



October 3, 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-19-0038

RE: Livestock Subcommittee – Use of Excluded Method Vaccines in Organic Livestock Production

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Livestock Subcommittee's Proposal on the Use of Excluded Method Vaccines in Organic Livestock Production. The subcommittee is proposing a regulatory amendment regarding the use of excluded methods vaccines in organic livestock production.

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.

The Organic Trade Association is committed and actively engaged in fighting the proliferation of GMOs to protect organic agriculture and trade, and preserve farmer and consumer choice. We do not in any way support the use of excluded methods in the production of organic seeds, crops, ingredients or other production methods. However, we do acknowledge that the regulations currently provide for one narrow exception to the prohibition on excluded methods—GMO vaccines—provided they are approved in accordance with §205.600(a). We also acknowledge that GMO vaccines have been allowed since at least 2002. Therefore, we believe that any recommendation that is approved needs to completely and accurately assess the impact it would have on animal and human welfare and the organic livestock sector in general.

Summary

- ✓ We support NOSB's work towards a recommendation for vaccines that stands against the proliferation of GMOs in organic, while being practical in accepting the fact that some necessary vaccines are only available using excluded method technology.
- ✓ We support the NOSB fall 2019 proposal in principle, based on several key principles that align with OTA's Position on GMO Vaccines. We believe the NOSB's fall 2019 proposal on Vaccines from Excluded Methods is effective to meet these key principles. However, if NOSB passes this proposal, there are several outstanding issues that need to be addressed so that our identified key principles are upheld during rulemaking.

We offer the following more detailed comments:

I. OTA Position GMO Vaccines (“Vaccines made with excluded methods”)

The Organic Trade Association is committed and actively engaged in fighting the proliferation of GMOs to protect organic agriculture and trade, and preserve farmer and consumer choice. We do not in any way support the use of excluded methods in the production of organic seeds, crops, ingredients or other production methods. However, we do acknowledge that the regulations currently provide for one narrow exception to the prohibition on excluded methods—GMO vaccines—provided they are approved in accordance with §205.600(a).

We acknowledge that GMO vaccines have been allowed since at least 2002. Due to the lack of information or guidance about how to identify a GMO vaccine, certified livestock operations, with approval from their certifier, have chosen vaccines based upon effective disease prevention and not based on its GMO status. While not every certifier is allowing GMO vaccines and some certified operations have internal policies that do not allow for their use, generally speaking they have been allowed.

We acknowledge that some vaccines are only available in GMO form, and that prohibition of those vaccines would have significant impact on the organic livestock sector. For example, as described in OTA’s comments to NOSB in 2012, the large majority of organic poultry operations are using Salmonella vaccines as part of their preventive disease control program given the requirements to prevent Salmonella under the FDA Egg Safety Rule, and the only available vaccine for live *Salmonella typhimurium* (ST) is genetically engineered. Some state laws even require operators to administer certain vaccines (including GMO vaccines) for the prevention of certain animal diseases. Furthermore, as reported by NOSB in its 2009 Recommendation, the market for GMO vaccines is growing exponentially as a result of changing field conditions and technologic advances in production.

While OTA does not promote the use of GMO vaccines, it’s also unacceptable to move forward with a recommendation that prohibits use of GMO vaccines for preventive control if there is no conventionally produced alternative. We do not believe that organic producers should be at a disadvantage when it comes to providing adequate health care to their livestock. Vaccines are an integral part of a preventive livestock health care plan. Therefore, we support NOSB's work towards a recommendation for vaccines that stands against the proliferation of GMOs in organic, while being practical in accepting the fact that some necessary vaccines are only available using excluded method technology.

