

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: October 25, 2019

Subject: Use of Excluded Method Vaccines in Organic Livestock Production

NOSB Chair: Harriet Behar

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

Statement of the Recommendation:

The National Organic Standards Board members recognize the importance of vaccines in promoting animal health and welfare. The NOSB does not support the use of genetic engineering (excluded methods) in organic agriculture. However, there are times that a vaccine produced through excluded methods (as determined by the NOSB in its continuing dialog and recommendations on this subject), is the only vaccine available to prevent a specific disease. At times, the use of this vaccine produced through excluded methods might be required by state and/or federal governments. In order to provide all producers of organic livestock the tools they may need, and to maintain our position that when given a choice, organic production does not allow the use of excluded methods, the NOSB has developed a compromise position. The recommendation for the use of excluded method vaccines in organic livestock production requires that there are no commercially available alternatives that are not produced through excluded methods.

Many public commenters felt it was important for the National Organic Program to aid producers and certifiers in tracking which vaccines have been produced through excluded methods, and which ones do not have non-excluded method counterparts. Currently there are a limited number of vaccines that are made from excluded methods and do not have non-excluded method counterparts. The resources for finding this information to determine whether vaccines were produced using excluded methods is available in this recommendation document. In addition, the NOSB encourages the National Organic Program to work with the Accredited Certifiers Association on developing and maintaining a list, to aid producers in finding vaccines that meet the criteria set forth in this recommendation.

Rationale Supporting Recommendation :

The definition of “commercially available” is part of the regulation and a description of how this would be applied to a vaccine is in the attached recommendation. The current regulation allows vaccines from excluded methods to be used, provided they have been individually reviewed and approved for listing as a synthetic on the National List. The current listing? has proven to be cumbersome. The long timespan between the petitioning of a material and its

eventual placement on the National List does not provide organic livestock producers the vaccines they need now, or what they might need in the future, in a timely manner. This recommendation only allows vaccines from excluded methods if there are no vaccines available that have not been produced through use of excluded methods. This would provide vaccines needed by producers whether the need was caused by an emergency, was required by governmental agencies, or just as a way to prevent a disease from occurring in their livestock. New methods of genetic engineering continue to be introduced. However, the numerous NOSB recommendations since 2016 on excluded methods and the ongoing dialog and recommendations detailing which types of methods should be considered excluded, and which ones should not, informs the organic community and the National Organic Program if the method used to make the vaccine is to be considered excluded or not.

NOSB Vote:

Motion to change the USDA organic regulations at § 205.105(e). Addition to the current rule noted in bold.

(e) Excluded methods, except for vaccines: Provided, That, **vaccines produced through excluded methods may be used when an equivalent vaccine not produced through excluded methods is not commercially available.**

Motion by: Harriet Behar

Seconded by: Ashley Swaffar

Yes: 12 No: 0 Abstain: 1 Absent: 1 Recuse: 0

Outcome: Motion Passed

National Organic Standards Board
Livestock Subcommittee Proposal
Use of Excluded Method Vaccines in Organic Livestock Production
July 16, 2019

Introduction and Background

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 one 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 about which vaccines are allowed. 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. 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 October 2014: “Findings and Recommendations 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 November 2017, the NOSB 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 will use this recommendation to review new technologies as they develop. The October 2014 NOSB recommendation lists commonly used vaccines that are known to have been made through excluded method technology. The NOSB strives to correct this inconsistency, to increase the trust of the organic certification system 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 putting forth this proposal to have clarity in the use of vaccines from excluded methods, to provide certainty and consistency to both producers and certifiers in the determination of which specific vaccines can be used with organic livestock.

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 ([65 FR 80547, December 21, 2000](#)) 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 and Goals of this Proposal

The Livestock Subcommittee strongly supports the use of vaccines as an essential component of maintaining animal health and promoting animal welfare. Vaccines are an essential tool for livestock producers to prevent serious health events in both individual animals as well as their entire herds or flocks. Interstate and international movement of livestock may require specific vaccinations for animals to be transported and sold. 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. 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 NOSB, supported by the majority of public comment, 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 sometimes the only vaccines that are available are those made with excluded method technology.

In our discussion, we reviewed three options:

1. Allow all vaccines without any review or consideration if they were produced through excluded methods.
2. Allow vaccines from excluded methods, but only if they were individually reviewed and approved by the NOSB and placed on the National List by the NOP.
3. Allow vaccines from excluded methods, but only if a vaccine is not “commercially available” that had not been produced from excluded methods to effectively treat that health issue.

For option 1, the NOSB considered the issues below if there would be 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.

For option 2, the NOSB considered these issues if there was no change to the current two references in the USDA organic regulations, both within the regulatory text and on the National List.

