

At the request of members of the National Organic Program staff The Processing Taskforce was formed in September of 2002 to provide some clarity concerning what non-agricultural materials must be reviewed for use in processed products labeled as “organic” and “made with organic.” The taskforce is comprised of NOSB members: Mark King, Kevin O’Rell, Kim Burton, Jim Riddle, Goldie Caughlan, George Seimon, Ann Cooper, Dennis Holbrook, and Rosalie Koenig and industry professionals: Craig Weakley (past NOSB member), Steven Harper (past NOSB member), Zea Sonnebend (OMRI).

The taskforce sought to further define the materials review process for members of the organic industry producing processed products while recognizing other legal and regulatory text pertinent to the food industry as a whole. After much research, discussion and consideration the task force came to the following general recommendation.

**The taskforce recommends that direct and secondary direct food additives are subject to NOSB review. Indirect food additives are not subject to NOSB review.**

Understanding the current industry need for clarification of the materials review process the taskforce consulted the following resources:

- The Organic Foods Production Act of 1990
- The National Organic Program – Final Rule
- Code of Federal Regulations (CFR)
- Previous NOSB Recommendations
- Other Historically Significant Documents

As one of the primary statutory responsibilities of the NOSB, the materials review process is conducted in accordance with the Act and The National Organic Program – Final Rule with guidance provided from House Report 101-916 & Senate Report 101-357, as well as previous NOSB recommendations.

The Organic Foods Production Act stipulates that the NOSB shall develop a proposed National List for submission to the Secretary. The Act also directs the NOSB to convene technical advisory panels to provide scientific evaluation of materials considered for inclusion on the National List. Both the House and Senate reports provide basic guidance concerning the review process.

Senate report 101-357 states, “Several steps must be taken before an item appears on the National List in any of the above categories. First, the Organic Standards Board must review the substances in question based upon criteria cited in the bill and with the aid of the Board’s technical panels. The Board may decide what substances require review. As well, individuals may petition the Board to evaluate substances for inclusion on the National List.” Senate report 101-357 also states, “The secretary may not include exemptions for synthetic substances other than those exemptions recommended by the National Organic Standards Board. The Proposed National List represents the universe of synthetic materials from which the Secretary may choose.”

House of Representatives Report 101-916 is consistent and states, “The senate bill requires the secretary to establish a National List based upon a Proposed National List developed by the National Organic Standards Board. The secretary may not include exemptions for synthetic substances other than those recommended by the National Organic Standards Board.” “The House amendment contains the same provision, with an additional requirement that no substance be listed which has been prohibited by Federal Regulatory action.”

The NOSB has historically attempted to honor the intent of OFPA. The taskforce feels the language below sites some sections of OFPA and the NOP pertinent to the materials review process.

OFPA Section 6504 (1) reads as follows (emphasis added):

OFPA Section 6504 (1): “To be sold or labeled as an organically produced agricultural product under this chapter, an agricultural product shall have been produced and HANDLED without the use of SYNTHETIC CHEMICALS, except as otherwise provided in this chapter.”

OFPA Section 6510: Handling (a) For a handling operation to be certified under this title, each person on such handling operation shall not, with respect to any agricultural product covered by this title (1) add any synthetic ingredient during the processing or any post harvest handling of the product; (4) add any ingredients that are not organically produced in accordance with this title and the applicable organic certification program, unless such ingredients are included on the National List and represent not more than 5 percent of the weight of the total finished product (excluding salt and water).

NOP Section 205.2 (Definitions) reads as follows:

“Ingredient - Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.”

NOP Section 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

It is clear that the intent of the OFPA was that the scope of the NOSB’s responsibility for materials review be much broader than just the review of synthetic substances that would appear on the ingredient listing of certified organic products. In addition, the Final Rule includes a definition of “ingredients” that is more inclusive than materials that appear on the ingredient listing. Consistent with the OFPA, the NOP recognizes that an ingredient may or may not be included on the final label. Page 80641 the rule defines “processing aid” as “a substance that is added to a food for it’s technical or functional effect in the processing but is still present in the finished food at insignificant levels and does not have any technical or functional effect in that food.” This is one example of a food additive that is exempt from labeling requirements per 21 CFR 101.100. Furthermore, on page 80587 – (3) Labeling of products with minor ingredients; the NOP states, “Minor ingredients and processing aids must be treated as any other ingredient or substance which is used as an ingredient in or on the processing of an organically produced product. To be added as an ingredient or used in the processing of a product labeled “organic”, a minor ingredient must be from an organic agricultural source, if commercially available. If not commercially available, the ingredient must be an agricultural product or a substance consistent with the National List.” The OFPA, the Final Rule, the NOSB Recommendation (Incidental Food Additives, 1995), and historical organic industry practice all require scrutiny (NOSB review and placement on the National List) of processing materials that goes well beyond ingredients that appear on the ingredient listing of an organic product.

Numerous food additives such as; enzymes, clarifying agents, pH control agents, drying agents, etc., that fall under the definition of an ingredient, are exempt from labeling. The National List, as it currently stands, includes many of these types of materials and the NOSB has historically made recommendations to USDA on the National List status of these types of processing materials.

