Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP)

Date: October 28, 2010

Subject: Sunset Review of National List Substances (§205.603) allowed

in livestock production

Chair: Dan Giacomini

The NOSB hereby recommends to the NOP the following:

Rulemaking Action X
Guidance Statement
Other

Statement of the Recommendation (Including Recount of Vote):

At the Spring 2010 Meeting, 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. Because of ongoing discussions with the Environmental Protection Agency regarding EPA List 4-Inerts of Minimal Concern, that substance was voted on again at the Fall 2010 Meeting. As a result, there are nine (9) substances listed in the recommendation. The eight deferred substances were deferred until the Fall 2010 pending new Technical Reviews. Even though the new TRs were not forthcoming in time for the Fall meeting, given that all public comment received was in favor of relisting these substances, the NOSB voted to renew the additional Sunset 2012 substances on §205.603 of the National List.

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.

NOSB Vote:

| Moved: Kevin Engelbert | | Second: | Second: Jeff Moyer | | | | |
|------------------------|-------|----------|--------------------|---------|---|----------|---|
| Yes: 14 | No: 0 | Abstain: | 0 | Absent: | 0 | Recusal: | 0 |

National Organic Standards Board Livestock Committee Section 205.603 2012 Sunset Recommendation

July 27, 2010

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

Category Uses

- (a) As disinfectants, sanitizers, and medical treatments as applicable
- (b) As topical treatment, external parasiticide or local anesthetic as applicable
- (e) As synthetic inert ingredients

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.

There were eleven (11) materials deferred at the Spring 2010 NOSB Meeting pending new Technical Reviews (TRs), and one (1) material deferred pending the outcome of the collaborative effort between the NOSB Crops Committee and the Environmental Protection Agency (EPA) regarding List 4 Inerts. For further clarification on List 4 Inerts, please reference the NOSB final recommendation from the April 26-29, 2010 meeting. The TRs in question will not be available for review by the Livestock Committee until early 2011. Even though List 4 Inerts not longer technically exist, they are still recognized by the general public, and will be until a new list, appropriately labeled, becomes available.

Rather than defer these votes again, until the Spring 2011 meeting, a majority of the Livestock Committee believes, given the current Sunset process rules, that the deferred materials should remain on the National List.

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:
 - (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 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.

- (b) As topical treatment, external parasiticide or local anesthetic as applicable:
 - (1) Copper Sulfate

The Livestock Committee recommends deferral of the vote on the following materials in this use category until further technical information 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.
 - (1) EPA List 4---Inerts of Minimal Concern.

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

Committee Vote:

Motion: Daniel Giacomini Second: Jennifer Hall Yes: 6 No: 1 Abstain: 0 Absent: 1