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October 3, 2019

Ms. Michelle Arsenault, Advisory Committee Specialist
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. S.W.
Room 2642-S, Mail Stop 0268
Washington, DC 20250-0268

RE: Docket: AMS-NOP-19-0038
Livestock Subcommittee – Proposal - Use of Excluded Methods Vaccines in Organic Livestock Production

Dear Ms. Arsenault,

Oregon Tilth appreciates the work of the Livestock Subcommittee and the opportunity to provide additional comments on the use of livestock vaccines in organic production. We understand that the proposal represents the majority of public comments received on this topic at the Spring 2019 NOSB meeting. However, we have serious concerns about whether the use of commercial availability for organic livestock vaccines will benefit organic livestock, producers, certifiers and consumers. We support the continued allowance of vaccines as a class without restriction to ensure there are no barriers to providing preventative care for organic livestock as required in §205.238(a)(6). We believe consistency in implementation of standards and supporting producers' ability to provide humane, transparent care for livestock animals are critical are paramount for organic.

Vaccines are among the suite of measures identified at §205.238(a)(6) that livestock producers must use for preventative healthcare purposes. Just as producers must select animals that are adapted to their region, provide high quality feed, clean and humane living conditions, and reduce stress wherever possible, they are also responsible for using allowed healthcare inputs to prevent disease. With limited disease treatment options available, organic livestock producers are reliant on vaccines, in combination with the other animal health management practices, to prevent and treat disease. However, the addition of the significant time and paperwork burden of commercial availability approval that would now be involved in getting approval for vaccines would likely discourage some livestock producers from using vaccines altogether; this could have significant negative consequences on organic animal health and welfare, which is not in line with organic principles.

It is Oregon Tilth's understanding that the majority of vaccines are produced using some form of genetic modification (GM) technology. There is currently no system in place to easily identify all excluded methods used in vaccine production. We are concerned that the vaccines identified by APHIS as being genetically modified may not be genetically modified according to the definition and restrictions of the USDA National Organic Program (NOP).

Under this proposal, it would fall to certifiers to provide the ever-growing list of excluded technologies to manufacturers and await their response to determine if the operator is required to document commercial availability for the vaccine in order to grant approval. In the majority of cases, even if a vaccine is identified as being produced with GM technology, there will not be a non-GM alternative on the market due to the single-origin mass production nature of the vaccine industry. The proposal makes a case for the implementation of commercial availability restrictions driving the production of non-GM alternatives to meet the new demand. However, Oregon Tilth believes that the organic livestock industry's limited demand and the lack of regulatory burden on the vaccine producers, the added commercial availability requirement would not drive marketplace changes.

Oregon Tilth suggests the following to address this issue within the regulatory text that would ensure animal welfare and maintain compliance with the Organic Foods Production Act (OFPA):

1. Continue to allow vaccines and list them on the National List at §205.600(4) as a class without restriction, or
2. Amend §205.105(e) to remove the text after the term 'vaccines' so it reads: "*Excluded methods, except for vaccines.*" OR "*Excluded methods, except for all APHIS approved or exempt vaccines.*"

Option one would ensure that vaccines as a class will be re-reviewed every five years, and provide the opportunity for annotations to be added to prohibit specific forms or types of vaccines discovered to not meet the OFPA. Option two would remove the need for reviewing individual vaccines and continue their allowance without further review. It may not be necessary to reference USDA-APHIS requirements, as all vaccines must be licensed or exempt from federal regulation. Either approach will ensure animal welfare in organic livestock production without placing unnecessary burdens on the industry.

Thank you for your time and diligence in addressing this issue in a way that is practical and within the requirements of the regulation.

Respectfully submitted,
Oregon Tilth

Oregon Tilth is a leading certifier, educator and advocate for organic agriculture and products since 1974. Our mission to make our food system and agriculture biologically sound and socially equitable requires us to find practical ways to tackle big challenges. We advance this mission to balance the needs of people and planet through focus on core areas of certification, conservation, policy and the marketplace.