Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: October 30, 2020

Subject: 2022 Sunset Reviews - Livestock (§§ 205.603, 205.604)

NOSB Chair: Steve Ela

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

The NOSB recommends the following sunset substances be renewed:

Reference: 7 CFR §205.603 Synthetic substances allowed for use in organic livestock production

Butorphanol
Flunixin
Magnesium hydroxide
Poloxalene
Formic Acid
EPA List 4 - Inerts of Minimal Concern
Excipients

Livestock §205.604 Prohibited nonsynthetic substances
Strychnine

NOSB Vote: See below for votes and rationale supporting each recommendation

Butorphanol

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(5) Butorphanol (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.

Technical Report: 2002 TR
Petition(s): 2002 Petition
Past NOSB Action: 2002 Livestock Subcommittee recommendation; 09/2002 Meeting minutes and vote; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: National List Amended 12/12/2007 (72 FR 7049); Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

NOSB Review:
Butorphanol is used in livestock production as a pre-operative treatment of pain before surgery. Butorphanol belongs to a general class of drugs known as opiate agonists. It is commonly used as an anesthetic used to treat patients prior to surgery. Other related drugs in this class include buprenorphine, fentanyl, merperidine, and morphine. Xylazine, acepromazine, and butorphanol serve similar functions but each has its own specific advantages that make it the preferred treatment at the time: acepromazine has no analgesic activity, it is only a sedative; xylazine has both analgesic and sedative properties; and butorphanol is a pain killer with no real sedative activity" (TAP p24.) Although, "there are non-synthetic opiates (refers to a group of drugs used for treating pain), butorphanol is preferred for several reasons: it is associated with fewer adverse effects for the animal; it has less abuse potential in humans thereby reducing unwanted consequences if the drug is "diverted" to illicit use."

Public Comments:
Public comments from livestock producers were overwhelmingly in support for renewal of Butorphanol on the National List as a safe and effective treatment for pain before surgery; although other organic constituents noted that the use of Butorphanol was being used off-label and questioned why it was being allowed in ruminant (food and dairy) livestock.

NOSB Vote:
Motion to remove butorphanol from §205.603 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Scott Rice
Seconded by: Dan Seitz
Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Motion failed

Flunixin

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(12) Flunixin (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

Technical Report: 2007 TAP
Petition(s): N/A

Past NOSB Actions: 10/2002 NOSB recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: National List Amended 12/12/2007 (72 FR 7049); Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

NOSB Review:
The Spring and Fall 2020 public comments were overwhelmingly supportive of keeping flunixin on the National List. Several certifiers conducted surveys of their clients and reported to the NOSB that their clients used flunixin on their operations and desired to keep it in their 'toolbox" to use when needed for their livestock's well-being**.**

There were comments about residual of flunixin in inflamed tissues and questioned why we needed flunixin since its mode of action is identical to aspirin which is also on the National List, but producers respond that aspirin boluses are difficult to dispense, do not provide the pain relief as does flunixin, and takes longer to act on the pain levels.

Based on the prior Subcommittee review and public comments, the NOSB found flunixin compliant with OFPA criteria, and does not recommend removal from the National List.

NOSB Vote:
Motion to remove Flunixin from §205.603 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Sue Baird
Seconded by: Dan Seitz
Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Motion failed

Magnesium hydroxide

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(18) Magnesium hydroxide (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.
Technical Report: 2007 TR
Petition(s): 2002 Petition

Past NOSB Actions: 2002 NOSB recommendation; 11/2005 NOSB sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

NOSB Review:
Magnesium hydroxide is used as an antacid for temporary relief of an upset stomach and as a laxative for short-term relief of constipation. Magnesium hydroxide is used as a flame retardant and smoke depressant for temperatures exceeding 400 degrees Fahrenheit. It is also a general food additive used as a color-retention agent, drying agent, pH control agent, or processing aid. Magnesium hydroxide is also used as a fertilizer (in the form of lime) as a substitute for more expensive chemical fertilizers.

Public Comments:
Public comments from livestock producers were in overwhelmingly support for renewal of Magnesium Hydroxide on the National List as a safe and effective anti-acid and laxative agent in dairy cow management. One comment questioned why the restriction for use of Magnesium Hydroxide on §205.603(a)(1) when it is being allowed with no restrictions as a vitamin supplement livestock feed on §205.603(d)(3).