- Use of vaccines from excluded methods, at times the only vaccine to prevent the health issue, would not be available to some producers since their certifiers will continue to follow the current regulation as written.
- Certifiers who currently allow the use of excluded method vaccines, would continue to ignore the language of the regulation that requires these vaccines be in the National List before use, leading to a lack of consistency in implementation of the regulation, as well as confusion in the certification community resulting in some areas of the regulation to be ignored without consequences.
- The NOSB would need to solicit petitions for review of excluded method vaccines that are currently in use, to place them on the National List. Optimistically, the placement of these vaccines on the NL would take 2 to 4 years.
- In the case of a livestock disease outbreak, that can only be treated by excluded method vaccines, organic livestock producers would be at a disadvantage due to the lag time between the petitioning of a new excluded method vaccine and its eventual possible placement on the National List.

For option 3- change to the regulatory language could require that vaccines from excluded methods only be used when there are no commercially available vaccines produced without excluded methods.

Allowance for the use of nonorganic seeds and some nonorganic agricultural products in processed organic foods, is currently allowed when there is no “commercially available” organic alternative. The term “commercially available” is defined in the USDA organic regulations as:

Commercially available. 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.

- A clear definition of how “commercial availability” will be applied 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 organic buyers for these vaccines and showing a need for their continued manufacture.
- Might be difficult to clearly identify which vaccines are from excluded methods and which are not. Currently there is a list of widely used vaccines, but there may be others in use regionally or sporadically that are not listed.

Public Comment

At the April 2019 NOSB meeting, a discussion document was circulated with the following options and questions provided to the public for comment.

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?

The significant majority of the public responses supported option 3, changing the regulatory language to allow use of vaccines from excluded methods when no other vaccines were commercially available. There were some commenters that supported allowing all vaccines as a class, with no consideration applied if the vaccine was produced from excluded methods or not. There were no comments supporting the current regulatory language, which has led to inconsistency among certifiers in implementation of the regulation.

Determining commercial availability of a vaccine not produced through excluded method technology

The definition of commercial availability can be applied to vaccines in this manner.

- 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 non-excluded 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)

Resources to determine if a vaccine had or had not been produced through excluded methods

Commenters expressed concern that it could be difficult for both operators and certifiers to determine if there are commercially available vaccines not made from excluded methods. There are some references to aid in this determination. The August 2014 NOSB document, entitled "Findings and Recommendation in Response to September 2010 NOP Memorandum on Livestock Vaccines Made With Excluded Methods", provides a variety of references and labeling options to aid producers and certifiers in determining if the vaccine may have been produced using excluded method. A summary is excerpted here, with more detail found in the original document.

Label Guidelines: CVB (Center for Veterinary Biologics) regulations require that certain vaccine seed configurations have specific terms on the labels of branded vaccine products. These terms are required for a subset of biotechnology derived vaccines. While these terms are not added to the labels because an excluded method was used, CVB states that all such vaccines were created using methods that the NOP would exclude. The terms on labels that identify vaccines were made with excluded method are "Subunit," "Vector," and "Chimera." Because these vaccines are labeled with the identified terms, CVB can disclose a trade names list for all of these vaccines.

Product Code: The CVB requires that every biologic, including vaccines, produced must have a product code. The CVB guide on true names and product codes notes that the 5th digit of the product code may contain "D" or "R." The letter "D" in the fifth digit signifies that the vaccine is a nucleic acid vaccine. Such vaccines, also called DNA vaccines, are made with excluded methods and depend upon foreign genes being expressed in some of the cells of the vaccinated animals. The letter "R" in the fifth digit signifies the vaccine has a recombinant component or is a subunit protein derived from a recombinant organism. The recombinant designation only applies to components in the vaccine and not to methods used to make the vaccine such as genetically engineered cells that are used for cell culturing the vaccine seed.

In addition, the terms nucleic acid vaccine, naked DNA vaccine, RNA vaccine and genetic vaccine may be used to label vaccines produced through methods that are considered excluded by the NOSB.

An important reference is the USDA publication "*Veterinary Biological Products- Licensees and Permittees*", with the most current version from July 1, 2019 present at this link https://www.aphis.usda.gov/animal_health/vet_biologics/publications/CurrentProdCodeBook.pdf

Operators and certifiers can refer to this publication, and when using the coding system discussed above by the CVB, it would be the first step to determine if a vaccine, had or had not been produced through excluded method technologies. As a final confirmation, certifiers could provide an affidavit for 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. 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.

Another source of information is present in the NOSB requested Technical Review of “Vaccines Made from Genetically Modified Organisms” from 2011. While this information is somewhat dated, it can be used as a starting point for updating using more recent information.

