

**FORMAL RECOMMENDATION BY THE
NATIONAL ORGANIC STANDARDS BOARD (NOSB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)**

Date: 11-5-09

Subject: Vaccines

Chair: Jeff Moyer

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:	X
Guidance Statement:	_____
Other:	_____

Summary Statement of the Recommendation (including Recount of Vote):

This recommendation is to clarify which types of vaccines can be used to prevent disease and needless suffering of livestock. Previously, vaccines made by excluded methods were to be individually petitioned to the Board for allowance or prohibition for use. In reality since implementation of the Rule, certifiers have routinely allowed all vaccines, since they are used to prevent disease and needless suffering of animals. This recommendation will more closely align what has been occurring in the field since 2002. However, it will actually make it encumbent upon the producers and certifiers that vaccines made by non-excluded methods are located and used before those made by excluded methods can be used.

NOSB Vote: **Motion:** Hubert Karreman **Second:** Tina Ellor

Board vote: Yes - 11 No- 2 Abstain- 0 Absent - 2

Summary Rationale Supporting Recommendation (including consistency with OFPA and NOP):

Section 6509(d)(1)(C), of the Organic Foods Production Act of 1990, authorizes the use of vaccinations as an allowed healthcare practice in the production of organic livestock. This authorization was implemented through regulation at § 205.238(a)(6) of the National Organic Program standards. Those standards were published in the Federal Register on December 21, 2000 (65 FR 80548). Section 205.238(a)(6) provides that producers must establish and maintain preventive livestock health care practices including the administration of vaccines and other veterinary biologics. Further, vaccines were approved by the NOSB as a group at 205.603(a)(4) and ultimately put on the list without annotation (whereas some other materials listed do specify or limit the methods of production). It is clear that 6509(d)(1)(C), 205.238(a)(6) and 205.603(a)(4) don't mention anything about vaccines produced by excluded methods needing to be individually petitioned.

Response by the NOP:

National Organic Standards Board (NOSB)

Livestock Committee

RECOMMENDATION TO CHANGE 205.105 (e)

Current 205.105 (e):

(e) Excluded methods, except vaccines: *Provided*, That, the vaccines are approved in accordance with 205.600(a).

I. Introduction:

Vaccines are critical for the prevention of disease. Since antibiotics cannot be used therapeutically in organic livestock production without permanent removal from the organic system, prevention of disease is all the more important. Livestock producers should not be hindered in any way from using vaccines to help prevent morbidity and mortality for the animals under their care. Nor should the organic community in general be held back when it comes to such basic measures as prevention of disease through the utilization of vaccines, regardless of the method of production that occurs in federally regulated and licensed manufacturing facilities. To ensure that livestock producers are not hindered from preventing disease in their herds, the Livestock Committee is proposing to change the wording of 205.105(e) such that it is harmonized with the rest of the language of OFPA and the regulation in regards to vaccines.

II. Background:

It has come to our attention that one or more ACAs may be denying livestock producers the authority to use vaccines that the ACA previously allowed producers to use on the grounds that the vaccines are produced using excluded methods. Section 205.105(e) has been cited as the controlling regulation, creating in effect a bottle neck prior to the regulatory sections that also specifically speak to vaccine use. It will be shown that at no other location in OFPA or in the Regulation are vaccines disallowed in any way.

First, however, it should be emphasized that more and more vaccines are being produced using “excluded” methods. For instance, in a scholarly review paper on the current status of veterinary vaccines (Els N. T. Meeusen, et al., CLINICAL MICROBIOLOGY REVIEWS, July 2007, p. 489–510) it is clear that the majority of methods of vaccine production would be termed “excluded methods” by certified organic definitions. These production methods include: marker vaccines that have a gene deleted to allow differentiation from field strains for diagnostic purposes (example: foot and mouth disease vaccines), sub-unit vaccines from isolated genes that allow for completely safe, non-replicating vaccines (example: postweaning multisystemic wasting syndrome for swine), chimera viruses that combine two different viral DNAs (examples: recently developed poultry avian influenza vaccine and a west Nile virus vaccine for horses), live viral vector vaccines (example: new rabies

vaccine), and DNA vaccines (recently registered in 2005 in Canada to protect Atlantic salmon from infectious hematopoietic necrosis).