II. Background

Uncertainty has existed about the status of vaccines made from excluded methods (i.e. genetic engineering) that are permitted, which has caused inconsistencies between certifiers in what vaccines are allowed to be used in organic livestock production. Excluded methods are prohibited under §205.105(e) *except for vaccines*, provided that the vaccines are approved in accordance with §205.600(a) (i.e., reviewed in accordance with OFPA’s National List Criteria at 7 U.S.C. 6517 & 6518). Vaccines *are* listed on the National List under §205.603(a)(4). However, the listing which reads “Biologics—vaccines” does

not specifically reference those from excluded methods. NOP's 2010 position¹ (supported by the legal opinion of USDA's Office of General Counsel) is that GMO vaccines are allowed only if they are approved according to §205.600(a), and that NOSB still needs to review vaccines from excluded methods under the provisions of §205.600(a). The preamble to the NOP final rule supports this position by explaining that §205.105 was structured so that vaccines produced using excluded methods could only be used if they are affirmatively included on the National List. Therefore, the current exception at §205.105(e) to allow vaccines made with excluded methods only applies to those that are reviewed according to §205.600(a).

NOSB's work to accomplish the task of reviewing vaccines made with excluded methods under the provisions of §205.600(a) and to prepare for an affirmative decision to include vaccines made with excluded methods on the National List (if/as appropriate) has been extensive, and includes the following milestones:

- Requested development of a Technical Review² on vaccines made with excluded methods that used the criteria found at 7 USC 6517 and 6518 (as required by §205.600(a)).
- Convened a Working Group of NOSB, NOP, and staff from the Center for Veterinary Biologics (CVB) division of the Animal Plant and Health Inspection Service (APHIS) to develop information about the use and identification of vaccines made with excluded methods to support the NOSB's review of vaccines from excluded methods according to §205.600(a). The Working Group presented an Interim Report³ to the NOSB Livestock Subcommittee (February 5, 2013).
- Presented a comprehensive overview and recommendation⁴ on vaccines from excluded methods (August 2014), thereby responding to NOP's request for NOSB to review vaccines from excluded methods in accordance with §205.600(a). NOSB unanimously passed this recommendation in October 2014, and requested that NOP utilize the information within the NOSB recommendation to provide Guidance to NOSB, certifiers, and MROs on the use of vaccines made with excluded methods in organic livestock production.

NOP has not been able to act on the NOSB's recommendation because of the following challenges cited in the April 2019 NOSB Meeting Materials: "having an updated definition of excluded methods that determines if new technologies were to be excluded methods for organic, having a clear understanding if there were non-excluded method vaccine equivalents to excluded method derived vaccines and how to provide for use of excluded method vaccines if there was an emergency when only an excluded method vaccine could address the problem in a timely way."

The NOSB Livestock Subcommittee believes these issues have been clarified, and is ready to address the issue through a regulatory solution that will clarify the allowance of vaccines from excluded methods. The subcommittee has stated that it is committed to finding a pragmatic way to stand against the pervasive use of excluded methods in organic agriculture and foods, while being practical in accepting the fact that some necessary vaccines are only available using excluded method technology. At the spring 2019

¹<https://www.ams.usda.gov/sites/default/files/media/NOSB%20Memo%20Response%20to%20Rec%20from%20April%202010%20Meeting.pdf>

²<https://www.ams.usda.gov/sites/default/files/media/Vaccines%20from%20Excluded%20Methods%20report%202011.pdf>

³<https://www.ams.usda.gov/sites/default/files/media/LSInterimReportVaccineswithExcludedMthdsApr2013.pdf>

⁴<https://www.ams.usda.gov/sites/default/files/media/NOP%20Livestock%20Vaccines%20from%20Excluded%20Methods.pdf>

meeting, the subcommittee presented a discussion document⁵ with three options of clarifying the allowance of excluded methods vaccines in the regulations:

- Option #1: Follow the requirements of §205.105(e) and start reviewing known excluded method vaccines for individual placement on the National List. Under this option, individual vaccines made from excluded methods will need to be petitioned to NOP, reviewed by NOSB, and placed on the National List via NOP rulemaking.
- 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). Under this option, vaccines made from excluded methods would be allowed without further review or restriction.
- Option #3: Change §205.105(e) to read as follows:” (e) Excluded methods, except for vaccines: Provided, That, there are no commercially available vaccines that are not produced through excluded methods to prevent that specific animal disease or health problem.” Under this option, vaccines would not need to be individually reviewed by NOSB, but certifiers will need to conduct reviews to determine if the vaccine is made from excluded methods and whether the commercial availability restriction would apply.

