122 W. Jefferson Street | P.O. Box 821 | Viroqua, WI 54665 PH 608-637-2526 | FAX 608-637-7032 | mosaorganic.org

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Ms. Michelle Arsenault, Advisory Committee Specialist
National Organic Standards Board
USDA–AMS–NOP
1400 Independence Ave., SW.,
Room 2642-S., Mail Stop 0268
Washington, DC 20250–0268

Submitted via Regulations.gov.

RE: Docket # AMS-NOP-19-0038

NOSB Livestock Subcommittee Proposal - Use of Excluded Method Vaccines in Organic Livestock Production

Dear NOSB Members:

Thank you for the opportunity to provide comments on the Livestock Subcommittee Proposal regarding use of excluded method vaccines in organic livestock production. MOSA certifies approximately 2,150 organic operations throughout the United States, including approximately 870 livestock operations, and according to the Livestock Organic System Plans we have on file, about 500 operations use vaccines on their organic livestock. Vaccines are one of the most important classes of products in the organic livestock farmer's toolbox. The industry practice has long been to simply *allow* for the use of vaccines. To restrict usage needs careful consideration and planning. Like most certifiers, we have categorically allowed vaccines, so at this time we have only about 90 different vaccination or natural biological products recorded among nearly 10,000 entries in our extensive materials database. None of these reviewed vaccines have a GMO status documented. We are most interested in seeing the NOSB create a reasonable and practical direction for the review of vaccines, with a full set of resources that enables accuracy and efficiency in review.

MOSA can align with the subcommittee's goal to correct the inconsistency in usage of vaccines known to have been produced through excluded method technology, and "to increase the trust of the organic certification system and provide consistency and certainty for organic livestock producers." We could support a change to the USDA organic regulations to require the use of vaccines that are not produced with excluded methods when available over options produced with excluded methods. *However,* we would not fully support such a rule change without adequate resource development. We are concerned that adequate resources for an accurate and efficient review process may not exist. This proposal does not mention one of the most important requirements regarding vaccine use. National Organic Standards §205.238(a)(6) states, *"The producer must establish and maintain preventive livestock health care practices, including: Administration of vaccines and other veterinary biologics."* And, vaccines are listed

as the only synthetic biologics allowed at §205.603(a)(4). With this regulatory language and the industry's categorical allowance of vaccines, it's easy to interpret that vaccines are not just allowed, but actually required. To change this thinking will take time, education, and practicality.

In our comments for the spring NOSB meeting, we offered support for this direction, but also requested the development of adequate resources. We encouraged NOSB to take adequate time for such development. We can go along with moving forward with this proposal, but we also feel the recommendation could be postponed without harm, and bolstered with additional development of resources. As written, the proposal will be difficult for NOP to implement.

The proposal discusses an array of resources to determine if a vaccine had or had not been produced through excluded methods. The NOSB subcommittee suggests:

- *Looking the vaccine up on the Veterinary Biological Products document.* Each vaccine would need to be looked up in this list as a first step to verifying that it's not GMO.
    - *Label Terms "vector, chimera, and subunit" all indicate gmo status.*
    - *An R or D in the fifth digit of the label number in the VBP document indicates gmo status.*
    - *In addition, the terms nucleic acid vaccine, naked DNA vaccine, RNA vaccine and genetic vaccine may be used to label vaccines produced through methods.*
    - It's important to note: *"The APHIS publication also lists vaccines that had not been produced through excluded technologies that target the same disease, and would facilitate the search for commercially available vaccines that had not been produced through excluded methods."*
- *Using the Technical Evaluation Report (2011) (PDF) of Vaccines Made from Genetically Modified Organisms as a starting point.* Table 1: Selected Conventional and GMO Vaccines Used for Food Animals should be updated.
- *Certifier and public interest group collaboration to establish a list of excluded method vaccines that do not have available nonGE alternatives and which do have nonGE alternatives.* Understanding is needed regarding which vaccines are or are not produced through excluded methods.
- *Encouraging OMRI listing of vaccines.*
- *An affirmation for vaccine manufacturers to complete detailing whether or not their vaccines were produced through excluded methods, using the list of excluded method technologies maintained by the NOSB in this document.* Definitions between APHIS and the NOSB must be be in reasonable alignment. Development of an industry standard form would be ideal, and an opportunity for consistency and collaboration. We also have not worked in such a close relationship with vaccine manufacturers in the past, so relationship building would also be necessary. Organic agriculture is surely a very small portion of livestock vaccine manufacturers' customer base. When this is the case with other inputs, we often struggle to gather necessary information for review.