NOSB Vote:
Motion to remove magnesium hydroxide from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.603(a) if applicable: N/A
Motion by: Jesse Buie
Seconded by: Kim Huseman
Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Motion failed

Poloxalene

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(26) Poloxalene (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
Technical Report: 2001 TAP
Petition(s): 2000 Petition
Past NOSB Actions: 03/2001 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

NOSB Review:
Poloxalene is a copolymer of polyethylene and polypropylene ether glycol that is a non-ionic polyol surface-active agent. Poloxalene is a fast-acting synthetic material approved under the organic

regulations only for emergency treatment of bloat. In conventional agriculture, it is also used medically as a fecal softener and in cattle for prevention of bloat.

Altogether, about a dozen written comments on poloxalene were submitted prior to the April 2020 NOSB meeting. The large majority of comments either supported continued listing of the substance as necessary in emergencies when natural approaches to treating bloat are not effective, or stated that the substance was used by organic farming operations for emergency situations. The general consensus was that while poloxalene is rarely needed, in certain emergency situations it is essential. Two commenters stated that the NOSB should not relist poloxalene unless there is strong evidence of need; however, these commenters did not offer any conclusions in this regard.

Approximately the same number of comments were received prior to the October 2020 NOSB meeting, and the comments were largely identical to the comments received prior to the April 2020 NOSB meeting. Thus, the subcommittee continued to support relisting.

Based on the Livestock Subcommittee review and the comments received, the NOSB considers poloxalene to still be an important veterinary tool for organic producers and supports its relisting at this time.

NOSB Vote:
Motion to remove poloxalene from §205.603(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Dan Seitz
Seconded by: Nate Powell-Palm
Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Motion failed

Formic acid

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(3) Formic acid (CAS # 64-18-6) - for use as a pesticide solely within honeybee hives

Technical Report: 2011 TR
Petition(s): 2010 Petition
Past NOSB Actions: 2010 NOSB recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Added to National List, effective August 3, 2012 (77 FR 45903); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022
Subcommittee Review

NOSB Review:
Formic acid is a pesticide employed to control Varroa and tracheal mites in honeybee hives. Deployed in the form of a compressed pad inside the hive, the material volatilizes to kill mites throughout the hive including mites attacking broods and located externally on and internally in the adult bees.

The EPA first registered formic acid as a pesticide in 1999 as material control for Varroa and tracheal mites in honeybees. Formic acid kills mites by asphyxiation while not causing harm to the bees. Typically employed over a 21-day treatment period (per label instructions), the efficacy of formic acid in killing

mites has been found to be as high as 95%. Label recommendations instruct producers who treat hives with formic acid to not harvest honey from the hive for two weeks after the introduction of the formic acid pads. Natural sources of formic acid, which include coffee, nectars, some fruits, as well as the stings of ants and bees, have proven insufficient to extract commercially viable quantities.

Public comments were in favor for retaining Formic Acid on the National List for control Varroa and tracheal mites in honeybee hives even though most comments acknowledged there were still no NOP standards for apiculture production.

NOSB Vote:
Motion to remove formic acid at § 205.603 (b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Nathaniel Powell-Palm
Seconded by: Scott Rice
Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Motion failed

EPA List 4—Inerts of Minimal Concern

Reference: §205.603(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with non-synthetic 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
Technical Report: 2015 Limited Scope TR Nonylphenol Ethoxylates (NPEs) (one group only of List 4 inerts)
Petition(s): N/A
Past NOSB Actions: 02/1999 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

NOSB Review:
EPA List 4 Inerts are used for a wide range of applications including surfactants and adjuvants in pesticide formulations. While the EPA categorized lists (1, 2, 3, 4, 4A, 4B) provided guidance for evaluation of inert substances in organic production, these lists are no longer updated and have limited utility. The NOSB has devoted considerable time to discussing and debating how to address the placement of inerts on the National List. A comprehensive timeline authored by Terry Shistar of Beyond Pesticides is included in the Crops Subcommittee's EPA List 4 Inerts sunset review.

