

PUBLIC SUBMISSION

As of: 5/8/12 4:27 PM
Tracking No. 8100400a
Comments Due: May 03, 2012

Docket: [AMS-NOP-12-0017](#)

Notice of Meeting of the National Organic Standards Board

Comment On: [AMS-NOP-12-0017-0001](#)

Meetings: National Organic Standards Board

Document: [AMS-NOP-12-0017-1588](#)

LC-GMO-Vaccines-Jim Riddle, Organic Independents LLP

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General Comment

Additional Comments on the Livestock Committee's "Vaccines from Excluded Methods" draft recommendation

Submitted by Jim Riddle

The solution to the use of GMO vaccines in organic livestock production is elegant, simple, and LEGAL - if a GMO vaccine is truly needed, it should be petitioned for placement on the National List.

An "emergency" use allowance of synthetic substances not on the NL does not comply with OFPA. As the courts made clear in Harvey vs USDA, synthetic substances cannot be used unless they appear on the NL.

Some have suggested that the Livestock Committee's draft be amended to include a requirement that the GMO vaccine be reviewed within 18 months after emergency use. I doubt that such a condition would carry much weight in a court of law, unless OFPA is changed to allow emergency use of non-listed substances, pending review.

The Final Rule already allows the consideration of GMO vaccines, and the NOP and OGC have made it clear, since September 2010, that their use does not comply with OFPA, unless listed.

The LC should withdraw its proposal; invite petitions for specific GMO vaccines for consideration to be placed on the National List; and then conduct open, transparent, scientifically rigorous, and legal reviews, as described in OFPA and the Final Rule.

In the meantime, the NOSB should advise the NOP to provide producers, inspectors, and certifiers all of the tools and information they need to enforce the regulation.

Comments on the NOSB Livestock Committee's National List Proposal "Vaccines from Excluded Methods" April 3, 2012

Submitted by Jim Riddle, former chair, NOSB

Picture this headline, "National Organic Board Recommends Allowance of GMO Vaccines for Organic Livestock" with the sub-caption, "GMO-treated meat, milk, and eggs could be sold as "organic."" That is exactly what we are facing, should the Livestock Committee's draft recommendation be adopted by the full NOSB.

The LC's draft, along with the supporting Technical Review, are totally inadequate to justify the approval of an entire new class of genetically engineered livestock vaccines, even for "emergency" use, and the resulting negative impacts that such action could have on consumer confidence in all classes of organic products.

In the NOSB Evaluation Criteria table, the LC repeatedly states, "It is difficult to answer such question for a class as a whole." Despite the admission of insufficient information, the LC answered a solid "no" to numerous criteria questions about GMO vaccines, including: environmental contamination during manufacture; harm to the environment and biodiversity; detrimental chemical interactions; adverse biological and chemical interactions in agro-ecosystem; physiological effects on soil organisms, crops, or livestock; breakdown products; persistence; and harmful effects on human health.

Further in the draft, the LC states, "With bacterial GMO vaccines (which are predominantly administered via the mouth), there are concerns that the engineered bacteria may recombine with natural bacteria in the gastrointestinal tract. Furthermore, it is unclear how long the altered virus/bacteria will remain in the vaccinated animal."

The LC concluded that GMO vaccines fail to meet all three applicable evaluation criteria categories, yet the LC is recommending that they be allowed in organic livestock production for "emergencies."

The LC draft states, "The National Organic Program (NOP) received advice from the USDA General Counsel that GMO vaccines could only be allowed if specifically added to the National List. Currently, GMO vaccines are not on the National List." The LC's draft recommendation does not address the General Counsel's concern, since GMO vaccines would not be placed on the National List. Even if the LC's recommendation is adopted, GMO vaccines could not be used in organic livestock, unless they are fully specifically reviewed and placed on the National List as allowed synthetic substances.

The LC draft makes the claim that, "Producers are presently not required to ask to document use of GMO vaccines." Absolutely no substantiation is offered to

back up this assertion, such as a review of Organic System Plan forms used for organic livestock certification; interviews of ACAs, inspectors or organic producers; or data gained from a review of NOP accreditation audit reports.

The draft states, “Nonetheless, consumers continue to assume that all organic products reaching market are Non-GMO in production and handling.” As well they should, since the use of GMO vaccines is prohibited, as clarified by the NOP’s September 2010 memo to the NOSB. The LC has done no market analysis to assess the impact of the allowance of GMO vaccines on consumer confidence for all categories of organic products, but the LC draft does concede, “It is clear GMOs are not functionally equivalent in the eyes of the consumer in the organic marketplace and in the legal interpretation of NOP regulations.”

The LC draft says, “The TR does not point to a single or narrow group of problem diseases in organic livestock that are creating hardship and urgently need to be addressed with GMO vaccines.” Further, the LC draft states, “A review the USDA’s APHIS list of Livestock Vaccines, regulated by the Center for Veterinary Biologics, suggest that there are non-GMO vaccines available for virtually all common potential livestock sicknesses.” Is this a solution looking for a problem? No evidence of actual need for the use of GMO vaccines is presented in the LC’s draft.

The LC’s rationale for allowing GMO vaccines does not appear to be based on medical need; to protect animal welfare; or to prevent the spread of infectious diseases. The protect animal welfare, NOP section 205.238(c)(7) already prohibits organic livestock producers from withholding medical treatment from a sick animal in an effort to preserve its organic status. To control disease outbreaks, section 205.672 allows emergency treatment of organic livestock with otherwise prohibited substances under Federal or State emergency pest or disease treatment programs, with offspring from treated animals being allowed to be sold as organic, and milk from treated animals being sold as organic after one year. Treated animals can remain in the herd as breeding stock, keeping years of breeding intact.

No evidence of existing or impending emergencies is provided, and the draft includes no direct discussion of the most likely health emergencies where the use of GMO vaccines would be warranted.

In their own words, the LC justifies the proposed allowance of GMO vaccines so that organic livestock producers avoid “economic ruin” and “economic hardship.” I would like to remind the NOSB that economic conditions are not listed as criteria in OFPA or the Final Rule for the evaluation and approval of synthetic substances, and there is always the conventional market for animals that are treated with prohibited substances and fail to meet organic certification requirements.

The LC draft concedes, “The Livestock Committee has concluded that at this point in time there is not enough evidence of essential need to allow GMO vaccines as a class of substances for all diseases in livestock production,” yet the LC is recommending that the entire class be allowed for emergency treatment of organic animals, without the substances appearing on the National List.

The draft further states, “In general, GMOs are considered “excluded methods” and not consistent with organic production. In addition information in the TR and information received from other sources in the field did not indicate that GMO vaccines were essential to organic production at this time.”

The LC acknowledges that, “the construction of a usable list of GMO and non-GMO livestock vaccines is quite possible.” The NOSB should recommend that the NOP engage in an information campaign to empower producers, inspectors and certifiers with the knowledge and tools they need to prevent the use of GMO vaccines in organic livestock production.

I strongly encourage the NOSB to reject the Livestock Committee’s draft recommendation. If GMO vaccines are unknowingly being allowed, as the LC claims, then the focus should be on full and equitable enforcement of the existing requirements, rather than blanket allowances for “emergency” uses of GMO vaccines.

Respectfully submitted,

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