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May 2, 2012

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:

Thank you for the opportunity to provide comments to the National Organic Standards Board (NOSB) regarding the Livestock Committee Recommendation on Vaccines from Excluded Methods.

The Accredited Certifiers Association (ACA) represents 43 foreign and domestic accredited certifying agents.

The ACA is requesting that the Livestock Committee withdraw their recommendation regarding vaccines from excluded methods in order to permit further discussion on this topic. We believe that the organic community must have a broader discussion on this topic than the current comment period allows.

While the ACA fully supports the prohibition of products produced through excluded methods from organic production, we are concerned with the complete prohibition of vaccines produced through excluded methods, especially if there is no conventionally produced vaccine alternative available for the particular disease. We do not believe that organic producers should be at a disadvantage when it comes to providing adequate health care to their livestock and vaccines are an integral part of a preventive livestock health care plan.

The ACA believes that the withdrawal of the current recommendation would permit time for:

- a) Petitioning and NOSB review of individual vaccines produced by excluded methods for addition to the National List. However, we believe clarification will be needed regarding the

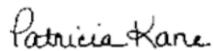
Livestock Committee determination that the “class” of vaccines derived from excluded methods *is not consistent with organic agriculture* and how this determination would impact the review of a specific vaccine derived from excluded methods petitioned for inclusion on the National List. It seems unlikely that individual vaccines would be approved if the same criteria were used.

- b) Clarification regarding the Committee Recommendation (pg. 10) whether the “and” at end of 2.(1) should be “or”. If the vaccine must be on the National List, normal practice is that the vaccine could be used at will. Is it the intention of the Committee that the vaccine could be used only during a Federal or State emergency pest or disease treatment program, even if the vaccine is on the National List? In effect, this would prohibit use of a vaccine produced from excluded method.
2. Modify 205.105 (e) as follows: Excluded methods, except for vaccines: Provided,
(1) *such vaccines are administered only due to a Federal or State emergency pest or disease treatment program, and*
(2) *such vaccines are approved in accordance with §205.600(a);*
- c) A determination by ACAs whether vaccines currently used by producers are produced by excluded methods. Historically, the majority of ACAs have been permitting the use of all vaccines, without individual review. As there currently is not a list of vaccines produced with excluded methods, we believe that NOSB, NOP and APHIS should begin work on gathering this information.
- d) The development of Guidance to ensure the vaccine review process is similar among certifiers, including regarding how far back through the manufacturing process the review must be conducted.
- e) Clarification pertaining to whether there are other government agency regulations that would impact or conflict with this recommendation. If a vaccine produced with excluded methods were the only source of a vaccine how would that impact producers? An example of this is the *Salmonella dublin vaccine*. As stated in the Committee Recommendation, there is no conventionally produced vaccine available. There are increasing requirements for the use of the salmonella vaccine. Organic producers must have an option to utilize a salmonella vaccine to protect their livestock.
- f) Additional information regarding exactly what constitutes a “Federal or State emergency pest or disease treatment program”. We note that in 2010 the US suffered a major outbreak of thousands of people 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. Has a Federal or State emergency pest or disease treatment program ever been declared? What is the length of time of an emergency declaration? Would a vaccine given during the time of outbreak even be effective against the disease? Vaccines are generally used to prevent disease, rather than treatment for a disease.

The ACA urges the NOSB Livestock Committee to withdraw the Recommendation on Vaccines from Excluded Methods, begin the work of review of vaccines known to be produced by excluded methods to determine if they can be placed on the National List, and provide the clarifications requested above. It is imperative that producers are not impacted by removal of vaccines when no alternative is available.

We thank you for beginning the discussion on this important topic and for the opportunity to provide comments.

Sincerely,

A handwritten signature in cursive script that reads "Patricia Kane".

Patricia Kane
Coordinator