May 3, 2012

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2648-So, Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS–NOP–12–0017

**RE: Livestock Committee – GMO Vaccines**

Dear Ms. Arsenault:

Thank you very much for this opportunity to provide comment on the National Organic Standard's Board (NOSB) Livestock Committee Recommendation on GMO Vaccines.

OTA is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 49 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy.

OTA is committed and actively engaged in fighting the proliferation of GMOs to protect organic agriculture and trade, and preserve farmer and consumer choice. We do not in any way support the use of excluded methods in the production of organic seeds, crops, ingredients or other production methods. However, we do acknowledge that the regulations currently provide for one narrow exception to the prohibition on excluded methods—GMO vaccines—provided they are approved in accordance with § 205.600(a)[1]. We also acknowledge that GMO vaccines have been allowed since at least 2002. Therefore, we believe that any recommendation that is approved needs to completely and accurately assess the impact it would have on animal and human welfare and the organic livestock sector in general in order to chart the best course away from GMO vaccines.

This recommendation proposes a change to the current regulations that would allow GMO vaccines only in a declared emergency and, further, that at such time producers could use GMO vaccines without losing organic status of livestock. The recommendation also proposes changes to the definition of "emergency treatment program." The entire recommendation applies to the class of vaccines derived

[1] § 205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients - 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).

from excluded methods, but does not foreclose petitions for individual vaccines or a class of vaccines to treat specific diseases.

OTA respectfully asks the Livestock Committee to ***withdraw its recommendation*** in order to provide the organic sector more time for discussion and to allow more time to gather critical information. We greatly appreciate the extensive time that was obviously spent researching and writing the committee proposal. However, there are many unanswered questions and additional considerations that need more time than is allowed by the comment period. We have also noted inaccurate information in the TER that needs further review.

In support of working towards a recommendation that will align with the current regulations and best support organic producers' ideals and livelihood and organic consumers' expectations, OTA has compiled a list of the areas where further discussion and research are needed.

- **How will a new veterinary vaccine policy impact the livestock sector?**
  Vaccines, both non-GMO and GMO, have been in use for at least the last ten years. While not every certifier is allowing GMO vaccines and some certified operations have internal policies that do not allow for their use, generally speaking they have been allowed. As stated in the Technical Evaluation Report (TER) and committee recommendation, no data are available on how many GMO vaccines are being used in organic production because the majority of certifiers are not asking if the vaccine to be administered is GMO or non-GMO. OTA was able to find one certifier that was able to query the use of GMO vaccines by its certified clients. It reported that approximately 806,000 certified birds and 1,500 certified hogs would be potentially affected.

  We also know that the large majority of organic poultry operations are using Salmonella vaccines as part of their preventative disease control program. The use of vaccines, particularly the combination of both live *Salmonella typhimurium* (ST) and inactivated *Salmonella enteritidis (SE)*, are an essential part of the overall preventative approach given the requirements to prevent Salmonella under the FDA Egg Safety Rule. Given that the only available vaccine for live *Salmonella typhimurium* (ST) is genetically engineered, there could be potentially over five million organic birds impacted.

  The current usage of GMO vaccines by certified operators is critical information that must be collected in order to understand the potential impact this recommendation may have. While OTA does not promote the use of GMO vaccines, it's also unacceptable to move forward with a recommendation that prohibits use of GMO vaccines for preventive control if there is no conventionally produced alternative. We do not believe that organic producers should be at a disadvantage when it comes to providing adequate health care to their livestock. Vaccines are an integral part of a preventive livestock health care plan.

  *OTA is committed to forming an OTA Task Force on GMO Vaccines in order to collect data on how many GMO vaccines are being used in organic production, and to assess the time-frame, process and guidance that would be needed to transition to the use of available non-GMO vaccines.*

- **Do we have an accurate assessment of the proportion of GMO vs. non-GMO vaccines?**
  The information contained in the TER appears to be in conflict with information OTA as received from APHIS. The TER states that there are approximately 73 registered animal

vaccines (wild and domestic), of which 13 are GMO. Only two vaccines, Bovine and Avian Salmonellosis, appear to be presently available only as GMO.

**Regarding the number of registered vaccines, OTA sent the TER to APHIS and received the following response**:

I am not able to edit your document in its entirety, but the information from "the TER" you presented below is clearly erroneous and was not provided by me, although that is implied. Hopefully, you can yet modify the draft appropriately.