Table 1. Selected Conventional and GMO Vaccines Used for Food Animals^a		
Disease	Conventional vaccine/strain	GMO vaccine/strain
<i>Bacterial</i>		
Brucellosis (ruminants)	<i>Brucella abortus</i> , strain 19, strain RB51	None identified
Brucellosis (swine)	<i>Brucella suis</i> , strain 2	None identified
Anthrax (bovine, ovine, equine)	<i>Bacillus anthracis</i> , strain Sterne	None identified
Johne’s disease	<i>Mycobacterium paratuberculosis</i> strain 316F	None identified
Contagious bovine pleuropneumonia	<i>Mycoplasma mycoides</i> subsp. <i>mycoides</i> SC, strain T1/44	None identified
Avian salmonellosis	<i>Salmonella enteric</i> serov. Gallinarium, strain R9	<i>Salmonella typhimurium</i> vaccine, live culture

Table 1. Selected Conventional and GMO Vaccines Used for Food Animals^a		
Disease	Conventional vaccine/strain	GMO vaccine/strain
Bovine salmonellosis	None identified	<i>Salmonella dublin</i> vaccine
Poultry cholera	<i>Pasturella multocida</i> (various strains)	None identified
Cattle pasteurellosis	<i>Manheimia (Pasteurella) haemolytica</i> (various strains)	None identified
Swine atropic rhinitis	<i>Bordetella bronchiseptica</i> (various strains)	None identified
Bovine clostridiosis	<i>Clostridium perfringens</i>	None identified
<i>Escherichia Coli</i> in poultry	<i>Escherichia coli</i> vaccine, avirulent live culture	<i>Escherichia coli</i> vaccine, live culture
<i>Viral</i>		
Avian encephalomyelitis	Live and modified live virus	Avian encephalomyelitis-fowl pox-laryngotracheitis vaccine
Porcine circovirus (swine)	Type 2, killed virus	Porcine circovirus vaccine (Type 1 -Type 2 chimera, killed virus; and Type 2 killed, baculovirus vector)
Marek’s disease (poultry)	Live strains of Marek’s disease virus, serotypes 1, 2, or 3	Marek’s Disease-Newcastle Disease live virus vaccine, Serotypes 1 & 2 & 3, live Marek’s disease vector; and Marek’s disease live herpesvirus chimera
Newcastle disease (poultry)	Bursal-disease-newcastle disease-bronchitis vaccine, killed or live virus; live virus VG/GA strain; killed virus; and B1 type, B1 strain live virus	Newcastle disease-fowl pox vaccine, live fowl pox vector; and Marek’s disease-Newcastle disease vaccine, serotype 3, live Marek’s disease vector

Bursal disease (poultry)	Live or killed avian <i>bursitidis infectivae</i> virus type 1	Bursal disease-Marek's disease vaccine, Serotype 3, live Marek's disease vector
Fowl pox	Live fowl pox vaccine	Fowl pox-laryngotracheitis vaccine, live fowl pox vector
Fowl laryngotracheitis	Modified live virus vaccine	Fowl pox-laryngotracheitis vaccine, live fowl pox vector

*Sources: Frey (2007); USDA (2011)

Lastly, certifiers and the NOP could communicate with each other and develop a listing of excluded method vaccines, that do not have any commercially available equivalents and that were not produced through prohibited technologies, as well as excluded method vaccines that do have a commercially available equivalent that were not produced through excluded method technologies. Manufacturers of vaccines not produced through excluded method technologies, could choose to be OMRI listed as well. Public interest groups may also choose to do some of the research to aid certifiers and operators in understanding which vaccines are or are not produced through excluded methods.

The NOSB understands that this will add another layer of review for some operators, however, 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.

The NOSB continues to work on determining which types of technologies should be excluded from allowance in organic production, with a complete list of the reviewed technologies provided in the most recent recommendation. The NOSB, through this work, can provide the organic community with the excluded method determinations needed when new technologies are put into commercial use.

The current rule reads:

§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)

Subcommittee proposal

The NOSB Livestock Subcommittee recommends the following change to the National Organic Program Final Rule §205.105 (e) (Changes to the current rule noted in bold).

Motion to change the USDA organic regulations at §205.105 (e). (Additions to the current rule noted in bold).

*(e) Excluded methods, except for vaccines: Provided, That, **vaccines produced through excluded methods may be used when an equivalent vaccine not produced through excluded methods is not commercially available.***

Subcommittee Vote

Motion to change the USDA organic regulations at § 205.105 (e). Addition to the current rule noted in bold.

*(e) Excluded methods, except for vaccines: Provided, That, **vaccines produced through excluded methods may be used when an equivalent vaccine not produced through excluded methods is not commercially available.***

Motion by: Harriet Behar

Seconded by: Ashley Swaffar

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

Approved by Sue Baird, Subcommittee Chair, to transmit to NOSB July 17, 2019