



# BEYOND PESTICIDES

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April 30, 2012

National Organic Standards Board  
Spring 2012 Meeting  
Albuquerque, NM

## Re. Vaccines from Excluded Methods

Dear Board Members:

These comments are submitted on behalf of Beyond Pesticides. 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, 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 groups around the world.

**We urge the Board to reject the Livestock Committee recommendation to allow use of vaccines from excluded methods without review in “emergencies” and postpone action until it can address the issues in these comments.**

Of the approximately 73 registered animal vaccines, 13 are produced using excluded methods (GMO vaccines). Only two vaccines, Bovine and Avian Salmonellosis, appear to be presently available only as GMO. GMO vaccines are not legally allowed in organic production. This recommendation proposes a change that will allow GMO vaccines to be used without losing organic livestock status, only in a “declared emergency.”

The Livestock Committee states that the categorical approval of GMO vaccines fails all three criteria —need, impacts on humans and the environment, and compatibility with organic principles. However, the recommendation would allow unreviewed GMO vaccines to be used in organic production under certain prescribed “emergency” conditions. To approve an action acknowledged to fail all the criteria for that action does not follow the required regulatory process.

We don’t believe that the NOSB can get around the fact that even an emergency allowance would be violate board process in these circumstances. But we do understand the concern that leads the committee to propose allowing unreviewed vaccines in “emergency” conditions. Livestock producers have a lot to lose in the case of a serious disease outbreak, and we sympathize with the concern that in such a situation GMO vaccines may be the only option.

However, we are concerned about the possibility for abuse of such an emergency allowance, in part because we have seen how emergency exemptions for pesticide use have been misused, in spite of every effort to tightly define an “emergency.” We have seen in EPA’s emergency exemption program (under Section 18 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)) the allowance of unregistered uses of a pesticide and unregistered pesticides in an “emergency” under repeated and routine exemptions for predictable situations. In fact, emergency exemptions have become a way of building demand for new products —as products were granted exemptions year after year, growers became dependent on the product, and EPA has continued to allow use without evaluation of the data required for registration. We see a potential for a very similar outcome with GMO vaccines used under an “emergency” program.

Even if an “emergency” were well-defined in terms of the kind of an outbreak that might require extraordinary intervention, the use of unreviewed GMO vaccines would be counterproductive without some assurance that (1) the vaccine will prevent the disease in the animals, and (2) that the vaccine will not cause side effects that threaten the animals, their offspring, or the farm environment. Unfortunately, that assurance may not be possible. Veterinary vaccines are not subject to the same large, controlled challenge studies used to ensure efficacy of human vaccines.<sup>1</sup> In addition, there are four types of claims that support vaccine approval in the U.S.: prevention of infection, prevention of disease, aid in disease prevention, and aid in disease control.<sup>2</sup> It is important that producers get the kind of protection they need, and the existence of a vaccine for a particular illness does not ensure that protection.

If the NOSB were to allow GMO vaccines for emergencies, it must ensure that OFPA criteria are met.

The Board must address questions having to do with the need for the vaccines.

1. Are vaccines needed for illnesses for which GMO vaccines are the only ones available?
2. Do the proposed vaccines offer the necessary level of protection against disease?
3. What other means are available for preventing and treating these diseases?
4. If the problem is a general one of unavailability of non-GMO vaccines, how does the emergency provision help organic producers comply with general prohibitions on GMO vaccines?
5. What types of emergencies might require the use of these vaccines?

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<sup>1</sup> David Ramey, 2009. Animal Vaccines. Science-Based Medicine.

<http://www.sciencebasedmedicine.org/index.php/animal-vaccinations/>

<sup>2</sup> P.G.H. Jones, G. Cowan, M. Gravendyck, T. Nagata, S. Robinson, and M. Waits, 2007. Regulatory Requirements for Vaccine Authorisation, *Rev. Sci. Tech. Off. Int. Epiz.*, 2007, 26(2): 379-393.

The Board must address questions having to do with the materials and their impacts.

