizer review.

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



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Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association