Past public comments at sunset weighed heavily in favor of robust reviews of inert ingredients, due in large part to the fact that the original listing of inerts relied upon an EPA screening process which does not consider the OFPA criteria. Additionally, public comments indicated significant concern that, while inerts are not listed as active ingredients in many pesticide formulations, they nevertheless exert significant impact on the environment, terrestrial and aquatic ecosystems and human health. The

Livestock Subcommittee recognizes the public's deep concerns regarding these materials, while also acknowledging the significant impact that wholesale removal of EPA List 4 Inerts from the National List would have on the organic industry.

In the last two sunset reviews, the Board has voted to retain the listing of EPA List 4 Inerts while the organic industry, the NOP, and the EPA worked together to create a path forward that adequately reviews inerts for compatibility with organic production. In October 2015, the Board passed a recommendation proposing an annotation to remove the reference to EPA List 4, and move forward with a formal relationship to work with the EPA Safer Choice Program. The recommendation acknowledges the current nomenclature in use by the EPA regarding FIFRA 25(b) and 40 CFR 180.1122, while laying a framework for some inerts to be reviewed individually.

To date, the 2015 recommendation has not been implemented. The 2015 recommendation presents options for moving forward that are still relevant and necessary. **The board strongly encourages the NOP to move forward on this recommendation and add it to the regulatory agenda.**

Public Comments:
During the spring 2020 comment period, the Board again heard overwhelmingly from stakeholders that the inertia around this issue is unacceptable. As one comment noted, "It has now been five years since NOP committed to implementing the NOSB recommendation; ten years since EPA directly requested NOP to remove the reference in its regulations; and about 15 years since EPA Lists became obsolete. Yet the NOP regulations still refer to EPA Lists that were last updated in August 2004." Commenters expressed support for removing the reference in the annotation to EPA List 4 Inerts and moving the 2015 recommendation forward. Several comments provided detailed steps for how the NOP, NOSB and EPA Safe Choice Program can work together to accomplish this.

Public comments in the Fall 2020 NOSB meeting were equally divided with the same concerns expressed as was expressed in the Spring 2020 comment period. Though a path forward is well-defined, the timeline required to enact the 2015 recommendation is likely a lengthy one. Many EPA List 4 inerts used in compliant crop and livestock input formulations also appear on the EPA Safer Chemicals Ingredient List (SCIL), thus providing a viable transition to this more relevant list. Other inputs with inerts of known toxicity or other concerns would not move to the SCIL list and require reformulation and the subsequent registration and approval that is required of new regulated inputs. Ultimately, the reformulation of inputs to safer ingredients is a positive direction in which to move, one which meets consumer expectations and strengthens the integrity of the organic label. However, removal of the EPA List 4 reference with no immediate substitute will in the interim cause potential disruption to organic operations that rely on materials formulated with these inerts, removing essential tools in an already limited toolbox.

The Board is unanimous in its recognition that the listing for EPA List 4 inerts of minimal concern is long outdated and in need of removal. As well, the Board is united in its desire to remove this listing and replace it with one that provides an updated system to review material formulations. It is in how to move this issue forward that the Board diverges on its desired approach. In a split vote, some favored removing this listing to spur the program to act expediently and replace it with a workable alternative. Others felt this could pose disruption and uncertainty in a market already stressed by an ongoing pandemic and economic downturn.

After voting to retain this listing, the Board unanimously passed the following resolution:

> *In voting to relist EPA List 4 Inerts of Minimal Concern, the NOSB recognizes the vital importance of the substances included in this listing to the organic industry. However, in referencing a list*

that is no longer maintained, using a list on which no new substances can be added, and not allowing for review of individual or groups of materials, the use of List 4 ingredients on the National List is problematic and outdated. The NOSB recognizes that a viable program allowing for the review and use of these substances must be created before this listing can be removed. Therefore, the NOSB asks that the National Organic Program do the following:

1) work with the NOSB to develop a viable alternative process that allows for the review of many of the substances presently on EPA List 4 and has minimal disruption to the organic industry;

2) for substances that do not meet OFPA criteria for listing, work to provide a sufficient period for industry to change formulations and receive regulatory approval for the new formulations;

3) coordinate regularly with the NOSB on progress to develop an alternative to the EPA List 4 Inerts of Minimal Concern that allows for stakeholder input and the removal of the reference to EPA List 4 inerts on the National List.

