

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

Date: April 27, 2016

Subject: Annotation Change for Lidocaine and Procaine Use in Livestock Production

NOSB Chair: Tracy Favre

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

Guidance Statement:

Other:

Statement of the Recommendation:

Based on new information received during Sunset Review in 2015 and public comment, the NOSB recommends a reduction in the withholding period for both lidocaine and procaine from the present 90 days to 8 days for slaughter stock and 6 days for milk.

Rationale Supporting Recommendation:

Lidocaine and procaine are local anesthetics used to reduce or prevent pain during de-budding horns in livestock, or general minor surgery on mature livestock. They numb only the area to be worked on. Humane treatment of animals is critically important and the public expects high standards of animal welfare for organic livestock. A lengthy withholding period after treatment may result in animals not being treated in a timely manner, or not being treated at all.

Section 205.238 establishes a livestock healthcare practice standard permitting physical alterations needed to promote animal welfare in a manner which minimizes stress, and further that a producer must not withhold medical treatment in an effort to preserve its organic status.

The Food Animal Residue Avoidance Databank (FARAD) is 1 day for meat and 24 hours for milk after epidural use of lidocaine, and 4 days for meat and 72 hours for milk after subcutaneous use of lidocaine. The NOP in 2007 agreed that double the FARAD or FDA withholding times are appropriate.

NOSB Vote: 2 Motions

To amend §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.

Motion 1: That the deleted language be removed and underlined language be added at:
§205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(4) Lidocaine - as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Motion Passed

Motion 2: That the deleted language be removed and underlined language be added at:
§205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(7) Procaine - as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals.

Motion: Jean Richardson

Second: Francis Thicke

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Motion Passed

**National Organic Standards Board
Livestock Subcommittee
Proposal - Annotation Change for Lidocaine and Procaine Use in Livestock Production
January 19, 2016**

I INTRODUCTION:

Lidocaine and Procaine are local anesthetics. They are used to reduce or prevent pain during de-budding horns in livestock, or general minor surgery on mature livestock. They numb only the area to be worked on. Humane treatment of animals is critically important and the public expects high standards of animal welfare for organic livestock. A lengthy withholding period after treatment may result in animals not being treated in a timely manner, or not being treated at all. Based on new information received during Sunset Review in 2015 and public comment, the NOSB proposes a recommendation to reduce the withholding period for both lidocaine and procaine from the present 90 days to 8 days for slaughter stock and 6 days for milk.

II BACKGROUND:

When added to the National List in 1995, there was no scientific rationale for the 90 day withholding, and the NOSB analysis in their document entitled "Local Anesthetics" provided very little information.

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

In December 2007, after much public comment and consultation, the NOP agreed that the NOSB could require double FDA withdrawal times, or double FARAD times (when appropriate), on a number of livestock materials .

"..... As a proposed compromise to satisfy the intent of the NOSB, many commenters suggested that USDA should consider amending the annotations of Atropine, Butorphanol, Flunixin, Furosemide, Tolazoline, and Xylazine by establishing extended withdrawal periods, calculated using withdrawal times from the Food Animal Residue Avoidance Databank(FARAD).The FARAD is a National Food Safety Project administered through the USDA Cooperative State Research, Education, and Extension Service. It is a system designed to provide livestock producers, extension specialists, and veterinarians with practical information on how to avoid drug, pesticide and environmental contaminant residue problems. FARAD is a repository of comprehensive residue avoidance information. It is also sanctioned to provide "withholding period" (also known as withdrawal period) estimates to the U.S. Pharmacopeia-Drug Information (USP-DI) Veterinary Medicine Advisory Committee. Commenters suggested that USDA account for an extra margin of at least double the withdrawal times of FARAD to safely capture the intent of the NOSB.USDA agrees with the position"

"...Based on public comment, USDA consulted further with the FDA, concerning the ability to extend the withdrawal period on these approved drugs. Based on our consultations, USDA agreed to clarify the rationale for extending the FDA established withdrawal period. Secondly, USDA agreed to clarify the language used to authorize the use of the substances by indicating the extended withdrawal periods (at least two-times that required by the FDA) were only relevant for use of the substances under the NOP regulations. Therefore, to clarify our rationale for extending the withdrawal periods established by the FDA, we acknowledge that this determination was not based on scientific research or risk assessments. The decision to extend

the FDA withdrawal periods (or any other withdrawal period) for the use of Flunixin and Furosemide (and other substances) was based on consumer preference and the recommendations of the NOSB. FDA exercises full responsibility for determining and enforcing the withdrawal intervals for animal drugs. No food safety arguments are used or implied to support the use of extended withdrawal periods authorized under the NOP regulations. Rather, we determined that extended withdrawal periods are more compatible with consumer expectations of organically raised animals“ (72 FR 70479) .