The CVB database indicates a total of 1,983 licensed products (all products and forms). Unfortunately, our database does not provide the total number of licensed vaccines specifically. But they are listed and can be counted on Pages 24-47 of the product code book of all our licensed products, found on-line at the following website:

http://www.aphis.usda.gov/animal_health/vet_biologics/vb_licensed_products.shtml

My quick count of the ***general types*** of vaccines (not counting all the individual products and forms that are licensed, and from different manufacturers) ***is about 142***. But, that number does not include all the general types of bacterins and bacterial extracts (about 70) found on pages 48-55, nor the combination products (about 71 types) on pages 58-70.

The current list of licensed biotech-derived product types for livestock includes 5 inactivated products, 4 gene-deleted products (similar to agents encountered in the field but attenuated by removing virulence genes), and 7 vaccine strain-based products for one agent but containing an immunogen from another disease-causing agent. The complete list of biotech-derived product types for all animals contains 29 products (not including combination products).

**Regarding the number of GMO vaccines, to the best of our knowledge the information in the TER is inaccurate with respect to a conventionally available *Escherichia Coli* vaccine for poultry.**

The TER in Table 1 on Page 8 lists a conventional *Escherichia Coli* avirulent live culture vaccine for poultry. We checked with the APHIS list of licensed vaccines and with the manufactures of the listed vaccines and found that the conventionally produced E.coli vaccine (Company 337 – Arko Laboratories) is for swine only. The company does not make vaccines for poultry.

Excerpt from USDA APHIS Veterinary Biological Products Listing, April 5, 2013:

| | **Escherichia Coli Vaccine** | | |
|---|---|---|---|
| 1551.02 | Avirulent Live Culture | 337 | |
| 1551.R0 | Live Culture | 112 | 189 |
| 15R1.00 | Avirulent Live Culture | 337 | |

This means that there are actually three rather than two vaccines that are only available in GMO form: *Salmonella Dublin* (for bovine), *Escherichia Coli* (for poultry) and *Salmonella typhimurium* (for poultry).

- **Do certifiers and certified operators have the knowledge or necessary guidance to understand how to determine whether a vaccine is genetically modified?**
  The lack of access to an easily identified and up-to-date list of GMO vaccines is extremely problematic, and the definition of 'excluded methods' in the NOP regulation may not be consistent with the definitions or criteria used by the Animal and Plant Health Inspection Service (APHIS) or with certain vaccine manufacturers. As pointed out by the committee, "APHIS maintains a periodically updated list of all registered vaccines with coded alpha-numeric annotations that could allow a certifier or a producer to identify which individual vaccines are produced with GMO methods. Most producers are not aware of this list, and the coding on the list requires some skill to use properly. In addition, most vaccines are given as combinations of vaccines, which makes cross checking with the APHIS list a complex process."

  OTA spoke with one certifier who was under the impression that licensed vaccines with an "R" in their product code indicates that the vaccine was produced through "Recombinant" techniques. However, OTA received the following additional information from APHIS:

  > It should be noted that a product can be biotechnology-derived, e.g. a subunit (single immunogenic protein) vaccine, but not be genetically modified itself. It can be the very same protein found in a vaccine made from the entire microorganism, just separate and purified. The biotechnology-derived vaccines are indicated by an 'R' in their product code, as listed in the product code book. Not all of the 'R'-designated products are "GMO".

  Additionally, the APHIS list may not represent GMO products according to the NOP definition of excluded methods. There are differing opinions on whether "gene deletion or gene inactivation or gene transfer" renders a product genetically modified, yet the NOP regulation specifically includes "gene deletion" and "changing the position of genes" in the definition of excluded methods. While the TER identifies gene-deleted (inactivated) vaccines to be GMO, we have noted that the APHIS list of licensed vaccines shown below does not include an "R" in the code of any of the Live *Salmonella Typhimurium* (ST) Vaccines, which are produced through gene inactivation.

| | **Salmonella Typhimurium Vaccine** | | |
|---|---|---|---|
| 19C1.00 | Live Culture | 189 | |
| 19C1.01 | Live Culture | 196 | |
| 19C1.02 | Live Culture | 196 | 368 |

  It was also recently brought to our attention that one company manufacturing this vaccine issues a statement declaring that their attenuated (i.e. gene transfer) vaccine is non-GMO[2] (see attached).