The obvious trend is to vaccines being produced using genetic engineering, thus making the sourcing of vaccines not derived from genetic engineering more and more difficult. While “conventional” vaccine products are still available, it is obvious that the future for scientific breakthroughs in producing vaccines is through genetic manipulation, as cited from the scientific review article above. It should be noted that if an exotic (non-endemic) disease were to establish itself in a national herd which has had no exposure to it previously (i.e. hog cholera or foot and mouth disease), huge losses along with pain and suffering would occur. Any vaccine that could be rapidly produced to be used against such a scenario would undoubtedly use excluded methods. As some ACAs interpret the regulations currently, organic livestock producers would have to wait for the materials petition process to run its normal 18 month course before using such a vaccine. For the special case of vaccines, we simply cannot jeopardize the well-being of potentially millions of animals or the public by prohibiting selected vaccines because they may have been produced utilizing excluded methods.

III. Relevant areas in the Rule:

Section 6509(d)(1)(C), of the Organic Foods Production Act of 1990, authorizes the use of vaccinations as an allowed healthcare practice in the production of organic livestock. This authorization was implemented through regulation at § 205.238(a)(6) of the National Organic Program standards. Those standards were published in the Federal Register on December 21, 2000 (65 FR 80548). Section 205.238(a)(6) provides that producers must establish and maintain preventive livestock health care practices including the administration of vaccines and other veterinary biologics. Further, vaccines were approved by the NOSB as a group at 205.603(a)(4) and ultimately put on the list without annotation (whereas some other materials listed do specify or limit the methods of production). It is clear that 6509(d)(1)(C), 205.238(a)(6) and 205.603(a)(4) don’t mention anything about vaccines produced by excluded methods needing to be individually petitioned.

IV. Discussion:

We acknowledge that § 205.105(a)(6) provides that organic products must be produced and handled without the use of “Excluded methods, except for vaccines; Provided, That the vaccines are approved in accordance with § 205.600(a)”. However, when the final rule was published, vaccines were listed, without annotation, as allowed synthetics at § 205.603(a)(4). The preamble to the final rule addresses that § 205.105(a)(6) was structured so that vaccines produced using excluded methods could only be used if they are affirmatively included on the National List. This provision was created as an exception to the prohibition on the use of excluded methods and is only applicable to the production of vaccines. This exception was created to allow for the use of vaccines that may only be available in a form produced using excluded methods. The NOP concluded in 2000 that the potential impact of prohibiting vaccines produced using excluded

methods on animal production systems was unknown. It is highly likely that vaccines produced without the use of excluded methods are less available today than they were in 2000 and that this trend is constantly increasing. It should be recognized that unlike chemotherapeutic pharmaceuticals which have very specific unchanging formulae, biologics and vaccines are constantly being revised due to changing field conditions. Coupling ever changing vaccines due to dynamic field conditions and technologic advances in production, it is easy to see that there will be an exponential increase in the amount of vaccines produced by excluded methods. To conclude, the specific language of 205.105(e) is out of date and, moreover, it simply cannot be taken as a stand alone statement. Taken in its true context with the other regulations to which it is linked, it is imperative to change the wording of 205.105(e).

Even by reading section 205.105(e) as it is currently written, the logical progression of reading the regulation thus shows:

§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..” the product must be produced and handled without the use of:

(e) Excluded methods, except for vaccines: Provided, That the vaccines be 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).

§205.603 Synthetic substances allowed for use in organic livestock production.

In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production:

(a) As disinfectants, sanitizers, and medical treatments as applicable.

(4) Biologics – Vaccines.

In conclusion, for the special situation of vaccines - and vaccines only - the Livestock Committee would like to permanently clarify the situation on vaccines by truncating 205.105(e) to no longer make reference to excluded methods.

Should this recommendation pass at the full board level and submitted to the NOP for rulemaking, included in the affirmative vote is the request that the NOP continue to allow all vaccines that have been previously allowed by ACAs, indeed *require* that any

vaccines previously allowed stay allowed, including those derived from excluded methods, until rulemaking is completed.

V. Recommendation:

Following from the above logical progression, the Livestock Committee recommends:

§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..” the product must be produced and handled without the use of:

(e) Excluded methods, except for vaccines, Provided, that, vaccines made from non-excluded methods are used if commercially available.

VI. Committee Vote:

Motion: Hubert Karreman Seconded: Tina Ellor

Yes: 6 No: 0 Abstain: 0 Absent: 1