We appreciate the subcommittee's understanding that vaccines are an essential component of animal healthcare. As noted in the first paragraph of this letter, a great majority of our livestock producers use vaccines, and usually multiple vaccines are in use on an operation. Since spring, we've increased the number of recorded/reviewed vaccine products by approximately 40, and

we expect that over the next year or two we'll be able to gather information for all vaccine products in use on organic operations we certify. However, establishing the GMO status of all vaccines would take significant staff time. Aside from having to change our internal category listings, we would need to establish whether or not excluded methods were used for any vaccine product. During review of this proposal and the referenced documents, we noted the following statement in the NOSB October 2014: "Findings and Recommendations in Response to September 2010 NOP Memorandum on Livestock Vaccines Made With Excluded Methods". "*There are approximately 73 registered animal vaccines, of which 13 are GMO. Only 2 vaccines, Bovine and Avian Salmonellosis, appear to be presently available only as GMO.*" Is the beneficial impact of this proposal significant enough to require review of all vaccines in use? Reviewing 73 inputs to find only 11 where the operator should have looked at alternative non-GMO options seems like a relatively low risk in terms of overall GMO contamination in organic livestock production. Vaccines are usually a one-time use of a very small amount of input. Eleven inputs would have had to be evaluated against the now established commercial availability for vaccines criteria to determine allowance, and two would automatically qualify. It could be that all of the 11 would be found to be compliant. How significantly has the risk increased since 2014? Additional background information appears necessary to develop a practical review process. We would like to reduce instances of doing burdensome work for relatively little benefit.

Resources need to adequately, accurately, and clearly identify genetically modified vaccines for organic producers. At present it does not appear that we have a complete and clear set of resources to direct us to determine whether or not a vaccine was produced using excluded methods according to the NOSB's definition of excluded method technologies. The verification process seems hit or miss and only will work with a combination of review criteria, ending with a self declaration by the manufacturer, and should only be really required for a very few inputs in use. That doesn't seem very sound nor sensible. It would seem prudent to develop a process for verification that does not have significant impact on our input review capacity. Producers need clarity on when they should be looking for non-GMO options. At present, we are all having a challenge determining an adequate set of resources. So, it's impractical to expect farmers to know when they should be doing an organic search. It seems that certifiers would need to establish GE status of vaccines in use and then require the search be conducted before allowing for the continued use of vaccines found to be produced with excluded methods.

Our spring 2019 comment also asked for development of commercial availability guidance for vaccinations. The information provided in this proposal nicely meets that need. Thank you for establishing the criteria we'd use to develop an organic search form for vaccines. It would be ideal if the NOSB or NOP would develop a standard form for certifiers to use or minimally adapt for use. This is another opportunity for consistency in the industry.

We appreciate the three criteria for conducting an organic search for vaccines.

- *The vaccine is available in the specific route of delivery required by the operator (Injection, needle-free or transdermal, intranasal, ocular, oral, spray, topical.) (FORM)*
- *Information is present that details similar or not similar efficacies of the excluded and nonexcluded method vaccines for that specific illness or health problem (QUALITY)*

• *Sufficient volume of the vaccine is present for the operator to purchase in their region, within the timeframe necessary for perishable vaccines, to vaccinate their livestock. (QUANTITY)*

That stated, we are more interested in the process we develop to require that producers conduct an organic search.

Should this change move forward, a phase in period would be necessary. MOSA does not typically enforce NOSB recommendations or put forth resources based on NOSB recommendations. The NOSB discussed that "*with the 2+ years of lag time between NOSB approval of this regulatory change, and a NOP final rule, the identification and tracking system for the various types of vaccines could be put in place*." We encourage the NOSB to continue to work with appropriate parties to develop this identification and tracking system. Certifiers and other interested parties need to be able to review and comment on the efficacy of such resources.

We generally support the direction of the proposal but *with adequate resources and guidance for review*. Thank you for the opportunity to comment and for the longer than usual comment period. We would still like to see the NOSB strive for even longer but the extra days this fall have been appreciated. Thank you for your work on this topic.

Respectfully submitted,

The MOSA Certification Team