

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

Date: November 17, 2005

Subject: Sunset review of nonsynthetic National List substances used in handling

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 19 substances on section 205.605(a) of the National List. The NOSB voted to defer action on 2 substances on 205.605(a). A complete list of the recommendations to renew and defer appears below, along with the vote totals for the subsection.

Rationale Supporting Recommendation (including consistency with OFPA and NOP): Statements from the Handling Committee explaining the rationale supported through NOSB action are included in the recommendation 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: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food groups.”

(a) Nonsynthetics allowed

II. Committee Summary: Many commenters are proponents of keeping all materials on list 205.605 a. In addition, each substance on the list received many specific comments recommending their continued allowance in organic handling. One substance, yeast, had several comments supporting the continued use of this material, however a few comments objected to its continued use.

There were comments submitted supporting the continued use of agar-agar and tartaric acid. Both materials were listed in the Federal Register ANPR for Sunset Review, but because these materials were not on the December 21, 2000, National List, they are not to be considered as part of this Sunset review.

A few commenters stated that it was inappropriate for Section 205.605(a) of the National List to retain yeast for handling production because the commenters believe that this material is agricultural. The handling committee believes that the issue of agricultural versus non-agricultural is not in the scope of the Sunset process, therefore we recommend the continued use of this material.

III. Committee Recommendation(s):

The handling committee recommends the renewal of the following substances in this use category as published in the final rule:

- Acids (Alginic; Citric - produced by microbial fermentation of carbohydrate substances; and Lactic).
- Bentonite
- Calcium carbonate
- Calcium chloride
- Carageenan
- Dairy cultures
- Diatomaceous earth-food filtering aid
- Enzymes -must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.
- Kaolin
- Magnesium Sulfate, nonsynthetic sources only.
- Nitrogen-oil-free grades
- Oxygen-oil free grades
- Perlite- for use only as a filter aid in food processing
- Potassium chloride
- Potassium iodide
- Sodium bicarbonate
- Sodium carbonate

Waxes-nonsynthetic (Carnauba wax; and Wood resin).

Yeast - nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited (Autolysate; Bakers; Brewers; Nutritional; and Smoked - nonsynthetic smoke flavoring process must be documented).

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

Colors-nonsynthetic sources only

Flavors- nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

At the time these materials were added to the National List, there was no technical review conducted (i.e. TAP). The NOSB has determined that these materials warrant a more in-depth review and require additional technical information. The NOSB has requested TAP reviews for these materials in order to make recommendations for their continued use or prohibition.

The handling committee recommends not renewing the following substances in this use category based on the submitted evaluation forms:

None in this category

Moved: Julie Weisman Second: Bea James

Committee vote: 4 yes, 0 no, 1 absent

Board vote: 14 yes, 0 no

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

Date: November 17, 2005

Subject: Sunset review of synthetic National List substances used in handling

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 34 substances on section 205.605(b) of the National List. The NOSB voted to defer action on 2 substances on 205.605(b). The NOSB voted to remove 1 substance from 205.605(b). A complete list of the recommendations to renew and defer appears below, along with the vote totals for the subsection.

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

Statements from the Handling Committee explaining the rationale supported through NOSB action are included in the recommendation 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: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food groups.”

(b) Synthetics allowed

II. Committee Summary: Many commenters are proponents of keeping all materials on List 205.605 b. In addition, each substance on the list received many specific comments recommending their continued allowance in organic handling.

Many commenters supported, while one commenter objected, to the continued use of lecithin-bleached. One commenter stated that organic soy lecithin is now readily available; therefore lecithin-bleached should be removed from the list. The federal register notice (re- Sunset Review) asked commenters to provide evidence concerning viable alternatives for the substance they believed should be discontinued. Evidence was not supplied to support the comment regarding removal of lecithin-bleached, such as supply source, supply quantity, functionality, performance, test data and name and address of producers who have used the alternative under similar conditions. As a result, the handling committee recommends deferring this substance until further information can be obtained.

Many commenters supported, while one commenter objected, to the continued use of ethylene. The handling committee discussed the content of the objection and determined that the information presented in the objection was not new and did not provide evidence as requested in the federal register sunset review notice to support non renewal of ethylene. Also the 1999 TAP for ethylene properly considered and addressed the concerns of the objection.

Some commenters supported the continued use of “potassium tartrate made from tartaric acid” while one commenter objected. The commenter stated that this substance was improperly identified. NOSB commissioned one TAP review in 1995 on “potassium tartrate” and the review intent was to consider the substance known as “cream of tartar” which is properly known as potassium acid tartrate. Referencing “NOSB Processing Materials Decisions, June 2001” which states that potassium acid tartrate was also called potassium tartrate made from tartaric acid, the handling committee recommends not renewing the later substance because of duplication.

Some commenters requested a change in classification and/or annotation for certain materials, including glycerin, xanthan gum and tocopherols. In addition, some commenters requested that substances be added to the list, such as ground limestone and acetic acid. These requests are not considered a part of the Sunset Review. Sunset Review was established to evaluate the continued use or prohibition of substances currently on the National List. Therefore, these comments would require a specific petition to the NOP.

We received comments for inclusion of the following substances that were previously recommended by the NOSB to the National List: activated carbon, ammonium hydroxide, cyclohexylamine, diethylaminoethanol, octadecylamine and peracetic acid. These substances do not fall under the Sunset process, as they were not added to the National List on December 21, 2000, and they are currently part of a proposed rule, Docket # TM 0401 published September 16, 2005.

