

April 21, 2025

Ms. Michelle Arsenault National Organic Standards Board USDA-AMS-NOP

Docket: AMS-NOP-24-0081

RE: Livestock Subcommittee 2027 Sunset Livestock Substances

Dear Ms. Arsenault:

Thank you for this opportunity to provide feedback to the Livestock Subcommittee on its 2027 Sunset Livestock Substances. The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, material input providers, and others. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Each year, OTA conducts surveys of the trade to inform our position on the current year review of National List substances. Surveys are posted online and include a brief description of uses in organic production; the OTA draft position; a brief summary of public comments from the last sunset review; an indication of the Board's vote at last sunset review (unanimous vote to renew, majority vote to renew, or significant vote to remove); and any questions posed by the Subcommittee. Respondents are asked to provide any additional information related to the material, its usage, and compliance with National List criteria, including whether the material should remain listed. For agricultural materials, we ask for any information regarding the availability or history of unavailability in the appropriate form, quality, or quantity of the material as well as any new information on alternative substances.

Based on those surveys, OTA provides the following comments on the 2027 Sunset Livestock Substances:



Butorphanol | §205.603 (CAS #-42408-82-2)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i)Use by or on the lawful written order of a licensed veterinarian; and

(ii)A meat withdrawal period of at least 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.

- Uses in organic livestock production: Used as an anesthetic for surgical procedures.
- OTA Position: Butorphanol currently meets the criteria for continued listing: it does not appear to be harmful to human health or the environment, is necessary for organic production, there are no viable alternatives, and is consistent with organic livestock production.

Flunixin | §205.603 (CAS #-38677-85-9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA

- Uses in organic livestock production: Used to treat inflammation and pyrexia.
- OTA Position: Flunixin currently meets the criteria for continued listing: it does not appear to be harmful to human health or the environment, is necessary for organic production, there are no viable alternatives, and is consistent with organic livestock production.

Magnesium hydroxide | §205.603 (CAS #-1309-42-8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires use by or on the lawful written order of a licensed veterinarian.

- Uses in organic livestock production: Used as an antacid and laxative.
- OTA Position: Magnesium hydroxide currently meets the criteria for continued listing: it does not appear to be harmful to human health or the environment, is necessary for organic production, there are no viable alternatives, and is consistent with organic livestock production.

Oxytocin |§205.603 use in post parturition therapeutic applications

• Uses in organic livestock production: In nonorganic production, it can be used regularly to help nonorganic dairy cows relax and "let down their milk." In organic production, it is used "in post parturition therapeutic applications," an annotation that some find ambiguous.



• **OTA Position:** Given the Board's recommendation to remove this listing in its last review, based in part on two members with a large presence in the organic dairy sector, OTA is interested in hearing from members regarding the necessity of this substance and its consistency with organic production.

Poloxalene | §205.603 (CAS #-9003-11-6)—for use under 7 CFR part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat.

- Uses in organic livestock production: Used as an emergency bloat treatment.
- **OTA Position:** Poloxalene currently meets the criteria for continued listing: it does not appear to be harmful to human health or the environment, is necessary for organic production, there are no viable alternatives, and is consistent with organic livestock production.

Formic acid | §205.603 (CAS # 64-18-6)—for use as a pesticide solely within honeybee hives.

- Uses in organic livestock production: Used to control varroa mites in honeybees.
- **OTA Position:** Formic acid currently meets the criteria for continued listing: it does not appear to be harmful to human health or the environment, is necessary for organic production, there are no viable alternatives, and is consistent with organic livestock production.

Sucrose octanoate esters | §205.603 (CAS #s-42922-74-7; 58064-47-4)—in accordance with approved labeling

- Uses in organic livestock production: Used to control varroa mites in honeybees.
- **OTA Position:** Given the Board's recommendation to remove this listing in its last review, OTA is interested in hearing from members if there is a need for this substance, and whether the EPA-registered products containing this substance are in use by organic producers.

EPA List 4 Inerts | §205.603 As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. (1) EPA List 4—Inerts of Minimal Concern.

- Uses in organic livestock production: Used as inactive ingredients formulated with allowed pesticide active ingredients.
- **OTA Position:** OTA has commented extensively on this listing, which references a list no longer maintained by EPA. OTA recognizes the need to determine a solution that allows inert ingredients in pest control products that are vital to organic operations, meet OFPA criteria, and allow for the development of new products to meet the needs of organic operations. OTA generally supports the



recommended rulemaking options voted on at the October 2024 NOSB meeting and looks forward to further work on this from the NOP.

Until there is an alternative to this listing, OTA supports the continued listing to ensure organic operations have the tools essential to their success.

Excipients | §205.603 only for use in the manufacture of drugs and biologics used to treat organic livestock when the excipient is:

(1) Identified by the FDA as Generally Recognized As Safe;

(2) Approved by the FDA as a food additive;

(3) Included in the FDA review and approval of a New Animal Drug Application or New Drug Application; or

(4) Approved by APHIS for use in veterinary biologics.

- Uses in organic livestock production: Used as inactive ingredients formulated with allowed active medical treatment ingredients.
- **OTA Position:** Excipients currently meet the criteria for continued listing: they do not appear to be harmful to human health or the environment, they are necessary for organic production, there are no viable alternatives, and they are consistent with organic livestock production.

Strychnine | §205.604

- Uses in organic livestock production: Prohibited for use in organic production. Strychnine is a toxic alkaloid allowed in conventional agriculture for below-ground use to control pocket gophers.
- OTA Position: OTA supports the continued prohibition of strychnine in organic production.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Scott Rice Sr. Director, Regulatory Affairs Organic Trade Association

cc: Tom Chapman



Co-CEO Organic Trade Association