CCOF
Organic Certification Trade Association Education & Outreach Political Advocacy

May 3, 2012

Ms. Ann Michelle Arsenault
National Organic Standards Board
USDA–AMS–NOP
1400 Independence Ave., SW.
Room 2646–So., Ag Stop 0268
Washington, DC 20250–0268

Docket:

RE: NOSB Livestock Committee Agenda item: Proposal on Vaccines from Excluded Methods

Dear Ms. Arsenault and members of the NOSB:

CCOF thanks the National Organic Standards Board (NOSB) for the opportunity to comment on NOSB Livestock Committee Proposal on Vaccines from Excluded Methods (April 3, 2012).

CCOF has concerns about the Livestock Committee's Proposal dated April 3, 2012, regarding livestock vaccines made from excluded methods. Specifically, we believe that denying access to vaccines until there is an emergency is risky to both animal and human health. We believe that vaccines for preventive health care are an important and integral part of ensuring animal welfare and food safety.

We strongly believe that GMOs have no place in organic production methods. However, because vaccines are so critical to both human and animal health, when non-GMO vaccines are not available, vaccines from GMO sources must be accepted in organic livestock. We do not believe that vaccines from genetically modified sources would reduce the organic integrity of livestock products, contribute to the prevalence of genetically modified crops or livestock in agriculture, or pose a potential risk of GMO contamination of crops or livestock.

RECOMMENDATION:

On November 5, 2009, the NOSB voted to approve a final recommendation that would allow GMO vaccines if non-GMO vaccines were not commercially available by modifying the language of 205.105(e). We recommend that the committee recognize the work of the 2009 board and return to the previous committee's vote to allow GMO vaccines when non-GMO vaccines are not commercially available. This could be accomplished by recommending the following language:

> **§ 205.603 Synthetic substances allowed for use in organic livestock production.**
> In accordance with restrictions specified in this section, the following synthetic substances may be used in organic livestock production:
> (a) As disinfectants, sanitizer, and medical treatments when applicable.
> …
> (4) Biologics-Vaccines. May be from genetically modified sources when non-genetically modified sources are not commercially available.

RATIONALE:

CCOF is a strong supporter of exclusion of GMOs from organic production and in no way condones the use of GMO seeds, crops, ingredients or production methods to produce organic products. We do believe, however, that access to vaccines is critical to animal welfare and human health, and that when non-GMO vaccines are not available, GMO vaccines must be allowed.

The difference between crops and livestock produced using GMO methods and vaccines produced using such methods is recognized by other regulatory efforts. The EU organic regulations 2092/91 explicitly allowed GMO vaccines for use in European organic production. Under the terms of the recent U.S.-EU Equivalency Agreement, products from livestock raised in the EU and given GMO vaccines could be sold as organic in the U.S. The Non-GMO Project, which is on the forefront of the anti-GMO movement and verification process, includes a variance that allows for the use of GMO vaccines and other livestock medications.[1]

CCOF strongly supports full and complete exclusion of GMO seeds and crops, as well as cloned livestock. We also support the mandatory labeling of such products so that consumers can make informed choices in the marketplace. We believe that ensuring livestock producers have access to vaccines to protect animal welfare and human health is the ONLY appropriate use of GMO technology in organic production. The allowance for such GMO vaccines in the NOP regulations has been in place since 2002.

We understand that the Livestock Committee intends to allow for individual vaccines to be petitioned for inclusion on 205.603. However, because the current committee evaluation of vaccines from excluded methods determined that such vaccines should not be approved since they failed to meet the criteria of being "consistent with organic farming and handling," we are concerned that it will be impossible for a petitioned individual vaccine to meet the criteria.

It has come to our attention that there may be some confusion about whether the committee's intent was to use the word "and" between the two clauses of the proposed changes to 205.105(e)(1&2), or whether the intent was to use the word "or." If the word "and" is used, as in the written proposal, the requirement would be for a GMO vaccine to go through the petition process, be recommended for inclusion on the National List by the NOSB, and have rule making completed by the NOP prior to the vaccines use in a state or federal emergency situation. This is contradictory to how the state or federal emergency treatment clause is applied in the case of crop production, where the emergency treatment allows for the use of a product NOT on the National List. If the committee intended to use the word "or" in this section, then this is a major change from the proposal published. It would be unfair to move forward without allowing the public to give feedback on this entirely different meaning of the proposed language.

