



April 4, 2019

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National Organic Standards Board
USDA-AMS-NOP
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Washington, DC 20250-0268

Submitted via www.regulations.gov

RE: Document # AMS-NOP-18-0071

NOSB Livestock Subcommittee [Discussion Document - Use of Excluded Method Vaccines in Organic Livestock Production](#)

Dear NOSB members:

Thank you for the opportunity to provide comments on the discussion document regarding use of excluded method vaccines in organic livestock production. MOSA certifies approximately 2150 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. We have categorically allowed vaccines, so at this time we only have approximately 50 different vaccination products recorded in our materials database, none of which have a GMO status clearly documented. We are most interested in seeing the NOSB land at a reasonable and practical direction for the review of vaccines. 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, delay, or prohibit usage needs careful consideration and full understanding.

MOSA supports the concept of option #2 - *Approve all vaccines produced through excluded methods as a "class" of vaccines and place this class of vaccines on 205.603(a)(4)*. Such a decision maintains the status quo. However, as a way to avoid adding a "class" of materials produced through the use of excluded methods to the National List, we suggest the following revision. **§205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling. To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of: (e) Excluded methods, except for vaccines: *Provided, That, the vaccines are approved in accordance with §205.600(a)*;**

Vaccines are already on the National List at 205.603(a)(4) as an allowed category of synthetic materials. If a problem did arise with a particular material or method of production, the petition

process could be followed for *addition* of an annotation to resolve the concern. Certifiers rely on annotations to point us in the desired direction.

We *could also* align with a direction toward doing a more thorough review, but only with established resources and guidance to ensure we begin review of vaccines with consistency among certifiers and material review organizations. More details on such a proposal are needed. The NOSB could:

- 1) Develop a list of vaccines enabling certifiers to make allowed and prohibited decisions quickly and efficiently. It must immediately be clear which vaccines we should *not* allow. Farmers often can't delay vaccine use for a lengthy review process. The reference list must be kept up to date. We know some resources and tools for review exist, but we are not aware of a resource that can accurately and reliably verify excluded method status for all vaccines.
- 2) Develop commercial availability guidance for vaccinations. If commercial availability searching is required, and with widespread vaccine use, consistency among certifiers will be needed. We don't want to burden effective livestock management systems with recordkeeping requirements that do not have added benefit for the organic operation. We need to know specifically what will be required to show commercial unavailability. In order to effectively regulate the use of GMO vaccines, it seems that we regulators should have the answers, specifically, which vaccines are and are not available from excluded method free sources, as well as the best practice for certifiers to follow to consistently require clients to discontinue a currently used GMO vaccine when it is found that a nonGMO variety of vaccine is commercially available. It is our understanding that, at least in some cases, the GMO vaccines are the only ones available. A phase-in period would likely be needed for a change with this impact. That harkens back to the need for a clear and transparent list of allowed and prohibited vaccines, or a clear set of directions and resources to use for determinations. To be sure everyone is on the same page, we'll need to be sure we have done our homework to get us all there.

Making any decision to allow for excluded methods in organic agriculture seems out of line with the intent of organic practices. However, it's also clear that the standards recognized the importance of vaccines in an organic system. Since MOSA was founded 20 years ago, we have allowed vaccines. Keeping up with the changing technologies used to produce vaccinations is of value, but that doesn't change the importance of vaccines in livestock management.

We suggest that this topic remain under discussion for 2019 to allow for adequate information gathering and sharing. Thank you for your work on this challenging issue. We are available for your questions.

Respectfully submitted,

The MOSA Certification Team