  *OTA believes that any recommendation passed needs to be accompanied with companion guidance that provides certified operators and certifiers with instructions on how to identify*

[2] Lohmann Animal Health's AviPro® Megan® Egg (APHIS 19C1.02) and AviPro® Megan® Vac 1 (APHIS 19C1.01)

*GMO vaccines. This guidance should be completed and passed at the same time as the recommendation. NOSB needs to work with NOP and APHIS to further define and identify GMO vaccines based on the APHIS List of Licensed Veterinary Products, or come up with an alternative list that does the same. This information is necessary to support the current recommendation or a recommendation that would allow for GMO vaccines ONLY when non-GMO vaccines are unavailable.*

- **Will a categorical prohibition of GMO vaccines allow for individual vaccines to be petitioned to the National List?**
  The current committee evaluation of Vaccines from Excluded Methods determined that such vaccines as a category should not be approved since they failed to meet the criteria of being "consistent with organic farming and handling" and they failed the "essential & availability" criteria. Since the class of materials has failed to meet the criteria for compatibility, consistency and essentiality, it seems unlikely that any individual product could meet the criteria if the committee evaluates the individual products consistently with this group evaluation. Therefore, we're concerned about the feasibility of petitioning individual GMO Vaccines onto the National List if a non-GMO version is not available.

- **Will small and large producers be able to access combination vaccines that do not include a GMO vaccine? What are the impacts of needing to administer single vaccines?**
  The recommendation points out that because multiple vaccines are often combined into one dosage, a single GMO vaccine could rule out the administration of six other non-GMO vaccines, if the non-GMO vaccines were not available in singular or non-GMO formulations. The TER did not identify vaccines that would be unavailable in non-GMO form due to the combination of vaccines. However, it's our understanding that while APHIS notes the use of recombinant technology in a number of single disease vaccines, there are a number of vaccines on the market and in use by farmers that combine a number of diseases together. These multi-disease vaccines packages may not be clearly identified if only one of the vaccines contains GMO technology.

  It is also our understanding that farmers may prefer to use such vaccine packages as it may reduce the period that the animal suffers from reduced immune systems following vaccination. According to the TER, while most GMO vaccines have a non-GMO alternative, some of these packages may not be fully available in non-GMO form currently. This information is ultimately unknown. One reason that livestock producers, particularly poultry producers, confine their animals from the outdoors is due to the waiting period for vaccinations to build immunity. Requiring the use of individual vaccines could mean additional vaccination treatments, which would lead to longer times to develop immunity, and possibly more confinement of animals. Also, although it may be possible for larger producers to work with vaccine manufacturers to custom formulate non-GMO combination vaccines, this will likely be very challenging to smaller producers who are purchasing vaccines off the shelf.

- **How will the current recommendation impact the Livestock Recommendation on outdoor access for poultry and current FDA discussions on Egg Safety?**
  OTA is concerned about the impact a rushed effort may have on the sensitive topic of outdoor access for organic poultry. OTA is fully in support of outdoor access for livestock, and the Board passed a recommendation that clarifies the requirement for organic poultry to have access to the outdoors, defined as "contact with soil when seasonally appropriate and the sky overhead and without a solid floor or walls." However, there is presently considerable pressure

being placed on FDA that challenges the compatibility of the proposed soil-based system with food safety, claiming that the proposal is in direct conflict with the FDA's Egg Safety Rule and its requirement to reduce the number of human Salmonella infections from eggs.

OTA firmly believes that outdoor access for birds on the soil does not increase the risk of Salmonella and should not be a factor in the discussion. We also recognize that certified poultry operators have increased pressures per the FDA Egg Safety Rule as well as from their customer and consumer base to ensure that no positive samples are found during environmental testing for Salmonella. While vaccines are not required as part of the Egg Safety Rule, most if not all poultry producers include Salmonella vaccines to round out their overall preventive program. The risk of a foodborne illness is not one they are willing to take. We're concerned about the impact the loss of the Salmonella vaccine will have on the organic livestock sector, and we're especially concerned about how this may be perceived by FDA. We need FDA to feel confident that organic poultry operators with outdoor access have all the tools necessary to prevent the transmission of Salmonella onto the farm.

- **Should we further explore the 2009 NOSB Recommendation to allow GMO Vaccines when non-GMO alternatives are commercially unavailable?** The previous NOSB proposal of 2009 recommended that GMO vaccines be allowed provided they are commercial unavailable in non-GMO form. In response, OGC weighed in and clarified that GMO vaccines are allowed only if they are approved according to § 205.600(a). NOP, in turn, requested NOSB to evaluate GMO vaccines to OFPA criteria so it could submit a recommendation to add GMO vaccines to the National List. To this point, NOSB has taken only some of the initial steps requested by NOP. The Board has evaluated GMO vaccines according to OFPA criteria. However, NOP suggested that the Board include in its review the status of genetically modified vaccines and assess the economic impact of using commercial availability criteria for non-GMO vaccines. We believe this is an area that needs considerably more work. We also believe it's appropriate for this Board to support and further explore the previous Board's recommendation on commercial availability.