REASONING AGAINST THE CURRENT PROPOSAL:

The current proposal recommends that GMO vaccines can't be used by organic livestock producers unless there is a declared federal or state emergency treatment program; we believe this is the wrong approach. Vaccines are not intended for the treatment of an outbreak of disease but are used as a preventive measure. United States law mandates that children who attend public school be vaccinated against a number of formerly prevalent diseases, such as measles. It would be irresponsible to wait until

[1] http://www.nongmoproject.org/wp-content/uploads/2009/06/NGP-Standard-v8-Final1.pdfcontent/uploads/2009/06/NGP-Standard-v8-Final1.pdf

there was outbreak of measles among elementary school children severe enough to warrant a declaration of emergency by the state before vaccinating children for this preventable disease. Furthermore, NOP regulations section 205.238(a)(6) clearly and specifically requires the use of vaccines for "preventative livestock health care practices."

In 2010, the U.S. suffered a major salmonella outbreak when thousands of people became sickened by salmonella in eggs that were traced back to two Iowa egg producers. This outbreak involved the recall of nearly 550 million eggs. However, no federal or state emergency was ever declared, or mandatory vaccinations of birds required. Poultry and bovine Salmonellosis vaccines were identified by the Technical Evaluation Report as being unavailable in non-GMO forms at this time, and therefore would not be allowed for use by organic producers under the current Livestock Committee recommendation unless such an emergency treatment program was declared. In 2010, the FDA estimated that eggs cause at least 142,000 incidences of salmonella-based illnesses in the United States annually. According to an article in the *New York Times*,[2] the prevalence of salmonella infections stemming from eggs in Britain was cut severely by the implementation of rules that encouraged widespread vaccinations of poultry for Salmonellosis. It is irresponsible to wait until thousands, hundreds, or even dozens of people get sick or potentially die before allowing the use of a vaccine that could have prevented the outbreak. Additionally, the use of the vaccine after such an outbreak would do nothing to prevent the disease in existing flocks.

Another significant issue is that it is often unclear which vaccines are GMO. Until ACAs have a source to reliably find out whether a vaccine is from an "excluded method," it is unreasonable to expect that we can require that such vaccines not be used. It is our understanding that the list provided in the Technical Report is incomplete. CCOF reviewed the APHIS list for products using recombinant technology and compared this to a list of brand name products; see letter from CCOF to NOSB dated 12/15/2010. However, as we noted in that letter, using the APHIS list does not give us all types of genetic modification, nor does it necessarily facilitate a farmer or certifier's ability to look at a product label and determine if is acceptable for use. It is 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 (such as the MMR vaccine for children, which targets measles, mumps, and rubella at once). These multi-disease vaccine packages may not be clearly identified if only one of the vaccines contains GMO technology. Many farmers may prefer to use such vaccine packages in case they reduce the period that the animal suffers from reduced immune systems following vaccination. According to the Technical Report, while most GMO vaccines have a non-GMO alternative, some of these packages may not currently be fully available in non-GMO form.

One reason that livestock producers, particularly poultry producers, confine their animals from the outdoors is 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. Additionally, fear of disease, such as salmonella, is one of the main conventional arguments for not allowing poultry animals outdoors to scratch in the dirt. Allowing for a robust vaccination program supports the goal of allowing substantial outdoor access for animals, poultry in particular.

[2] http://www.nytimes.com/2010/08/25/business/25vaccine.html?_r=1&ref=contamination_and_recalls

CONCLUSION:

We strongly agree that GMO crops and livestock have no place in organic production. We also believe that passing a recommendation that could have harmful effects on human or animal health is irresponsible. We request that the Livestock Committee reconsider the proposal put forward by the committee on November 5, 2009.

Again, CCOF thanks you for the opportunity to provide our comments, and we sincerely thank the Livestock Committee for their time and efforts on this complex subject. We are available to answer any questions you might have about our comments.

Sincerely,

Cathy Calfo, Executive Director/CEO

Jake Lewin, Chief Certification Officer

CCOF is a nonprofit organization founded in 1973. It is one of the oldest and largest organic certification agencies in North America. CCOF serves as a trade association for more than 2,300 certified organic producers and 300 supporting members, in 33 states and three countries.