1. What kinds of genetic modifications will be allowed?
2. What are the risks associated with these modifications and their use in vaccines to the treated animals, people who consume the meat, and the ecosystem?
3. What questions need to be asked about GMO vaccines?
4. What additives are in GMO vaccines that might not be in non-GMO vaccines?<sup>3</sup>

The Board must address issues of compatibility with organic principles.

1. Why should the general prohibition on excluded methods be waived in the case of vaccines?
2. How do inspectors and certifiers verify compliance with the rule?

Finally, the Board must address issues specifically related to a policy of allowing use of an otherwise prohibited substance in an “emergency” situation.

1. What is an emergency? What kind of emergency would require the use GMO vaccines?
2. How long does the emergency last?
3. Who can declare an emergency?
4. What kind of alternatives would need to be considered before deciding that an emergency justifies use of GMO vaccines?
5. What kinds of provisions for public notice and comment, criteria for approval of the vaccine, reporting and recordkeeping, and revocation of an emergency declaration should be required?

### **Some Thoughts on Structuring a Process for Emergencies that May Require GMO Vaccines**

Two sections of the regulations deal with “emergencies” affecting organic producers. §205.672 deals with situations in which “a prohibited substance is applied to a certified operation due to a Federal or State emergency pest or disease treatment program.” §205.290(a) allows variances from certain requirements for the following reasons:

- (1) Natural disasters declared by the Secretary;
- (2) Damage caused by drought, wind, flood, excessive moisture, hail, tornado, earthquake, fire, or other business interruption; and
- (3) Practices used for the purpose of conducting research or trials of techniques, varieties, or ingredients used in organic production or handling.

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<sup>3</sup> A.R. Spickler and J.A. Roth, 2003. Adjuvants in Veterinary Vaccines: Modes of Action and Adverse Effects, J.Vet. Intern. Med.17: 273-281.

We suggest that both of these sections need to be applied to meet the kinds of conditions proposed by the Livestock Committee. First, the committee would require that the use of the vaccines be limited to emergencies as defined for purposes of §205.672, "A mandatory program authorized by a Federal, State, or local agency for the purpose of controlling or eradicating a pest or disease." Second, the committee seeks to describe restrictions on the use of the vaccine that would more properly fit under §205.290. One way of addressing the overlap here would be to add to §205.290(a):

- (4) A Federal or State emergency pest or disease treatment program:*
- (a) in response to a widespread threat to the life of livestock,*
  - (b) that requires the use of a vaccine, when only vaccines made by excluded methods are available, and*
  - (c) is limited to one year in duration.*
  - (d) In the case that such a treatment program is made under §205.290(a)(3), no further use of the vaccine may occur without review and listing of the vaccine on the National List, and is limited to one year in duration without possibility of renewal.*

However, §205.290 would still require that those GMO vaccines be reviewed by the NOSB:

- (e) Temporary variances will not be granted for any practice, material, or procedure prohibited under §205.105.*

Therefore, we propose the following system for ensuring that the review takes place:

1. The NOSB must develop for inclusion on the National List a list of GMO vaccines that would be allowed under variances in emergency situations. [Note that the NOSB has broad discretion to look at materials, as long as it subjects the review to its public review and comment procedures.]
2. The Livestock Committee must review the (two) known vaccines for which there is no conventional alternative. In the process, the committee must identify issues unique to GMO vaccines that must be addressed in their review.
3. The NOSB must request to be notified by APHIS of any GMO vaccines for which a license has been applied for use in cases where there is no available non-GMO vaccine.
4. In the case of a situation in which there is not time for review to take place before the need for the vaccine, the vaccine may be used under §205.290(a)(3), provided that any products sold from such treated animals are labeled, "Produced with the experimental use of a GMO vaccine under emergency conditions."

We suggest that further restrictions that have been proposed for the use of GMO vaccines be placed in annotations to the list of GMO vaccines allowable in an emergency.

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Since the committee has stated that the use of unreviewed GMO vaccines fails all the criteria for approval, the board must not sanction any action that allows the use of GMO vaccines without review of the specific vaccines. We believe that the system we have sketched out above is a minimum for ensuring that GMO vaccines are not used without the review required by OFPA.

Sincerely,

A handwritten signature in cursive script, appearing to read "Terry Shistar".

Terry Shistar, Ph.D.  
Board of Directors