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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

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

RE: National List Proposal Vaccines from Excluded Methods

Introduction:

Oregon Tilth opposes the use of genetically modified inputs in organic agriculture, however we have concerns with the livestock committee's proposal on GMO vaccines. We believe that the committee proposal contains inaccuracies about the use of vaccines in livestock production and did not contain sufficient information regarding the use of GMO vaccines in organic livestock production. For the following three reasons we believe that the proposal should be withdrawn from voting at this meeting:

1. The document proposal refers to vaccines as a "treatment" for disease, instead of a preventative measure
2. The issue of essential need of GMO vaccines is not sufficiently defined or researched
3. A complete list of GMO vaccines is unavailable and GMO vaccine use in organic production is largely unknown

Discussion:

The document refers to vaccines as **treatments** in multiple locations. The definition of a vaccine is, "a preparation of killed, weakened, or fully infectious microbes that is given (as by injection) to produce or increase immunity to a particular disease". A vaccines mode of action is to stimulate the body to create antibodies preventing an infectious disease in the future. Vaccines are typically used as a preventative

measure in livestock production. By contrast, the committee's proposal indicates that vaccines are used as a treatment for disease, and requires that GMO vaccines be only used in emergency situations. However, it was not well-researched if vaccines have **ever** been used as part of a state or federal emergency pest or disease treatment program. The question was not addressed in the TR because it was never posed. To fully understand the impact of the presented rule change, the answer to this question must be known. Note that the National Organic Program Regulations list vaccines under §205.238(a)(6) indicating that the producer must establish and maintain preventative livestock healthcare practices, including administration of vaccines and other veterinary biologics.

The proposal states that there is not enough evidence of essential need for the use of GMO vaccines. However, the TAP review found that there are two vaccines that cannot be produced by non-GMO methods. We would like to remind the committee that vaccines have been viewed as "essential" by past and present NOSB Committees. As noted above vaccines are specifically listed as a preventative livestock healthcare practice in the National Organic Program Regulations, and two out of the three Guidance documents to be presented at this meeting list the use of vaccines as a tenet of good animal welfare.

The document indicates that a complete list of GMO vaccines was not found by the committee and it was unknown the amount that were used currently by organic operations. Oregon Tilth was also unable to acquire this information prior to submission of this comment. Therefore, the impact of day-to-day certification activities is largely unknown and could not be commented on. We assert that more time is needed to research the use of vaccines in organic production prior to making a final rule change recommendation. In the meantime, we support the development of guidance involving the review of vaccines by ACAs. Ideally, this guidance will also contain a list of GMO and non-GMO vaccines that can be easily referenced.

Summary:

Oregon Tilth urges the committee to withdraw this proposal for voting at this spring meeting. It is imperative that the inaccuracies about vaccine use and the necessary research be conducted prior to formulating a proposed rule change. After proper consideration by the committee and the identification (or development) of a complete list of GMO and non-GMO vaccines, Oregon Tilth would support a commercial availability requirement. This would meet the criteria outlined in the proposal. This topic is very important to organic livestock production and should be given thorough research and consideration prior to proposed rule changes.

Respectfully submitted,

Oregon Tilth, Inc.

Oregon Tilth, Inc. is a non-profit 501(c)(3) organization that supports and promotes biologically sound and socially equitable agriculture. Oregon Tilth offers educational events throughout the

state of Oregon, and provides organic certification services to organic growers, processors, and handlers internationally. An NOP accredited certifier since 2002, Oregon Tilth currently certifies over 650 farms and ranches and over 600 handlers in more than 35 states affording us a broad perspective of current practices and challenges faced by organic producers and handlers.