

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

Date: Nov. 5, 2009

Subject: Chlorhexidine

Chair: Jeff Moyer

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: _____
Guidance Statement: _____
Other: Material Annotation Technical Corrections & Clarifications

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

This recommendation seeks to modify one of the annotations associated with Chlorhexidine to reflect how it is commonly utilized as an antiseptic, to help avoid using antibiotics.

At the October 1999 meeting of the NOSB chlorhexidine was voted to be allowed with the annotation "for medical procedures conducted under the supervision of a licensed veterinarian". No mention was made about limiting it to surgical procedures conducted by a veterinarian. Indeed, the wording of the original annotation that the NOSB passed would nearly accomplish the goal stated in the Introduction (farmers should also be able to use it).

NOSB Vote: **Motion:** Hubert Karreman **Second:** Kevin Englebert
Board vote: Yes - 13 No- 0 Abstain- 0 Absent - 2

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
CHLORHEXIDINE 205.603(a)(6)
September 9, 2009

Current 205.603(a)(6):

(6) **Chlorhexidine**--Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

Introduction:

Chlorhexidine is a common disinfectant used by the medical profession for hygiene purposes. Chlorhexidine comes commercially prepared as an antiseptic solution, surgical scrub, ointment, teat dip and other formulations. As annotated it is *only* allowed as an alternative teat dip and for surgical purposes conducted by a veterinarian. Chlorhexidine's excellent germicide properties can be critical to the effective cleansing of infected areas and body lesions, conditions which occur independent of surgical procedure or teat dipping. It can be gentler than iodine and potentially causing less inflammation on the surface to which it is applied. This recommendation seeks to more closely reflect the use of chlorhexidine by veterinarians and farmers for antiseptic purposes and hygienic cleansing of wounds that may be encountered when tending animals. As currently annotated, veterinarians and farmers cannot use it other than during surgery or as an alternative teat dip. It should be stated that this recommendation does not in any way intend to alter the second sentence which refers to chlorhexidine as an alternative teat dip.

Background:

It has come to the attention of various people in the livestock health care community that the limits upon the use of chlorhexidine as annotated in 205.603(a)(6) reduce the options for treating wounds and other infected areas of livestock. The limitation that only veterinarians can use it only for surgical procedures is overly restrictive as chlorhexidine can be used to cleanse very infected areas needing medical attention and thus potentially preclude the need for reverting to antibiotics. For example, a mature animal being de-horned may later become infected at the site of dehorning. While the farmer will often try home remedies first, a call to the veterinarian is often placed when the infection does not subside. Vigorous scrubbing with chlorhexidine impregnated sponges will often cleanse the area well enough that antibiotics don't have to be used (as would be likely done in the conventional sector). This is exactly why the annotation needs to change since the example of cleansing an infected dehorning site would not be technically allowed due to it not being a surgery per se.

In fact, at the October 1999 meeting of the NOSB, chlorhexidine was voted to be allowed with the annotation "for medical procedures conducted under the supervision of a licensed veterinarian". No mention was made about limiting it to surgical procedures conducted by a veterinarian. Indeed, the wording of the original annotation that the NOSB passed would nearly accomplish the goal stated in the Introduction (farmers should also be able to use it).

Relevant areas in the Rule:

Chlorhexidine has already gone through the public process of being approved by the NOSB (and renewed through sunset in 2007) at 205.603(a)(6). At the time of sunset review, the Board was specifically told that annotations could not be changed.

Additionally, the change in annotation would help to strengthen the implementation of 205.239(a)(3): The producer must establish and maintain preventive livestock health care practices, including: Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites. Example: an infected area on an animal needs to be thoroughly cleansed to minimize the occurrence of disease.

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 physical alteration, such that may cause bleeding at the time of the procedure and open an area to infection could be properly addressed by usage of chlorhexidine as a germicide.

Recommendation:

205.603(a)(6) Chlorhexidine--Allowed as a germicide for medical and surgical procedures. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

Committee Vote:

Motion: Tina Ellor

Seconded: Jeff Moyer

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