

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

Date: November 17, 2005

Subject: Sunset review of National List substances used in livestock production

Chair: Jim Riddle

(sign)

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

Guidance Statement:

Other: X

Statement of the Recommendation (including Recount of Vote): The NOSB voted to renew 20 substances on section 205.603 of the National List. The NOSB voted to defer action on 7 substances on 205.603. The NOSB voted to renew 1 substance on 205.604, with none deferred. Votes were taken on each subsection. A complete list of the recommendations to renew and defer appears below, along with the vote totals for each subsection.

Rationale Supporting Recommendation (including consistency with OFPA and NOP): Statements from the Livestock Committee explaining the rationale supported through NOSB action precede each of the recommendations presented below. A compilation of all deferred substances, complete with specific questions identified by the NOSB, are submitted to the NOP under separate cover.

Response by the NOP:

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

II. Category Use

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

III. Committee Summary: Some commentors were proponents of keeping all materials on list 205.603. Of those commentors who mentioned specific substances within this use category, the continued listings of alcohols – ethanol and isopropanol, aspirin, biologics – vaccines, chlorhexidine, chlorine materials – calcium hypochlorite, chlorine dioxide and sodium hypochlorite, electrolytes – without antibiotics, glucose, glycerine, hydrogen peroxide, iodine, magnesium sulfate, oxytocin and phosphoric acid were specifically mentioned. Several commentors stated that chlorhexidine, chlorine materials (calcium hypochlorite, chlorine dioxide, sodium hypochlorite), oxytocin, ivermectin, and, hydrogen peroxide should be removed from the list. Several commentors also requested clarification of the annotations for iodine and phosphoric acid. The purpose of the 5–year sunset review process is specifically for the renewal or removal of materials from the National List. Clarification of or changes in the annotation of a material will need to be submitted as a new petition and handled through the regular petition process to add or remove substances from the National List. The Committee disagrees with the commentors who recommend the removal of chlorhexidine from the list. The specific reasons given for removal (greater toxicity than other teat dip material on the national list) does not apply to the first annotation (allowed for surgical procedures conducted by a veterinarian). To address the concerns of the commentor, a change to the annotation would be required rather than removal from the National List. The Livestock Committee agrees with the commentors who supported the renewal of alcohols (ethanol and isopropanol), aspirin, biologics – vaccines, chlorhexidine, chlorine materials (calcium hypochlorite, chlorine dioxide and sodium hypochlorite,) electrolytes – without antibiotics, glucose, glycerine, hydrogen peroxide, iodine, magnesium sulfate, and phosphoric acid because their use does not negatively impact humans or the environment, is considered essential for organic production and is compatible with organic production practices. The Committee neither agrees nor disagrees with the commentors concerning oxytocin or ivermectin. These two materials are being deferred until additional information is obtained. One commentor stated that all synthetic substances should be prohibited for use in organic production; however, no evidence or rationale on how any of those substances violated OFPA was provided.

IV. Committee Recommendation(s):

Recommendations Based upon Comments Received – 205.603(a)

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

- (1) Alcohol
 - (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.
- (3) Biologics—Vaccines.

- (4) 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.
- (6) Electrolytes—without antibiotics.
- (7) Glucose.
- (8) Glycerine—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.
- (9) Hydrogen peroxide.
- (10) Iodine.
- (11) Magnesium sulfate.
- (14) Phosphoric acid—allowed as an equipment cleaner, *provided*, that, no direct contact with organically managed livestock or land occurs.

The Livestock Committee recommends deferring the vote on the following materials until further technical information is obtained. The materials to be deferred are:

- (5) 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) Calcium dioxide.
 - (iii) Sodium hypochlorite.
- (12) Oxytocin—use in postparturition therapeutic applications.
- (13) Parasiticides. 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 of breeding stock.

The Livestock Committee recommends not renewing the following substances:

None in this category

Moved: Nancy Ostiguy Second: Hue Kerriman

Committee vote: 5-yes; 0 no; 0 abstain

Recommendations Made that are Not Based upon Comments Received – 205.603(a)

None in this category

Moved: Nancy Ostiguy Second: Hue Kerriman

Committee vote: 5-yes; 0 no; 0 abstain

NOSB vote: 14 yes, 0 no

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

II. Category Use

(b) As topical treatment, external parasiticide or local anesthetic as applicable.

IV. III. Committee Summary: Some commentors were proponents of keeping all materials on list 205.603. Many commentors supported the continued listing of copper sulfate, iodine, lidocaine, hydrated lime, mineral oil, and procaine. One commentor objected to the continued listing of hydrated lime because it is too harsh of a chemical to allow for direct contact with animals as a pest control agent, and it is hazardous to the humans who handle it. Some commentors requested clarification of the types of iodine that may be used in organic production. The purpose of the sunset review process is specifically to determine renewal or removal of materials from the National List. Clarification of or changes in the annotation of a material will need to be submitted as a new petition and handled through the regular petition process to add or remove substances from the National List. The Livestock Committee agrees with the commentors recommending the renewal of copper sulfate, iodine, lidocaine, mineral oil and procaine because their use does not negatively impact humans or the environment, is considered essential for organic production and is compatible with organic production practices. The Committee neither agrees nor disagrees with the commentors recommending the removal of hydrated lime from the National List. This material is being deferred until additional information is obtained. One commentor stated that all synthetic substances should be prohibited for use in organic production; however, no evidence or rationale on how any of those substances violated OFPA was provided.

IV. Committee Recommendation(s):

Recommendations Made that are Based upon Comments Received – 205.603(b)

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

- (1) Copper sulfate.
- (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.
- (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.

