



BEYOND PESTICIDES

701 E Street, SE ■ Washington DC 20003
202-543-5450 phone ■ 202-543-4791 fax
info@beyondpesticides.org ■ www.beyondpesticides.org

September 18, 2019

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW.,
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Docket ID # AMS-NOP-19-0038

Re. LS: Vaccines made with excluded methods

These comments to the National Organic Standards Board (NOSB) on its Fall 2019 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

The LS proposal to grant blanket approval of genetically engineered vaccines is not acceptable.

Beyond Pesticides recognizes both the importance of vaccines in promoting animal health and the complexity of the issue of evaluating vaccines. However, organic consumers believe that genetically engineered (GE) inputs are not intentionally used in organic food production, so the organic label may be undermined if GE vaccines are allowed without restriction. Therefore, we oppose the proposed rule change on vaccines made with excluded methods (VMWEM) and encourage the NOSB to insist on consistent application of the rules. We also encourage the NOSB to recommend guidelines and databases that will ensure consistent application of the rules and promote availability of necessary vaccines.

NOP must require consistency in application of regulations.

The Livestock Subcommittee dismisses some alternatives because of the inconsistency in the application of the rules by certifiers. This is unacceptable. The NOSB must clarify the intended application of the rules and insist that the National Organic Program (NOP) require consistent application of the regulation by accredited certifiers. This issue should be addressed in the peer review of NOP.

The NOSB must take steps to clarify allowable and prohibited vaccines.

The first step in ensuring clarity is the continued effort by the NOSB to refine the definition of excluded methods. This effort is necessarily ongoing, due to the constant flux in genetic engineering methods.

The second step that the NOSB must take is the development of a comprehensive classification system for all available vaccines. Through this system, available non-genetically engineered (GE) vaccines should be identified, along with their uses. The comprehensive list of all vaccines should identify which are allowed and which are not. At the same time livestock diseases, if any, for which no non-GE vaccine is available should be identified. Any VMWEM must be approved through the petition process, and essentiality must be demonstrated. Producers using such vaccines must also demonstrate the need for the vaccine.

The NOSB must clearly delimit urgent and non-routine conditions under which VMWEM may be used.

In 2012, the Livestock Subcommittee recommended (but the NOSB did not vote on) this proposal:

1. Modify language in 205.238(a) (6) as follows, change shown in italics.
Administration of vaccines and other veterinary biologics, provided, vaccines produced with excluded methods, can only be administered in accordance with §205.105(e).
2. Modify 205.105 (e) as follows: Excluded methods, except for vaccines: Provided,
(1) *such vaccines are administered only due to a Federal or State emergency pest or disease treatment program, and*
(2) *such vaccines are approved in accordance with §205.600(a);*
3. Modify language in 205.603(a)(4) as follows: Biologics—Vaccines, *provided, with regard to vaccines produced with excluded methods, the requirements of 205.105(e) are satisfied.*
4. Change the Definition of “Emergency pest or disease treatment program” in section 205.2 with the additions shown in italics.
Emergency pest or disease treatment program. A mandatory program authorized by a Federal, State or local agency for the purpose of controlling or eradicating a pest or disease, except for a program requiring substances described in section 205.105(e) regarding only vaccines produced with excluded methods, in which case such program is defined as a mandatory treatment program authorized by a declared Federal or State emergency for the purpose of controlling a pest or disease.

The 2012 LS proposal recognized the seriousness of allowing any form of GE in organic production, which is not the case with the current LS proposal. However, the 2012 proposal does not allow for speedy response to an urgent disease problem. It does not allow organic

livestock producers to be proactive in protecting their herds and flocks. In general terms, the conditions that must be met are:

- (1) There is a serious threat to organic livestock.
- (2) Urgent action must be taken—protecting organic livestock must require action in less time than is required to approve and list a new vaccine.
- (3) There must be no commercially available non-GE vaccine for the use.

We propose a variation of the 2012 LS proposal:

1. Modify language in 205.238(a) (6) as follows, change shown in italics.
Administration of vaccines and other veterinary biologics, provided, vaccines produced with excluded methods, can only be administered in accordance with §205.105(e).
2. Modify 205.105 (e) as follows: Excluded methods, except for vaccines: Provided,
(1) *such vaccines are administered only due to an urgent need for a vaccine, and*
(2) *no non-genetically engineered vaccines are commercially available for the required use.*
3. Modify language in 205.603(a)(4) as follows: Biologics—Vaccines, *provided, with regard to vaccines produced with excluded methods, the requirements of 205.105(e) are satisfied.*
4. Add a definition of *vaccine crisis* in section 205.2:
Vaccine crisis: A disease outbreak requiring universal national or regional vaccination requiring the use of vaccines made with excluded methods. This crisis must be declared by the state or national department of agriculture.

Exceptions to organic standards require greater transparency.

Consumers are adamant that genetic engineering does not belong in organic food production. Because the public understands food certified organic to be grown or produced without GE organisms and full transparency in organic labeling is a central tenet of organic production, we propose that labeling be required for all end-product produced with animals treated with GMO vaccines under an emergency situation. Thus, a fifth point must be added:

5. Required Labeling on finished food treated with GMO vaccine. We recommend the following labeling: “Organic by definition does not permit the use of genetically engineered ingredients or inputs. However, a crisis required the treatment of an animal used in this product with a genetically engineered vaccine for which an alternative was not available.”

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Shistar". The signature is written in a cursive style with a prominent flourish at the end.

Terry Shistar, Ph.D.
Board of Directors