

**FORMAL RECOMMENDATION BY THE
NATIONAL ORGANIC STANDARDS BOARD (NOSB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)**

Date: 11-5-09

Subject: Xylazine

Chair: Jeff Moyer

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: _____

Guidance Statement: _____

Other: Clarify annotation to correct mistake made by NOSB on
Wednesday Sept. 18, 2002

Summary Statement of the Recommendation (including Recount of Vote):

This recommendation is to clarify the annotation for xylazine which was made by the Board on Wednesday September 18, 2002. The petitioners were not asked if the annotation would be acceptable and consistent with what the petitioners were seeking with the material, but a Board member made a motion to change the annotation, which was seconded, and the entire Board then voted on the material.

The original petitioner, who now sits on the current Board and is part of the Livestock Committee, is seeking to delete the faulty annotation that was created in 2002.

NOSB Vote: Motion: Hubert Karreman Second: Dan Giacomini

Board vote: Yes - 13 No- 0 Abstain- 0 Absent - 1

Summary Rationale Supporting Recommendation (including consistency with OFPA and NOP):

See above

Also, in an e-mail from OGC (via NOP) on March 24, 2009, it was stated: "In terms of the board recommending a substance to be added to the national list without a petition, (An OGC person sees) nothing in the OFPA or NOP regulations that would prohibit such action. (Another OGC person) agrees as well, and indicated that he believes the original NL was created by the board without any petitions. In either event, it would seem like the board's primary function is to make recommendations concerning the NL (to add, remove, renew, etc.) and that petitions are just one mechanism through which the board can make such recommendations."

Response by the NOP:

National Organic Standards Board (NOSB)
Livestock Committee
RECOMMENDATION TO CHANGE ANNOTATION OF
XYLAZINE 205.603(a)(23)

November 5, 2009

Current 205.603(a)(23)

(23) Xylazine (CAS -7361-61-7)--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;
- (ii) The existence of an emergency; and
- (iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Introduction:

This recommendation seeks to more closely reflect the use of xylazine by veterinarians to use with certified organic livestock. Xylazine is the only alpha-2 agonist approved for organic livestock, which means it is the only one available for sedation of animals to carry out procedures, both during emergencies and non-emergencies. The goal of this change in annotation is to delete part (ii) "The existence of an emergency". For the purposes of this document, an emergency may be defined as an unplanned event requiring immediate action. In fact, there are simply many more times that xylazine is needed for scheduled/planned procedures as compared to actual emergencies. While the intent of this recommendation is to delete (ii), the other annotations (i) and (iii) will not be altered.

Background:

Only veterinarians can procure xylazine as it is a prescription medication. It is an extremely valuable tool in the sedation of ruminants in order to carry out procedures since it causes profound sedation for short periods and, to a lesser degree, analgesia. It is a critically important tool for any veterinarian to be able to use for livestock work as it can effectively immobilize an animal so that neither the animal nor the veterinarian (and assistants) get injured.

It should be noted that xylazine is the only listing on 205.603 which requires "the existence of an emergency". How this term came about is quite interesting and goes back to the discussions of September 18, 2002 (official transcript pgs.559-597). An overview of that discussion follows.

Initially xylazine was petitioned such that it could only be used "once in the lifetime" of an animal. Early on during the voting motion to allow xylazine, a friendly amendment to remove the annotation of "once in a life time" was made by a Board member and the motion passed. Then through a long discussion that was punctuated by a lot of

wonderings about how xylazine is used by veterinarians, how the Board should not interfere with the professional judgment of veterinarians, and not wanting to allow any synthetic to be used routinely, someone then suggested through all the discourse that “the existence of an emergency” seemed to be what the Board was trying to get at. And the annotation was then inserted. Whether an official amendment to add such wording is unclear. It is also not clear if the petitioners were asked by the Board if the insertion was workable.

Interestingly, the next petitioned substance the Board tackled that day was butorphanol (an opioid agonist/ antagonist with properties parallel to morphine when used in livestock). In that discussion, the term “the existence of an emergency” was specifically pulled out since butorphanol is used during and after surgery for pain relief primarily – and not all surgeries are true emergencies (as defined in the Introduction of this recommendation). For example, the operation to correct a left displaced abomasum in a cow is not an emergency per se whereas a cesarean section almost always is in veterinary medicine. Yet strong pain relief, such as afforded by butorphanol, is indicated in both situations. During the discussion, Board members wondered if lidocaine (on the list already) would be sufficient. The answer came back that, no, it wouldn't be because it was only a local anesthetic while butorphanol is systemic in its action. In reading the transcripts it is apparent that the Board in general had a discussion consisting of greater continuity with butorphanol than they did with xylazine and that a more clear line of logic was followed. The term “the existence of an emergency” was dropped for butorphanol due to the realization that there will be times that such medicine will be needed without an outright emergency occurring. This is absolutely true for xylazine as well.

Xylazine is actually used more for non-emergency sedation purposes (planned procedures) and less in actual outright emergencies. For instance, if a dairy cow's teat is damaged (for whatever reason) and the teat canal needs opening, xylazine would definitely be indicated so the animal doesn't kick the veterinarian in the head when performing the procedure. Is it an emergency? No. More commonly, if older animals with larger horns are to be dehorned, xylazine is critical for the proper sedation and restraint of the animal. Is it an emergency? No. And, on rare occasion, a very fractious animal may need xylazine to allow examination for pregnancy. Is it an emergency? No. Other types of odd and occasional situations could be described that occur but are not outright emergencies. Yet the letter of the law states that xylazine can *only* be used in emergencies. Unfortunately, there are no other materials on the National List that provide the pharmacologic action that xylazine provides for effective sedation. Looking back to the September 18, 2002 transcripts, it shows a Board member asking for no annotations on medicines such as xylazine or butorphanol since they are only to be used by veterinarians anyway i.e. let the medically trained professional decide why and how best to use the prescription medicine. It should be emphasized that no other material on 205.603, other than xylazine, is limited to emergency use only. Xylazine, for the reasons and examples stated above, should not be tied to such a severe limitation.

Relevant areas in the Rule:

Xylazine has already gone through the public process of being approved by the NOSB at 205.603(a)(23).

Additionally, the change in annotation would help to strengthen the implementation of 205.239(a)(4): Provision of conditions which allow for exercise, freedom of movement, and reduction of stress appropriate to the species; Example: sedating a highly stressed,

fractious animal which needs to be examined out in the pasture due to a cut from a fence that happened a couple days ago.

The proposed change in annotation would also assist in the appropriate implementation of 205.239(a)(5): The producer must establish and maintain preventive livestock health care practices, including: Performance of physical alterations as needed to promote the animal's welfare and in a manner that minimizes pain and stress. Example: any time a physical alteration that requires immobilization of an animal, such as during dehorning mature animals or castrating older animals.

Recommendation:

205.603(a)(23):

(23) Xylazine (CAS -7361-61-7)--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 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Committee Vote:

Motion: Tina Ellor **Second:** Jeff Moyer

Yes: 7 No: 0 Abstain: 0 Absent: 0