The Livestock Committee recommends deferring the vote on the following substances until further technical information is obtained:

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

The Livestock Committee recommends not renewing the following substances:

None in this category

Moved: Nancy Ostiguy Second: Hue Kerriman
Committee vote: 5-yes; 0 no; 0 abstain

Recommendations Made that are Not Based upon Comments Received – 205.603(b)

None in this category

Moved: Nancy Ostiguy Second: Hue Kerriman
Committee vote: 5-yes; 0 no; 0 abstain
NOSB vote: 14 yes, 0 no

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

II. Category Use

(c) As feed supplements

V. III. Committee Summary: Some commentors were proponents of keeping all materials on list 205.603. Of those commentors who mentioned specific substances within this use category, the continued listing of milk replacers was mentioned. Many commentors supported the continued use of milk replacers. One commentor asked why non-organic milk replacer needs to be on the National List as organic milk replacers are available. The Livestock Committee neither agrees nor disagrees with the commentors concerning milk replacers. This material is being deferred until additional information is obtained. One commentor stated that all synthetic substances should be prohibited for use in organic production; however, no evidence or rationale on how any of those substances violated OFPA was provided.

IV. Committee Recommendation(s):

Recommendations Made that are Based upon Comments Received – 205.603(c)

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

None in this category

The Livestock Committee recommends deferring the vote on the following substances until further technical information is obtained:

Milk replacers—without antibiotics, as emergency use only, no nonmilk products or products from BST treated animals.

The Livestock Committee recommends not renewing the following substances:

None in this category

Moved: Nancy Ostiguy Second: Hue Kerriman

Committee vote: 5-yes; 0 no; 0 abstain

Recommendations Made that are Not Based upon Comments Received – 205.603(c)

None in this category

Moved: Nancy Ostiguy Second: Hue Kerriman

Committee vote: 5-yes; 0 no; 0 abstain

NOSB vote: 14 yes, 0 no

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

II. Category Use

(d) As feed additives.

VI.III. Committee Summary: Some commentors were proponents of keeping all materials on list 205.603(d). Of those commentors who mentioned specific substances within this use category, the continued listing of trace minerals and vitamins were mentioned. None of the commentors specifically stated that trace minerals and vitamins use in organic production should be discontinued. The Livestock Committee agrees with the commentors that use of trace minerals and vitamins should be continued because their use does not negatively impact humans or the environment, is considered essential for organic production and is compatible with organic production practices. One commentor stated that all synthetic substances should be prohibited for use in organic production; however, no evidence or rationale on how any of those substances violated OFPA was provided.

IV. Committee Recommendation(s):

Recommendations Made that are Based upon Comments Received – 205.603(d)

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

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

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

The Livestock Committee recommends deferring the vote on the following substances until further technical information is obtained:

None in this category.

The Livestock Committee recommends not renewing the following substances:

None in this category

Moved: Nancy Ostiguy Second: Hue Kerriman

Committee vote: 5-yes; 0 no; 0 abstain

Recommendations Made that are Not Based upon Comments Received – 205.603(d)

None in this category

Moved: Nancy Ostiguy Second: Hue Kerriman

Committee vote: 5-yes; 0 no; 0 abstain

NOSB vote: 14 yes, 0 no

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

II. Category Use

(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.

VII. III. Committee Summary: Some commentors were proponents of keeping all materials on list 205.603(e). Of those commentors who mentioned specific substances within this use category, the continued listing of EPA List 4 inerts was mentioned. None of the commentors specifically stated that use of EPA List 4 inerts in organic production should be discontinued. The Livestock Committee agrees with the commentors recommending the renewal of EPA List 4 inerts because their use does not negatively impact humans or the environment, is considered essential for organic production and is compatible with organic production practices. One commentor stated that all synthetic substances should be prohibited for use in organic production; however, no evidence or rationale on how any of those substances violated OFPA was provided.

IV. Committee Recommendation(s):

Recommendations Made that are Based upon Comments Received – 205.603(e)

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

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

The Livestock Committee recommends deferring the vote on the following substances until further technical information is obtained:

None in this category.

The Livestock Committee recommends not renewing the following substances:

None in this category

Moved: Nancy Ostiguy Second: Hue Kerriman

Committee vote: 5-yes; 0 no; 0 abstain

Recommendations Made that are Not Based upon Comments Received – 205.603(e)

None in this category

Moved: Nancy Ostiguy Second: Hue Kerriman

Committee vote: 5-yes; 0 no; 0 abstain

NOSB vote: 14 yes, 0 no

I. List: 205.604 Nonsynthetic substances prohibited for use in organic livestock production

II. Category Use

(a) Strychnine

VIII. III. Committee Summary: Some commentors specifically mentioned that strychnine should remain as a prohibited substance on the National List. The Livestock Committee agrees with the commentors that strychnine should remain as a prohibited substance on the National List because its use negatively impacts humans and the environment, is not considered essential for organic production and is not compatible with organic production practices.

IV. Committee Recommendation(s):

Recommendations Made that are Based upon Comments Received – 205.604

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

(a) Strychnine.

The Livestock Committee recommends deferring the vote on the following substances until further technical information is obtained:

None in this category.

The Livestock Committee recommends not renewing the following substances:

None in this category

Moved: Nancy Ostiguy Second: Hue Kerriman

Committee vote: 5-yes; 0 no; 0 abstain

Recommendations Made that are Not Based upon Comments Received – 205.604

None in this category

Moved: Nancy Ostiguy Second: Hue Kerriman

Committee vote: 5-yes; 0 no; 0 abstain

NOSB vote: 14 yes, 0 no