



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: Livestock Subcommittee – Use of Excluded Method Vaccines in Organic Livestock Production (Discussion)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Livestock Subcommittee's Discussion Document on Use of Excluded Method Vaccines in Organic Livestock Production. The subcommittee is inviting discussion on three possible regulatory solutions regarding the use of vaccines produced through excluded methods.

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 acknowledge and appreciate the tremendous amount of work that NOSB has put forth on this issue.
- ✓ There are positive aspects to all of the regulatory solutions. However, within the limited comment period, OTA was not able to conduct a complete and thorough evaluation of the options or fully engage our membership to the extent needed to endorse any one specific option.

We offer the following more detailed comments:

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

OTA 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.

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 the USDA’s Office of General Counsel) is that GMO vaccines are allowed only if they are

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

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 which 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 current 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 states 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.

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>

Three Regulatory Solutions:

In the Subcommittee's discussion document⁵, three possible regulatory solutions are presented to the public for feedback.

- **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. (Note: A more streamlined way to implement this option would be to amend §205.105(e) to remove the phrase, “Provided, That, the vaccines are approved in accordance with §205.600(a).”)

- **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.

Feasibility of identifying a vaccine as being made from excluded methods

Options #1 and #3 are both contingent upon the ability to identify if a vaccine is made from excluded methods. For Option #1, this information is necessary to determine if the vaccine needs to be petitioned for inclusion on the National List. For Option #3, this information is necessary to determine if the vaccine is subject to a commercial availability restriction.

The main barrier to previous attempts to identify a vaccine as being made from excluded methods was that the current regulatory definition for “excluded methods,” on its own, is inadequate to clarify methods relevant to vaccine manufacturing. In the past several years, NOSB has conducted extensive work on excluded methods terminology, with a breakthrough recommendation passed in fall 2016 that includes a set of supplemental definitions, criteria for review of new technologies, and a list of technologies that have been determined to be an excluded method. This recommendation, along with subsequent recommendations that continue to clarify new terms and technologies, will greatly improve the efforts of the organic industry to determine whether a vaccine manufacturing method should be classified as excluded. Although there may be some outstanding “to be determined” technologies that are relevant to vaccines, there is at least a set of criteria and a process for NOSB to conduct the evaluation and make a determination. For example, transposons (used in animal vaccines) are listed as “to be determined,” and two forms of transposons are included in the spring 2019 NOSB agenda for determination. It is important

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

for the NOSB Recommendations on Excluded Methods Terminology to be formalized as 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.

Another barrier to previous attempts to identify a vaccine as being made from excluded methods was the challenge of obtaining information about a vaccine's manufacturing process in order to evaluate whether the process involves an excluded method. Vaccine manufacturers may not be able to disclose manufacturing information due to patent protections or other need to maintain confidential business information. This will remain a challenge going forward.

For vaccines whose manufacturing process cannot be obtained, there are very limited options for determining if the vaccine is made with excluded methods. According to the 2014 NOSB Recommendation, if an APHIS-registered vaccine label uses the terms "Subunit," "Vector," or "Chimera," one can reliably identify that vaccine as being made with an excluded method. The resources appear to end there. APHIS product codes are not reliable for determining whether a vaccine was made using technologies that would be considered excluded methods under the NOP regulatory definition.

If Options #1 or #3 are pursued, the industry will face challenges in positively identifying whether a vaccine is made with excluded methods due to the challenges of obtaining sufficient information about the vaccine manufacturing process in order to conduct the evaluation of the vaccine against the NOP definition and NOSB recommendations for excluded methods terminology. Additional guidance will need to be developed that provides certified operators and certifiers with instructions on how to identify vaccines made from excluded methods. There may be cases where this challenge is unsurmountable, and a vaccine will default to being classified as an excluded method due to a lack of information to prove otherwise.

Feasibility of evaluating commercial availability of vaccines *not* from excluded methods

Option #3 is contingent upon the ability to identify if a vaccine is made from excluded methods (as described above), and also the ability to identify if an alternative version *not made from excluded methods* is commercially available to prevent that specific animal disease or health problem.

Commercial availability restrictions are not new to the regulations (definition at §205.2; restrictions on seeds and planting stock at §205.204(a)(1); restriction on yeast in products for human consumption at §205.605(b); restrictions on non-organic agricultural minor ingredients at §205.606). However, such restrictions are based on commercial availability of organic forms, which can be clearly verified by an organic certificate. Operators that are responsible for conducting a commercial availability search for organic forms have a clear method of determining whether a form is organic or not, and can document their search for verification by their certifier. On the other hand, a commercial availability search for forms *made with excluded methods* is an exercise that will be new to the organic regulatory scheme. If operators are required to conduct their own search for vaccines made without excluded methods, it will be a complex and technical process of attempting to identify individual vaccines as being made from excluded methods, which involves several challenges (as described above). If Option #3 is pursued, operators will be challenged to conduct their own commercial availability searches for vaccines made without excluded methods. Additional guidance will be needed to support operators in this effort.