  The committee pointed out challenging issues that commercial availability presents. However, the major advantage to commercial availability is that it will more closely align what has occurred in the field since 2002 while making it incumbent upon the producers and certifiers that non-GMO vaccines are located and used before those made by excluded methods can be used. As explained earlier, NOSB and NOP would need to work with APHIS and issue guidance surrounding a list or method that can be used to positively identify GMO Vaccines. The guidance could also set parameters based on the list for determining commercial availability that would simply tie to the existence or non-existence of a non-GMO alternative. OTA believes further exploration of this approach may lead to solutions that could help mitigate the concerns expressed by the committee regarding commercial availability.

In closing, the livestock committee states, "The GMO exception policy must be fair to accommodate both the organic producer's ideals and livelihood and the organic consumer's expectations."

OTA believes that more time is needed to collect the facts, receive and evaluate the extensive public comment, and refine the best approach that should be taken. The committee proposal would result in a change to a status quo practice that's been in place for over a decade. Considering the magnitude and complexity of the issue and the potential animal welfare and food safety issues at hand, we hope NOSB will agree to take the required time needed to pass a fully vetted recommendation.

Again, on behalf of our members across the supply chain and the country, OTA thanks the NOSB for the opportunity to comment.

Respectfully submitted,

Gwendolyn Wyard
Associate Director of Organic Standards and Industry Outreach
Organic Trade Association (OTA)

CC: Laura Batcha
Executive Vice President
Organic Trade Association (OTA)

**Attachment A:** Non-GMO Statement from Lohmann Animal Health, 4/18/2011

Lohmann Animal Health

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4/18/2011

To Whom It May Concern:

All Lohmann Animal Health International vaccines are made from naturally attenuated, non-GMO strains. This includes the following inactivated and live vaccines:

AviPro® 101 Coryza
AviPro® 101 Coryza Gold
AviPro® 104 MG Bacterin
AviPro® 105 ND
AviPro® 105 ND Chick
AviPro® 106 Reo
AviPro® 108 FC3 Platinum
AviPro® 108 FC4
AviPro® 109 SE4
AviPro® 109 SE4 Conc.
AviPro® 111 PMV1
AviPro® 201 ND-IB
AviPro® 202 ND-IBD
AviPro® 206 BD3-Reo
AviPro® 221 ND-IB2
AviPro® 226 BTO2-Reo
AviPro® 233 ND-PMV3 Conc.
AviPro® 304 ND-IB-MG
AviPro® 329 ND-IB2-SE4
AviPro® 329 ND-IB2-SE4 Conc.
AviPro® 331 ND-IB2-BD3
AviPro® 401 ND-IB-IBD-Reo
AviPro® 431 ND-IB-BD3-Reo
AviPro® 432 ND-IB2-BD3-Reo
AviPro® 441 ND-IB-BTO-Reo
AviPro® 442 ND-IB2-BTO2-Reo
AviPro® AE Tremblex
AviPro® AE-Pox
AviPro® IB Ark
AviPro® IB M48
AviPro® Vibursa CE
AviPro® IBD Xtreme
AviPro® LT
AviPro® MG F
AviPro® ND B1
AviPro® ND Visota
AviPro® ND-IB Sohol
AviPro® ND-IB Vibanco
AviPro® ND-IB Polybanco
AviPro® Pigeon Pox P
AviPro® Pox CEO
AviPro® Pox TC
AviPro® Megan® Egg
AviPro® Megan® Vac 1

Here at Lohmann Animal Health International, we define the GMO process as when enzymes are added to cleave between sections of DNA which adds a foreign section of DNA which re-combines with the broken DNA and causes it to join with the foreign section of DNA creating a new strand which creates a new organism. In the case of our Megan® products, we added naturally occurring plasmids known to

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infect and subsequently damage bacterial DNA in nature. The bacteria were then analyzed in the media post exposure and those organisms that were damaged in a way that made them mild and safe for use in the vaccine strain were selected. This is the same process that occurs naturally in the environment without interference; however, the process in this case was done in a lab and managed. For these reasons, our Megan® line is not considered GMO. In creation of any live vaccine, the bacteria or virus used is created to be mild and safe by a process to reduce virulence of any field strain.

Should any further information be needed, please feel free to contact your Area Sales Manager or myself.

Sincerely,

Katrina Bragg
Product Manager
Lohmann Animal Health International
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