

**National Organic Standards Board
Livestock Subcommittee
Discussion Document
Annotation Change for Lidocaine and Procaine Use in Livestock Production
July 31, 2015**

I INTRODUCTION

Lidocaine and Procaine are local anesthetics. They are used to reduce or prevent pain during de-budding horns in calves, or general minor surgery on mature cows. 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 may result in animals not being treated in a timely manner, or not treated at all. Based on new information received during Sunset Review of these materials the Livestock subcommittee requested a Technical Report on Lidocaine and Procaine for use in organic livestock production, and seeks public comment on a possible annotation change to reduce the withholding period from 90 days to 8 days for slaughter stock.

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. The NOSB had not requested a Technical Report on these materials until this summer.

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](#))

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.

Lidocaine: §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

Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))
Sunset Date: 6/27/2017

Procaine: §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 after administering to livestock intended for slaughter and 7 days after administering to dairy animals

Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))
Sunset Date: 6/27/2017

IV DISCUSSION

During the present Sunset Review of Lidocaine and Procaine the Livestock subcommittee was unable to find any record of the rationale for the much 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 for subcutaneous use of lidocaine it is 4 days for meat and 72 hours for milk.

FARAD provides information on procaine only as it relates to procaine combined with an antibiotic 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. Further information on procaine is needed.

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

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

Public comment did not provide any alternatives, did not provide any scientific rationale for the lengthy withholding period, and recommendations were received suggesting that a very short withholding period, such as 5 days would be scientifically acceptable.

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.

There appears to be public support to reduce the Withholding period in order to ensure humane treatment of animals. The 90 day withholding period is far in excess of the withholding period used in conventional livestock production.

The Livestock subcommittee has requested a Technical Report on lidocaine and procaine used in livestock production. Following receipt of public comment in response to this Discussion Document, and the findings presented in the Technical Report, the NOSB may develop a Proposal to amend the withholding period of lidocaine and procaine.

V REQUEST FOR PUBLIC COMMENT

1. Is Lidocaine widely used; under what circumstances is it used; how is it administered; should the withholding period be the same in all animal species?
2. Is Procaine used; under what circumstances; how is it administered; should the withholding period be the same in all animal species?
3. Should the annotation for Lidocaine at 205.603(b) be amended as follows?

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 after administering to dairy animals

4. Should the annotation for Procaine at 205.603(b) be amended as follows?

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 after administering to dairy animals.

Motion to change annotations for lidocaine and procaine on §205.603

Motion: Jean Richardson

Seconded by: Francis Thicke

Yes: 4 No: 0 Abstain: 0 Absent: 2 Recuse: 0