For the fall 2019 meeting, the subcommittee presents a proposal⁶ that vaccines from excluded methods may be used when an equivalent vaccine not produced through excluded methods is not commercially available. This proposal would implement Option #3 as described in the last meeting’s discussion document. The subcommittee’s proposal includes information about how to determine commercial availability of a vaccine not produced through excluded method terminology.

III. Key principles regarding the restricted use of vaccines

The Organic Trade Association supports NOSB's work towards a recommendation for vaccines that stands against the proliferation of GMOs in organic, while being practical in accepting the fact that some necessary vaccines are only available using excluded method technology. The NOSB Fall 2019 proposal is to amend §205.105(e) to allow vaccines from excluded methods **only when** an equivalent vaccine not produced through excluded methods is not commercially available.

OTA identifies several key principles that should underlie any future recommendation for vaccines used in organic livestock production in order to align with OTA’s Position on GMO Vaccines. We believe the NOSB’s fall 2019 proposal on Vaccines from Excluded Methods is effective to meet each of these principles, as described below. Based on these principles, we support the spirit and direction of the proposal because of the underlying principles that it represents.

1. GMO vaccines are more narrowly restricted than what is being done under status quo.

Generally speaking, GMO vaccines have been allowed without further scrutiny or restriction. However, more specific scrutiny of GMO vaccines is needed than what is currently being done under the status quo. Blanket or carte blanche approvals of GMO vaccines are not aligned with historical and legal interpretations of the regulations, which required NOSB to give consideration of vaccines under the National List criteria under §205.600(a). The NOSB fall 2019 proposal is

⁵ <https://www.ams.usda.gov/sites/default/files/media/LSVaccinesExcludedMethodsDDWebApril2019.pdf>

⁶ <https://www.ams.usda.gov/sites/default/files/media/LSVaccinesExcludedMethodsProposalFall2019.pdf>

effective in adding further scrutiny/restriction on vaccines from excluded methods than what is being done under current practices.

2. Preference is given to non-GMO equivalent alternatives.

Although there has always been one narrow exception in the regulations for the use of excluded methods in vaccines, the overarching and clear tenant of regulations is to prohibit GMOs in the production and handling of organic production. In cases where a non-GMO alternative is commercially available, such an exception is not needed, and the non-GMO alternative should be encouraged. The NOSB fall 2019 proposal is effective in adding a requirement that non-GMO versions are used when commercially available.

3. Organic producers have access to safe and effective vaccines to promote animal welfare.

Vaccines are an integral part of a preventive livestock health care plan and are essential for promoting animal welfare. Even though some vaccines are only available using excluded method technology, organic producers should be at a disadvantage when it comes to providing adequate health care to their livestock. The NOSB fall 2019 proposal is effective in ensuring that organic producers have timely access to vaccines that are necessary to prevent that specific animal disease or health problem.

4. Certification agencies reach consistent determination about which vaccines are allowed.

Consistent enforcement of the regulations is critical for ensuring a level playing for organic operations. Currently, there are inconsistencies between certifiers about which vaccines are allowed. The NOSB fall 2019 proposal is effective in clarifying consistent requirements for verifying the restricted allowance of vaccines from excluded methods.

