PENNSYLVANIA CERTIFIED ORGANIC

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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

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

Dear Ms. Arsenault,

Pennsylvania Certified Organic welcomes the opportunity to provide comments to the National Organic Standards Board. PCO is an NOP-accredited certifying agent that certifies more than 650 operations in the mid-Atlantic region, including around 170 crops operations, 360 livestock operations, 100 processor/handler operations and various combinations of the three categories.

PCO would like to provide comments on the following agenda items:

Livestock Committee
- Vaccines from Excluded Methods

Compliance, Accreditation and Certification Committee
- Sanitizers and "100% Organic" Products
- Criteria for Material Review by Material Review Organizations

Vaccines from Excluded Methods

PCO requests that the committee withdraw the recommendation on Vaccines from Excluded Methods from this meeting's agenda to allow for further discussion and research on this important topic. PCO agrees that vaccines from excluded methods should only be allowed if specifically reviewed and approved by the National Organic Standards Board and added to the National List. This recommendation as written would present

significant challenges to both producers and certifiers without necessarily increasing organic integrity. This recommendation would have a significant impact on the tools farmers can use to ensure healthy animals and safe food and on the certifiers that are tasked with enforcing unclear parts of this recommendation. PCO has identified the following areas of the recommendation that require additional research, discussion, and clarification.

1) The committee acknowledged in the recommendation that Federal or State emergency pest or disease treatment programs are rare. In fact, it seems as though the committee is unaware of a single emergency treatment program that has ever been declared that required the use of a vaccine. This knowledge is critical to understanding if the exception to allow GMO vaccines in these scenarios would ever be useful to a producer.

2) The technical review reveals that non-GMO vaccines are currently available for all but two diseases: avian and bovine salmonella. It could be a significant food safety risk for producers to not be able to vaccinate for salmonella, one of the most notorious food borne illnesses in the country. Most poultry producers certified by PCO rely on vaccinations to ensure the highest level of food safety in their products. Are there are other FDA regulations that require the use of vaccines for some diseases, including salmonella? This information is critical to avoid regulatory conflict and unnecessary burdens on organic producers. In this case, the allowance of GMO vaccines if a non-GMO alternative is commercially unavailable may be appropriate, as recommended by the Livestock Committee in 2009.

The fact that the recommendation would prohibit producers from routinely vaccinating for salmonella is not a concern for the committee. On pg. 17, the committee says that instead of vaccinating, salmonella can be prevented with proper management practices. Vaccines are listed as one of several preventative livestock health care practices that are allowed at 205.238(a). However, there is not a hierarchy among the practices listed in this section, so there is no regulatory requirement for producers to only use vaccines unless other preventative practices are not effective to manage disease.

3) The recommendation hinges on the ability to determine if a vaccine is produced by excluded methods. Currently, there is not a clear way to do this.

The APHIS list only identifies vaccines that contain recombinant DNA, but does not address the other production methods that would be considered "excluded" by the definition of excluded methods in the organic regulations. As an organization that has reviewed over 3,300 livestock input materials (half of which are for health care), PCO knows that direct inquiry with manufacturers, especially the large corporations producing livestock health care products, is challenging. Relying on direct inquiry as a means to determining GMO status will result in certifiers allowing different vaccines, depending on which certifier was able to obtain the information, as well as potentially limit the number of vaccines available for producers to be able to use if the manufacturer is unwilling to provide this information.

In order for certifiers and material review organizations to be able to identify vaccines from excluded methods and enforce this recommendation, there must be clear

guidance on what excluded methods are prohibited and how far back in the production process should excluded methods be verified.

4) The recommendation would allow animals treated with GMO vaccines during a declared emergency to keep their organic status. Is that not saying that the organic integrity of the treated animal is not affected by the use of a GMO vaccine? If there were any indication that the use of GMO vaccines adversely affects the organic integrity of the animal, then treated animals would not be allowed to stay in organic production regardless of a declared emergency. Also, it is telling that the Non-GMO Project, an organization committed to preserving non-GMO products in the marketplace, does not exclude the use of GMO vaccines. The committee may benefit from more research into the real affect (or lack thereof) that the use of GMO vaccines has on the organic integrity of animals and animal products.

5) The committee states on pg. 14 that it is not the intent of this recommendation to "preclude the possibility of successful future petitions to the NOSB for specific GMO vaccines or for GMO vaccines as a class for specific animal diseases". However, this recommendation is effectively stating that GMO vaccines as an entire class of materials is not compatible with organic production. It is hard to imagine that any individual vaccine from excluded methods would be found to be compatible, since this recommendation declares that the entire class of vaccines from excluded methods is not compatible. Clarification is needed on how the committee believes that this recommendation does not preclude GMO vaccines from being successfully petitioned for inclusion on the National List.

Sanitizers and "100% Organic" Products

PCO would like to contribute to the discussion on sanitizers used in the production and processing of products labeled as "100% organic", by answering the questions posed in the CAC committee's discussion document. PCO suggests that the National Organic Standards Board consider the merger of the 100% organic and >95% organic categories, and all products with >95-100% organic content would be labeled as "organic". It may be the solution to this particular issue concerning the use of sanitizers on 100% organic products, among others.

1. Does the 100% Organic label claim hold value for you?
Products in the "100% organic" category hold value simply by being composed of and processed with only organic ingredients. Products in the >95% organic category have just as much organic integrity as a product in the "100% organic" category. The use of an NOP-approved non-organic processing aid or ingredient does not diminish the organic integrity with which the raw agricultural products were produced.