



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

Docket: AMS-NOP-12-0017; NOP-12-06

RE: NOSB Livestock Committee Agenda Item - Vaccines from Excluded Methods

Dear Ms. Arsenault:

We thank you for the attention that the National Organic Standards Board has dedicated to the topic of vaccines derived from excluded methods. Midwest Organic Services Association certifies around 700 organic livestock producers, and we anticipate that this decision could have a strong effect on their management practices.

While we clearly stand opposed to the use of most genetic engineering in organic agriculture, we simply do not see evidence that vaccines derived from GM viruses and bacteria pose the same risks as GE plants and animals, which were the core of the discussion when the Organic Food Production Act labeled GMOs as “incompatible with organic agriculture.” The NOP is not currently operating with the understanding that all GMOs should be prohibited from all aspects of organic production: GMO ingredients are included as excipients in a number of products approved for organic production, and GMO crop residues are allowed for application to organic land. With these and the following thoughts in mind, we cannot support the complete prohibition of vaccines produced through genetic engineering, especially in cases where a conventionally produced alternative is not available.

The greatest concern we have is from a food safety standpoint. According to the technical report compiled by ICF International for the National Organic Program, no conventional vaccine exists for the prevention of salmonellosis in poultry. In the wake of various salmonella outbreaks and egg recalls in recent years, the Food and Drug Administration continues to stress the importance of the salmonella concern, unrolling their latest installment of the Egg Safety Rule effective July 9th of this year. Although vaccinations are not required by the rule, FDA discussion makes it clear that the requirement was and is still being considered.

WEBSITE: www.mosaorganic.org

ADDRESS: P.O. Box 821, 122 West Jefferson Street, Viroqua, WI 54665

EMAIL: mosa@mosaorganic.org **PHONE:** 608.637.2526 **FAX:** 608.637.7032

As an organic certifier, we see prevention – including vaccination programs – as a central tenet of organic production, as expressed in § 205.238 Livestock health care practice standard. Many of our Associates echo this view and express that removing the option to vaccinate against harmful bacterial strains would hamstring their ability to supply safe products for the organic market. We also feel that such action would not be in full consideration of the hazards that can arise from a severe pathogen outbreak.

We share the views articulated by the Accredited Certifiers Association (ACA), including the concern that speedy implementation of the rule as written would be impossible. At present, those certifiers who have discussed their investigations into the origins of specific vaccines agree that it is extremely difficult to determine whether or not a vaccine is considered to be produced using excluded methods. Non-GMO statements from manufacturers do not always define GM production the same way it has been outlined in the technical report presented to us (or perhaps the language simply isn't clear to those of us whose primary training is not in the field of genetics) and the APHIS directory only offers partial answers. If certifiers are expected to enforce compliance with a GM vaccine prohibition, we need guidance on what resources are available in order to ensure that our processes of evaluation is comprehensive and consistent. This knowledge and these shared policies will not surface overnight. Again, we stress the need for further investigation, and we request guidance from the National Organic Standards Board with regard to accurate, consistent application of the rule. A task force made up of representatives from the certifier community and the NOSB would seem appropriate to recognize and address many of the challenges related to this topic.

We also note that the question of GMOs in vaccine production calls for research on many levels, some of which are beyond the scope of either certifying bodies or the NOSB and are more within the realm of university and industry research. As such, the topic of GMO vaccines fits perfectly into the Research Priorities Framework as outlined in a concurrent NOSB proposal (which we wholly endorse). Future research could provide avenues for the development of acceptable alternatives to GMO vaccines.

On a final note, it is interesting that the Non-GMO Project, “a non-profit organization committed to preserving and building sources of non-GMO products, educating consumers, and providing verified non-GMO choices,” are under a temporary variance that excludes them from verifying vaccine sourcing at this time. We find it telling that even those whose scope pertains *specifically to non-GMO verification* have not yet implemented a full set of verification procedures. This speaks to the formidable challenges inherent in that charge.

This difficulty could be part of the reason why, according to the NOP's technical report, the topic of GMO vaccines is conspicuously absent from the most updated EU standards, as well as the Japan Agricultural Standard for Organic Production. IFOAM also exempts vaccines from their wide-scale prohibition on GMOS. On the other hand, we read that GMO vaccines are not allowed in organic production in Canada. This begs the question of whether Canadian certifiers have effective assessment tools and consistent policy for

evaluation. If so, we have a lot to learn from them, but again, this cannot happen overnight.

Based on these comments and others elucidated by the ACA, we ask for a withdrawal of the current proposal. We advocate a task force made up of certification specialists and NOSB members for the development of a reliable “tool-box” and consistent, industry-wide evaluation framework before any prohibition is made on GMO vaccines, *especially* those with no conventional alternatives. Consumers look to organic food as the safe alternative, and we find it crucial that this assurance is not compromised.

We look forward to learning more in this area and welcome any questions or comments related to the topic.

Sincerely,

Midwest Organic Services Association
Certification Department