

National Organic Standards Board
Livestock Subcommittee Discussion Document
Use of Excluded Method Vaccines in Organic Livestock Production
February 19, 2019

Introduction and Background

The Livestock Subcommittee requested that the “use of vaccines in organic livestock production made through excluded methods” be placed on the NOSB’s work agenda, and this request was approved on November 6, 2018. There are two areas in the organic regulations that address use of vaccines; one on the National List (NL) of allowed and prohibited substances, and in the section that details excluded methods. Through public comment and direct interaction with certifiers and organic producers, it became apparent that there are inconsistencies between certifiers in what vaccines are allowed to be used. Some certifiers do not allow the use of excluded method vaccines, relying on the NOP regulation at §206.105 (e) which only allows use of this type of vaccine if it has gone through NOSB review and NOP placement on the National List. Other certifiers allow any type of vaccine to be used, and may or may not inquire if the vaccine has been produced through excluded methods or not. These certifiers rely on the presence of vaccines on the National List at §205.603(a)(4) without any restriction or clarifying annotation.

This issue was reviewed by the NOSB in August 2014, with a [“Findings and Recommendation in Response to September 2010 NOP Memorandum on Livestock Vaccines Made With Excluded Methods”](#). Challenges that prevented immediate attention to this issue included: 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.

In August 2017, the NOSB Materials Subcommittee passed a [recommendation](#) that addresses how to determine if specific technologies should be considered excluded or not, with descriptions, terminology and a listing of excluded, not excluded and yet-to-be-determined methods. The NOSB is using this recommendation to review new technologies as they develop. The August 2014 NOSB recommendation lists commonly used vaccines that are known to have been made through excluded method technology. With these issues clarified, the current NOSB is ready to address this issue and provide consistency and certainty for organic livestock producers.

The Subcommittee recognizes the importance vaccines play in the prevention of livestock disease. When an organic livestock producer loses one or more of their animals, there is the loss of the animal’s production capability, as well as a loss of time and resources associated with the breeding and selection that resulted in that specific animal. Breeding and selection often take years or even decades. When an animal is lost, all of those years of breeding and their unique genetics are also lost. The use of vaccines as a preventative can protect this long-term investment in genetic improvement, and vaccines remain an important tool in the organic livestock producer’s toolbox to protect the investments that producers have in individual animals as well as their herds or flocks. The possibility of a livestock health emergency is real, and the NOSB is addressing it now in order to have a solution in place before a crisis might occur.

Relevant Areas of the Rule and Guidance

From the NOP Rule:

§205.2 Terms defined

Biologics. All viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.

Commercial availability. The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

Excluded methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

§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)

§205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

(a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

The [preamble to the National Organic Program final rule](#) (FR Vol. 65, No. 246, page 80554 or page 14 of the pdf) states:

The Act allows use of animal vaccines in organic livestock production. Given the general prohibition on the use of excluded methods, however, we believe that animal vaccines produced using excluded methods should not be allowed without an explicit consideration of such materials by the NOSB and without an affirmative determination from the NOSB that they meet the criteria for inclusion on the National List. It is for that reason that we have not granted

this request of commenters but, rather, provided an opportunity for review of this narrow range of materials produced using excluded methods through the National List process.

Excerpt from [NOP Memo to NOSB](#) dated September 30, 2010

The NOP's understanding is that excluded methods are prohibited under Section §205.105(e) *except for vaccines*. Further, this exception applies to vaccines that are produced through excluded methods only if those GMO vaccines are approved according to 205.600(a). Vaccines are listed under §205.603(a)(4) under "Biologics-Vaccines". The NOSB has not reviewed vaccines in accordance with §205.600(a). The listing under §205.603(a)(4) of Biologics-Vaccines does not include the allowance of GMO vaccines. The NOP requested a legal review from USDA's Office of General Counsel (OGC) to determine whether vaccines produced through excluded methods are currently allowed under 205.603(a)(4). The OGC opinion supports the position that GMO vaccines are allowed only if they are approved according to 205.600(a).