IV. Further work by NOP to uphold key principles

If NOSB passes this proposal, there are several issues that still need to be addressed by NOP so that these principles are upheld during rulemaking. These issues address administrative and enforcement aspects of implementing the NOSB fall 2019 proposal. Although these items are necessary to be addressed, we do not feel that these are barriers to our support of the underlying principles of NOSB's fall 2019 proposal. As stated by the Board in the NOSB spring 2012 Livestock Subcommittee review of GMO Vaccines: *"The NOSB should recommend policy based on what is consistent with an organic system of production rather than administrative and enforcement exigencies. A key factor regarding GMO vaccines is: are we making the decision based on the proper considerations? NOSB is a policy body, not an administrative or enforcement body. NOP is responsible for administering and enforcing policy related to GMO vaccine use."*

Therefore, we direct these outstanding items to NOP:

1. **Confirm that NOSB has completed its review of GMO vaccines under the provisions of §205.600(a) to ensure compliance with the legal opinion of USDA’s Office of General Counsel.** Such review was requested by NOP in its 2010 Memo⁷ and must be verified as complete prior to proceeding with any regulatory amendments. This is extremely important given that the NOSB fall 2019 proposal would *remove* the language from the regulations that currently requires GMO vaccines to be reviewed under the provisions of §205.600(a).
2. **Ensure that the GMO vaccines are included in the Sunset Review of the listing of vaccines on the National List.** Under the NOSB fall 2019 proposal, the restricted allowance of GMO vaccines would appear in §205.105(e), which is separate from the existing listing of “Biologics – vaccines” on the National List at §205.604(a). When the listing of “Biologics – vaccines” at §205.604(a) undergoes its scheduled Sunset Review, the restricted allowance of GMO forms should be incorporated into that review. This way, NOSB can collect information on whether/which GMO vaccines are being allowed, and evaluate whether the restricted allowance of GMO complies with the criteria for the National List.
3. **Protect organic producers from being mandated to use a GMO vaccine when a non-GMO version is commercially available.** Future situations could occur when a state or federal mandate requires the use of a GMO vaccine to control a certain disease outbreak (e.g. as part of a Federal or State emergency pest or disease treatment program.) In these cases, we do not want to see organic producers pressured or required to use vaccines that would otherwise be prohibited by the organic regulations. If an equivalent non-GMO alternative is commercially available to control the specific disease, organic producers should be allowed to use such non-GMO vaccine. NOP should work with USDA, FDA, EPA and other relevant agencies and/or State Departments of Agriculture to ensure that these policies are aligned and organic producers are protected.
4. **Support certification agencies and certified operators with guidance on identifying vaccines from excluded methods and enforcing the commercial ability restriction.** The NOSB fall 2019 proposal identifies resources to determine if a vaccine had or had not been produced through excluded methods, and other helpful information for how to apply the definition of commercial availability to vaccines (with specific consideration of vaccine efficacy and delivery method). Incorporating such information into guidance, instruction, and/or training materials will support accurate and consistent implementation of the restriction, and ensure that certifiers can provide efficient review and approval of Organic Systems Plans that include usage of restricted materials such as GMO vaccines. Additionally, NOP should formalize NOSB Recommendations on Excluded Methods Terminology into NOP Guidance so that this valuable information can become an official resource to support efforts to identify if a vaccine is made from excluded methods. NOP should also continue to support NOSB work agenda items on excluded method terminologies related to vaccines. For example, some forms of transposons (used in animal vaccines) are still listed as “to be determined” in the NOSB Excluded Methodology Chart.

⁷<https://www.ams.usda.gov/sites/default/files/media/NOSB%20Memo%20Response%20to%20Rec%20from%20April%202010%20Meeting.pdf>

V. Conclusion

The Organic Trade Associations continues to support NOSB's work towards a recommendation for vaccines that stands against the proliferation of GMOs in organic, while being practical in accepting the fact that some necessary vaccines are only available using excluded method technology. We support the NOSB fall 2019 proposal in principle, based on several key principles that align with OTA's Position on GMO Vaccines. We believe NOSB's fall 2019 proposal on Vaccines from Excluded Methods is effective to meet these key principles. However, if NOSB passes this proposal, there are several outstanding issues that need to be addressed so that our identified key principles are upheld during rulemaking.

On behalf of our members across the supply chain and the country, OTA 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