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

Date: **April 29, 2010**

Subject: **Sunset Review of National List substances (§205.603) allowed in livestock production**

Chair: **Daniel G. Giacomini_** **_____**

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: _X_ __
Guidance Statement: _____
Other: ____ _ ___

Summary Statement of the Recommendation (including Recount of Vote)**:** The NOSB voted to renew 26 substances in section 205.603 of the National List, with Iodine recommended for use in 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable *and* 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable. The NOSB voted to defer action on eight (8) substances in section 205.603 of the National List.

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

Board vote: Yes - 14 No - 0 Abstain - 0 Absent - 1

Summary Rationale Supporting Recommendation (including consistency with OFPA and NOP)**:** Statements from the Livestock Committee explaining the rationale, supported through NOSB action, precedes the recommendation presented below.

Response by the NOP:

NOSB Livestock Committee – Sunset Recommendation – 2012

I. List: 205.603 Synthetic substances allowed for use in organic livestock production

II. Category Uses

(a) As disinfectants, sanitizers, and medical treatments as applicable
(b) As topical treatment, external parasiticide or local anesthetic as applicable
(c) As feed supplements
(d) As feed additives
(e) As synthetic inert ingredients
(f) As excipients

III. Committee Summary

To abide the current rules for the Sunset process, for the Livestock Committee to put forth a recommendation that would allow a material on the National List to expire, significant evidence must be found by the Committee or presented by the public that there is no further need for the substance, because naturals exist that can supplant their use. Or, evidence must exist that a substance fails the criteria by which it was originally put on the National List. Public comment against a material on the National List is not sufficient to recommend removal. Also, clarification of or changes to the annotation of a material cannot be dealt with during the Sunset process; a new petition would need to be submitted and handled through the regular petition process.

Given the constraints of the current Sunset Review process, the Livestock Committee determined which of the materials on 205.603 had enough current information to recommend re-listing, and which materials needed further technical information (TRs). The committee received no evidence from the public that would indicate an individual material should be allowed to sunset, either because a natural now exists that would supplant its use, or because there is new evidence that it now fails the criteria for listing. The materials presently recommended for re-listing include their current annotation.

DL-Methionine does not appear in this Sunset Review because it was re-petitioned on July 31, 2009 with a different annotation and, therefore, will be handled through the regular petition process.

IV. Committee Recommendations:

The Livestock Committee recommends the renewal of the following substances in the use category 205.603.

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

(3) Atropine (CAS #–51–55–8)—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:

(i) Use by or on the lawful written order of a licensed veterinarian; and

(ii) A meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.

(4) Biologics—Vaccines.

(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.

(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.

(8) Electrolytes—without antibiotics.

(9) 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.

(13) Hydrogen peroxide.

(14) Iodine.

(15) 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.

(17) Oxytocin—use in postparturition therapeutic applications.

(18) Paraciticides. Ivermectin—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(19) Peroxyacetic/peracetic acid (CAS #–79–21–0)—for sanitizing facility and processing equipment.

(20) Phosphoric acid—allowed as an equipment cleaner, *Provided* , That, no direct contact with organically managed livestock or land occurs.

(21) 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.

(22) Tolazoline (CAS #–59–98–3)—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) Use only to reverse the effects of sedation and analgesia caused by Xylazine; 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.

(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.

The Livestock Committee recommends deferral of the vote on the following materials in this use category until further technical information is obtained:

(1) Alcohols.

(i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive.

(ii) Isopropanol-disinfectant only.

(2) Aspirin-approved for health care use to reduce inflammation.

(7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

(10) Furosemide (CAS #–54–31–9)—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 that required by the FDA.

(11) Glucose.

(12) Glycerine—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

(16) Magnesium sulfate.

The Livestock Committee recommends not renewing the following substances in this use category:

None

The Livestock Committee recommends the renewal of the following substances in the use category 205.603.
(b) As topical treatment, external parasiticide or local anesthetic as applicable:

(2) Iodine.

(3) 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.

(4) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.

(5) Mineral oil—for topical use and as a lubricant.

(6) 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.

(7) Sucrose octanoate esters (CAS #s–42922–74–7; 58064–47–4)—in accordance with approved labeling.

The Livestock Committee recommends deferral of the vote on the following materials in this use category until further technical information obtained:

(1) Copper sulfate

The Livestock Committee recommends not renewing the following substances in this use category:

None

The Livestock Committee recommends the renewal of the following substances in the use category 205.603.
(c) As feed supplements:

None

The Livestock Committee recommends deferral of the vote on the following materials in this use category until further technical information is obtained:

None

The Livestock Committee recommends not renewing the following substances in this use category:

None

The Livestock Committee recommends the renewal of the following substances in the use category 205.603.
(d) As feed additives:

(2) Trace minerals, used for enrichment or fortification when FDA approved.

(3) Vitamins, used for enrichment or fortification when FDA approved.

The Livestock Committee recommends deferral of the vote on the following materials in this use category until further technical information is obtained:

None

The Livestock Committee recommends not renewing the following substances in this use category:

None

The Livestock Committee recommends the renewal of the following substances in the use category 205.603.
(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic 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.

None

The Livestock Committee recommends deferral of the vote on the following materials in this use category until further technical information is obtained:

(1) EPA List 4—Inerts of Minimal Concern.

The Livestock Committee recommends not renewing the following substances in this use category:

None

The Livestock Committee recommends the renewal of the following substance in the use category 205.603.
(f) Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Appliction or New Drug Appliction.

The Livestock Committee recommends deferral of the vote on the following materials in this use category until further technical information is obtained:

None

The Livestock Committee recommends not renewing the following substances in this use category:

None

Moved: Dan Giacomini Second: Wendy Fulwider

Committee vote: 6 - yes; 0 - no; 2 - absent; 0 - abstain

Kevin K. Engelbert, Chair

NOSB Vote:

Motion: Jeff Moyer

Second: Tina Ellor

Yes: 14 No: 0 Absent: 1 Abstain: 0