III. Committee Recommendation(s):

The handling committee recommends the renewal of the following substances in this use category as published in the final rule:

Alginates

Ammonium bicarbonate- for use only as a leavening agent

Ammonium carbonate- for use only as a leavening agent

Ascorbic acid

Calcium citrate

Calcium hydroxide

Calcium phosphates (monobasic, dibasic, and tribasic).

Carbon dioxide

Ethylene - allowed for post-harvest ripening of tropical fruit and degreening of citrus.

Ferrous sulfate for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).

Glycerides (mono and di) - for use only in drum drying of food

Glycerin - produced by hydrolysis of fats and oils.

Hydrogen peroxide

Magnesium carbonate - for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic."

Magnesium chloride - derived from sea water.

Magnesium stearate for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic."

Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.

Ozone

Pectin (low-methoxy)

Phosphoric acid - cleaning of food-contact surfaces and equipment only.

Potassium acid tartrate

Potassium carbonate

Potassium citrate

Potassium hydroxide- - prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process

Potassium iodide - for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic."

Potassium phosphate - for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic."

Silicon dioxide

Sodium citrate

Sodium hydroxide - prohibited for use in lye peeling of fruits and vegetables.

Sodium phosphates - for use only in dairy foods.

Sulfur dioxide for use only in wine labeled "made with organic grapes," Provided, that, total sulfite concentration does not exceed 100 ppm.

Tartaric acid

Tocopherols - derived from vegetable oil when rosemary extracts are not a suitable alternative.

Xanthan gum

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

Lecithin – bleached

Chlorine materials disinfecting and sanitizing food contact surfaces, Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).

The handling committee recommends not renewing the following substances in this use category based on the submitted evaluation forms:

Potassium tartrate made from tartaric acid

Moved: Goldie

Second: Andrea

Committee vote: Yes – 5 No- 0

11-8-05

Background: There was a discussion and recommendation to defer lecithin - unbleached in 205.606 until the HC can obtain additional information. In order to be consistent in our presentation at the board meeting re this substance and to be clear on the distinct differences in the two classifications for lecithin (agricultural, synthetic) the following motion was accepted.

Motion to "revise the current 205.605b recommendation to defer lecithin-bleached until we obtain additional information".

Moved: Goldie Second: Bea

Committee vote: Yes – 4 No- 0 Absent - 1

11-17-05

Background: After discussion and review of the comment objecting to the continued use of ethylene and the 1999 TAP the following motion was accepted.

Motion to "revise the current 205.605b recommendation to renew ethylene.

Moved: Goldie Second: Andrea

Committee vote: Yes – 4 No- 0 Absent - 1

11-17-05

Background: In order to allow time to review the proposed TAP covering chlorine materials the following motion was accepted.

Motion to "defer chlorine materials"

Moved: Andrea Second: Julie

Committee vote: Yes – 4 No- 0 Absent - 1

NOSB vote: 14 yes, 0 no

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

Date: November 17, 2005

Subject: Sunset review of nonorganic agricultural substances on the National List used in handling

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 4 substances on section 205.606 of the National List. The NOSB voted to defer action on 1 substance on 205.606. A complete list of the recommendations to renew and defer appears below, along with the vote totals for 205.606.

Rationale Supporting Recommendation (including consistency with OFPA and NOP): Statements from the Handling Committee explaining the rationale supported through NOSB action are included in the recommendation 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: 205.606 Non-organically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

II. Committee Summary: Many comments were received supporting the retention of all five substances in section 205.606. In addition, comments were received opposing the re-listing of the substances on Section 205.606. These comments did not include adequate information supporting the removal of substances from the List as specified in the Federal Register notice regarding the Sunset of materials on the National List. The committee did not have data or evidence to support the position to remove any of the substances listed in Section 205.606.

Four of the five materials on list 205.606 received a substantial number of comments in favor of their continued need in organic handling. Several commenters cited that some substances were available in organic form, such as soy lecithin, and had concerns that there will be no market for the organically produced substance if the non-organically produced substance remained on the list. However, other commenters noted that the organic form is either insufficient in quantity or inadequate in form. No commenters provided adequate data to support their position.

Soy lecithin received conflicting comments regarding its availability in sufficient form. The TAP review of soy lecithin conducted in 1995 did not provide adequate information to help the committee make a determination for removal or continuation. Therefore, the committee recommends this substance be deferred until further information can be obtained.

Comments specifically opposing continued use of cornstarch, gums – water-extracted only, and kelp were based on the commenter’s assertion that these items are now commercially available in organic form. Information such as supply source, supply quantity, functionality, performance, test data, and name and address of producers, who have used the material under similar conditions, was not supplied by the commenters for the Board to make a decision to discontinue the use of these materials under section 205.606. In addition, no comments were received from manufacturers or suppliers of these substances regarding availability in appropriate form, quality or quantity. Because such information was not provided in any of the comments the handling committee recommends the continued use of these materials.

There were no comments specifically opposing the continued use of Pectin (high-methoxy).

III. Committee Recommendation(s):

The handling committee recommends the renewal of the following substances in this use category:

Cornstarch (native)

Gums – water-extracted only (Arabic, guar, locust bean, carob bean)
Kelp – for use only as a thickener and dietary supplement
Pectin (high-methoxy)

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

Lecithin-unbleached

The handling committee recommends not renewing the following substances in this use category based on the submitted evaluation forms:

None in this category

Moved: Julie Weisman Second: Bea James
Committee vote: Yes 4 No 0 Absent 1

NOSB vote: 13 yes, 0 no, 1 abstain