NOSB Vote:
Motion to remove EPA List 4—Inerts of Minimal Concern from §205.603 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Scott Rice
Seconded by: Sue Baird
Yes: 6 No: 9 Abstain: 0 Absent: 0 Recuse: 0

Motion failed

Excipients

Reference: §205.603(f) Excipients—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.
Technical Report: 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/2002 NOSB minutes and vote; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 12/27/2018 (83 FR 66559)
Sunset Date: 3/15/2022

Subcommittee Review

NOSB Review:
There are more than 8,000 food, drug, and cosmetic excipients available for conventional production; however, excipients currently appear in the USDA National Organic Program (NOP) regulations at §205.603 for use in the manufacture of drugs used to treat organic livestock when the excipient is identified by the FDA as: 1) Generally Recognized As Safe (GRAS); 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 (Animal and Plant Health Inspection Service) for use in veterinary biologics. Additionally, excipients are allowed in "nutritive supplements" listed at § 205.603(a)(21).

Excipients are defined in §205.2 as "any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance)." Excipients are used in New Animal Drug Applications (NADAs) approved by FDA, and in animal health care products that do not carry NADA registration. They are also used in New Drug Applications (NDAs) in drugs marketed for human consumption that may be administered to animals, such as aspirin.

Excipients are used for a great number of applications in animal drug and health care products but are delineated into broad categories based on the major reasons the excipient is used. "Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained- release matrices, and coloring agents." (§ 205.2)

Public comments received during the 2020 NOSB Spring and Fall meetings stated that listing excipients as a class of substances as opposed to reviewing each individual substance has caused some discrepancies in certifier approvals. Some commenters stated that Excipients are not always reviewed by certification agencies when considering direct vs. indirect food additives, how those may be used, and their compliance with the excipient annotation since the annotation only says, "approved by the FDA as a food additive". Some public comments stated that some certification agencies permit the use of indirect food additives only in health care products that are intended for external application (e.g., teat dips) while others do not permit them at all. Others permit indirect food additives in all types of health care products, including oral and injectable formulas despite the fact that injectable vitamins and minerals with excipients as part of their formula do not appear on the National List.

Despite the above public comments, the public commenters stated overwhelmingly that excipients must remain on the National List until the further review work can be done. Certifiers, Livestock producers and organic industry leaders listed hundreds of approved livestock health products that would have to be removed from the livestock health toolboxes if excipients were removed from the National List.

The NOSB was asked to commit to identifying and reviewing individual excipients to bring the clarity needed. The NOSB agrees with the public comments that more review work needs to be undertaken for individual excipient substances, but because of the immense economic and livestock humane impact of removing the listing for excipients, they do not support the removal at this time.

Based on prior Subcommittee reviews and public comments, the NOSB found excipients compliant with OFPA criteria, and does not recommend removal from the National List.

NOSB Vote:
Motion to remove excipients from §205.603 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Sue Baird
Seconded by: Jesse Buie
Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Motion failed

Strychnine

Reference: §205.604 Nonsynthetic substances prohibited for use in organic livestock production.
The following nonsynthetic substances may not be used in organic livestock production:
(a) Strychnine
Technical Report: None
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (crops only); 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review

NOSB Review:
Strychnine is a toxic alkaloid that is a transparent crystal or white, crystalline powder. It was widely used in poison (toxic) baits to kill rodents and other mammals and is a common adulterant of many illicit (street) drugs. Exposure to strychnine can be fatal. It is colorless, odorless and has a bitter taste.

Strychnine can be absorbed into the body by inhalation or ingestion. It can also be injected into the body when mixed with a liquid. Strychnine is rapidly metabolized and detoxified by the liver. This substance is also well-absorbed and acts very rapidly, producing muscular hyperactivity, which can quickly lead to respiratory failure and death.

Strychnine has been placed in Toxicity Category I by the EPA, indicating the greatest degree of acute toxicity, for oral and ocular effects; inhalation toxicity is also presumed to be high. According to the USDA, above-ground uses were canceled in 1988; however, it remains registered for below-ground use to control damage caused by pocket gophers.

Based on prior Subcommittee reviews and public comments, the NOSB found Strychnine non-compliant with OFPA criteria, and does not recommend removal from the National List §205.604.

NOSB Vote:
Motion to remove strychnine from §205.604 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Nathaniel Powell-Palm
Seconded by: Jesse Buie
Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Motion failed