Operators and certifiers alike may be challenged in conducting commercial availability searches for custom vaccines and combination vaccines (multiple vaccines are often combined into one dosage / multi-disease vaccine packages). However we anticipate that certifiers can adapt existing policies they may have in place for custom/combination inputs already subjected to commercial availability restrictions (e.g. seeds; colors).

In the Subcommittee's discussion document, two questions related to commercial availability are presented to the public for feedback.

- *What type of documentation would be used to prove non-commercial availability of vaccines produced without excluded methods?*

Operators that use a vaccine made with excluded methods would need to document their effort to search for vaccines made *without* excluded methods in appropriate form, quality, or quantity to fulfill the intended function (i.e. is specific to an animal disease or health problem). Certifiers are the ultimate decision makers of whether an operator's commercial availability documentation is sufficient. We anticipate that certifiers could adapt existing documentation requirements for other inputs already subjected to commercial availability restrictions (e.g. seeds; substances on §205.606).

- *When reviewing vaccines under commercial availability, are there special issues that should be considered?*

See above.

Other considerations for the use of vaccines

Federal or state mandated vaccinations: Some organic operations may be subject to federal or state mandated vaccinations. It is important that organic operations are not mandated to use vaccines that could jeopardize their organic certification status.

- Option #3 may not be a viable option for accommodating federal or state mandated vaccines. For example, if a mandated vaccine is made from excluded methods, an organic operation would need to demonstrate commercial unavailability of alternative vaccines not made from excluded methods in order to comply with the mandate. The state or federal agency may or may not approve use of the non-excluded method alternative.
- Option #2 is the most preferable option for accommodating federal or state mandated vaccines. Under this option, organic operations would have a level playing field with conventional operators to use the vaccines as required by federal or state mandates.

Timeliness of approval: In order for vaccines to be an effective preventive health care tool, livestock operations need approved access to such tools in a timely manner so that animals can be vaccinated at the appropriate time to protect against disease. Timely approval is important for the use of newly developed vaccines and/or vaccines that are needed as an emergency response.

- Option #1 is not a viable option for accommodating the timely use of a new vaccine because it would involve the time-consuming process of NOSB review and NOP rulemaking (which may take years) to provide for the allowance of a new vaccine.
- Option #2 is the most viable option for accommodating the timely use of a new vaccine and/or a vaccine needed for an emergency response, because the operator could use any vaccine without needing to evaluate whether the vaccine was made with excluded methods, or to conduct a commercial availability search for non-GMO alternatives, or to go through the NOP rulemaking process.

Economic impact analysis: In the NOP's 2010 memo⁶, NOP suggested that the Board include in its review an assessment of the economic impact of using commercial availability criteria for non-GMO vaccines. This assessment has not been conducted, and we believe this is an area that needs considerably more work if Option #3 is pursued.

Preferred Options (Summary)

All of the regulatory solutions presented in the discussion document are effective in standing 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. Additionally, all of the options will level the playing field of certified livestock operations by ensuring that all certifiers are following a consistent practice in reviewing and allowing vaccines from excluded methods. These options also do not preclude the option of submitting petitions to the National List to prohibit individual vaccines that may not comply with National List criteria. For these reasons, there are positive aspects to all of the regulatory solutions.

Option #1 is not a preferred option, primarily due to inability to accommodate the timely use of a new vaccines, which would prevent operators from providing full and comprehensive preventive care for organic livestock.

Option #2 is preferable in terms of accommodating the timely use of a new vaccine, and emergency use of vaccines, and accommodating federal or state mandated vaccinations, while also eliminating the challenge of identifying vaccines as being made with excluded methods (which may be an unsurmountable challenge in some cases).

Option #3 is not a preferred option in terms of accommodating federal or state mandated vaccinations, and also involves the challenges of needing to identify vaccines as being made with excluded methods (which may be an unsurmountable challenge in some cases), and also needing to determine if alternative versions not made from excluded methods are commercially available to prevent that specific animal disease or health problem. However, there are positive considerations for this option. This option makes it incumbent upon organic producers to seek out and use non-GMO vaccines before those made by excluded methods can be used, which aligns with an underlying premise of organic to avoid GMOs. It is unclear at this time whether this option is feasible given the aforementioned challenges.

⁶<https://www.ams.usda.gov/sites/default/files/media/NOSB%20Memo%20Response%20to%20Rec%20from%20April%202010%20Meeting.pdf>

Conclusion

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. 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 non-GMO alternative. The options presented in the discussion document are effective to meet this goal, although each option presents unique challenges and considerations. Within the limited comment period, OTA was not able to conduct a complete and thorough evaluation of the options or fully engage our membership to the extent needed to endorse any one of the specific options. However, we look forward to continuing to explore these options with our members, and will be in a better position to comment on a more specific proposal on this topic should it be presented in the fall.

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