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Sunset Review took place in 2015, and lidocaine and procaine were approved for continued listing at the October 2015 NOSB Meeting in Stowe, Vermont. (On a motion to Remove, Vote 0:14)

III RELEVANT AREAS OF THE RULE:

Section 205.238 Livestock healthcare practice standard.

(a) The producer must establish and maintain preventive livestock healthcare practices, including ...

(5) performance of physical alterations as needed to promote the animal’s welfare and in a manner that minimizes pain and stress;

...

(c) The producer of an organic livestock operation must not: ...

(7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled or represented as organically produced.

Section §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable ...

(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

...

7) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

IV DISCUSSION:

During the 2015 Sunset Review of Lidocaine and Procaine the Livestock subcommittee was unable to find any record of the rationale for the very extended withdrawal period of 90 days for these materials when used on slaughter stock. Historical NOSB and NOP documents from 1995 to the present were reviewed. The December 2007 commentary (72 FR 70479) cited above implies that perhaps the 90 days is a doubling of the FDA or FARAD withholding period, but no such 45 day withholding was found in FDA or FARAD or other sources.

In FARAD the recommended withdrawal interval for lidocaine in cattle is listed as 1 day for meat and 24 hours for milk after epidural use of lidocaine, and 4 days for meat and 72 hours for milk after subcutaneous use of lidocaine.

FARAD provides information on procaine only as it relates to procaine with an antibiotic as part of delivery and thus it would not be used in organic production. Procaine on its own is apparently not readily available in the US and public comment from veterinarians only suggests a similarity with lidocaine. Procaine was recommended for continued listing because no public comment was provided to recommend its removal on any criteria. However procaine appears to be rarely used in organic livestock production.

During Review of these materials the NOSB in its initial request for public comment asked:

- * Since this material was last reviewed have alternative materials emerged?
- * What is the scientific rationale for what appears to be an excessively long withdrawal period?
- * Is there research to indicate that a shorter withdrawal period would be appropriate?

Public comment did not provide any alternatives to these materials, did not provide any scientific rationale for the lengthy withholding period, and recommendations were received suggesting that a very short withholding period would be scientifically acceptable. Public comment agreed with the rationale of using double the FARAD time for conventional production.

In contrast to butorphanol, which is a systemic anesthetic, lidocaine and procaine numb only the area to be worked on. Science indicates that the half-life of lidocaine and procaine in all animals studied is very short, typically less than one hour.

Based on new information and public comment during Sunset Review, the NOSB developed a Discussion Document to allow public comment on a possible annotation change. Public comment was received in Fall 2015 and discussion took place at the October 2015 NOSB meeting.

Public comment indicates that there appears to be broad public support from farmers, dairy organizations, industry groups and consumer groups to reduce the withholding period in order to ensure humane treatment of animals. The public finds that a 90 day withholding period is far in excess of the withholding period used in conventional livestock production. Public comment supports a recommendation for slaughter stock withholding period of 8 days, which is double the FARAD recommendation for subcutaneous use in conventional livestock. The public supports a recommendation for withholding for milk of 6 days, which is double the FARAD recommendation of 72 hours (3 days) for conventional milk production.

V RECOMENDATION:

To amend Section 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals

(7) Procaine —as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals.

Sub Committee Vote : - Two Motions

1. That the deleted language be removed and underlined language added at:
205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals

Motion: Jean Richardson

Second: Francis Thicke

Vote: 6 Yes 0 No 0 Abstain 0 Absent 0 Recuse

2. That the deleted language be removed and underlined language added at:

205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(7) Procaine —as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals.

Motion: Jean Richardson

Second: Francis Thicke

Yes: 6 No: 0 Abstain: 0 Absent: 0 Recuse: 0