The NOP recommends that the NOSB review GMO vaccines under the provisions of §205.600(a). The NOP suggests that the Board request a technical review for biologics-vaccines, including the status of genetically modified vaccines and an assessment of the economic impact of using commercial availability criteria for non-genetically modified vaccines. After the Board completes the evaluation according to the OFPA criteria, it may submit a recommendation to the NOP to add GMO vaccines to the National List of Allowed and Prohibited Substances.

Discussion

The Livestock Subcommittee strongly supports the use of vaccines as an essential component of maintaining animal health and promoting animal welfare. Currently, §205.105(e) requires excluded method vaccines be reviewed and placed on the National List before use. This approach is impractical for a variety of reasons:

- There are new individual vaccines continually being developed; the NOSB will have difficulty reviewing these in a timely manner.
- Putting each of the excluded method vaccines on the NL is a lengthy process (2+ years) and puts organic livestock at risk in emergency situations when that vaccine may be needed immediately.
- Some excluded method vaccines may be patented and there may be confidential information that will not allow NOSB standard review of the material.
- Both the European Union and Canadian organic standards do not differentiate between the use of excluded method vaccines or standard vaccines, putting US organic livestock producers at a disadvantage when addressing animal disease.
- Some certifiers observe this restriction, and do not currently allow any excluded method vaccines, while others ignore this restriction and allow excluded method vaccines or do not determine if a vaccine is made from an excluded method or not. This inconsistency causes problems for some producers and may lead to "certifier-shopping". Any time we can correct an inconsistency, we increase the trust of the organic certification system for both producers and consumers.

The Livestock Subcommittee, and we believe the full NOSB, is committed to not endorsing the blanket use of excluded method technologies. We seek to find a pragmatic way to stand against 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. Here are some considerations if there is an allowance of excluded method vaccines “as a class” with no restriction.

- This is what is currently done in Europe and Canada.
- Less documentation needed by operators and certifiers.
- Allows for use of needed vaccines in an emergency with no restrictions.
- New excluded method technologies might provide additional animal health effects beyond just control of a specific disease, having a carte blanche approach might have unintended consequences beyond our intention of preventing animal illness.
- Might open the door to more use of excluded methods in organic.

As a third option, the regulatory change could require that vaccines from excluded methods only be used when there are no commercially available vaccines produced without excluded methods. This option, somewhat of a compromise between the two options above, has its own set of issues.

- We need a clear definition of “commercial availability” when searching for vaccines made without excluded method technology and what documentation is sufficient to prove this search.
- Operators and certifiers are accustomed to “commercial availability” since it applies to use of organic seed and agricultural products found on §205.606.
- Would allow for quick use of an excluded vaccine in an emergency, when no other option is available.
- Encourages market availability of vaccines not made with excluded methods by providing buyers for these vaccines and showing a need for their continued manufacture.
- Might be difficult to clearly identify all vaccines are from excluded methods and which are not. We have a current list of widely used vaccines, but there may be others used regionally or sporadically that we do not have clear information.

Questions for the public

The Livestock Subcommittee sees three possible regulatory solutions and asks the public to provide feedback.:

1. Follow the requirements of §205.105 (e) and start reviewing known excluded method vaccines for individual placement on the National List.
2. Approve all vaccines produced through excluded methods as a “class” of vaccines and place this class of vaccines on 205.603(a)(4).
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.

In addition, please provide information on the following:

4. What type of documentation would be used to prove non-commercial availability of vaccines produced without excluded methods?
5. When reviewing vaccines under commercial availability, are there special issues that should be considered?

Vote in Subcommittee

Motion to accept the “Use of Excluded Method Vaccines in Organic Livestock Production” discussion document

Motion by: Harriet Behar

Seconded by: Ashley Swaffar

Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Scott Rice, Subcommittee Chair, to transmit to NOSB February 19, 2019