**It is this committee's opinion that 21 CFR 101.100 Food; Exemptions from Labeling and 21 CFR 170.3 Food Additives; Definitions, validates past and future NOSB recommendations on materials review.**

The following text from 1995 depicts the findings of the NOSB in relation to incidental food additives (21 CFR definition); this text supports the review of additives that may not appear on the ingredients panel.

**In 1995 the NOSB Recommendation "Incidental Food Additives in Organic Foods" was adopted and submitted to USDA.**

*The Food and Drug Administration's Code of Federal Regulations (CFR), Title 21, Part 170.3 (o) lists the types of ingredients that may be added to foods for the purpose of imparting physical or technical functional effects to the food. This list includes many categories of ingredients including anti-caking agents, colors and coloring adjuncts, emulsifiers, leavening agents, processing aids (\*see definition below), stabilizers and thickeners. These food additives must be listed as ingredients on food product labels unless exempted from the labeling requirements in 21 CFR, Part 101.100. 21 CFR, Part 101.100 (a) (3) describes incidental food additives that are exempt from food labeling requirements and do not need to be listed in the ingredient statement of food product labels. Incidental food additives are present in food in insignificant levels and do not have any technical or functional effect in that food. Such incidental food additives include 1) substances that are incorporated into the food as a result of being an ingredient of another food (Example: An ingredient in pasta sauce is diced tomato that contains citric acid for pH control. Citric acid must be listed as an ingredient in the diced tomatoes. But the pasta sauce label does not have to list citric acid as an ingredient unless additional citric acid is added during the processing of the pasta sauce. And 2) processing aids that: i) are added to the food during the processing but are removed from the food before packaging, ii) are added to the food during processing, are converted to constituents normally present in the food, and do not significantly increase the amount of these constituents normally found in the food; iii) are added to the food for their technical or functional effect during processing but are present at insignificant levels in the final product and have no technical or functional effect in the final product.*

**1995 NOSB Recommendation: Although incidental food additive may not appear in the ingredient statement of foods labeled as organic foods, these additives must be subjected to the same National List evaluation process as other processed food ingredients.**

Further, the NOSB (in 1995) also provides guidance for processors concerning the use of synthetic incidental processing aids. The board recommended the review of incidental processing aids plus the thorough documentation of need as well as demonstrated progress towards replacement or discontinued use.

**1995 NOSB Recommendation: Organic processors must list all incidental processing aids that are added to their organic foods during processing in the Organic Handling Plan. For each incidental processing aid used, the organic processor must document, to the satisfaction of the certifying agent, that the substance is non-synthetic or synthetic. For incidental processing aids that are synthetic, the organic processor must: 1) document that the food cannot be processed without the synthetic incidental processing aid; 2) document that a good faith effort has been made to source and develop a non-synthetic alternative; and 3) demonstrate progress over time in the effort to replace or discontinue use of the synthetic incidental processing aid.**

Although 21 CFR 101.100 and the NOP definition of “Processing Aid” reads that processing aids are substances that are “added” to the food, the NOSB Processing Taskforce points out that the 1995 NOSB recommendation was consistent with the definition of processing aid as per 21 CFR 170.3. The current NOSB and past NOSB members have used this definition as the precedence set thus far on the scope of material review.

“Definition of Processing aid per 21 CFR 170.3 (O)(24) “Processing aids”: **Substances used** as manufacturing aids to enhance the appeal or utility of a food or food component, including **clarifying agents**, clouding agents, catalysts, flocculants, **filter aids**, and crystallization inhibitors, etc.

We would like to further clarify this precedence by using 21 CFR 170-186; Food Additives, as recommendation of types of materials that may or may not fall under the scope of materials review.

**The NOSB Processing Taskforce recommends that all nonagricultural (nonorganic) substances that are classified as either direct, secondary direct, or GRAS food additives (21 CFR 172, 173, 180,181, 182 & 184) are subject to the National List Material Review Process.**

21 CFR 172 Food additives permitted for direct *addition* to food for human consumption

***Examples of materials reviewed by NOSB:***

- Morpholine – prohibited
- Amino Acids – allowed (only in livestock)
- Bakers Yeast – allowed
- Kelp – allowed
- Potassium iodide – allowed
- Silicon dioxide – allowed
- Natural Flavorings – allowed w/annotation
- Carrageenan – allowed
- Xanthan Gum – allowed
- Hydroxypropyl methylcellulose – prohibited

21 CFR 173 Secondary direct food additives permitted *in* food for human consumption

***Examples of materials reviewed by NOSB:***

Boiler water additives – one prohibited & four allowed w/annotation

Chemicals used in peeling of fruit – one allowed w/annotation (potassium hydroxide); one prohibited (sodium hydroxide)

Defoaming agents – two petitioned (one synthetic/one non-synthetic – petitions withdrawn because “organic” alternatives newly developed and commercially available)

21 CFR 180 Food Additives permitted in food or in contact with food on an interim basis pending additional study

21 CFR 181 Prior sanctioned food ingredients (only materials added to food)

21 CFR 182 Substances generally recognized as safe

***Examples of materials reviewed by NOSB:***

Natural Flavorings – allowed w/annotation

Phosphoric acid – allowed w/annotation

Calcium phosphate – allowed w/annotation

Glycerin – allowed w/annotation

Sodium phosphate – allowed w/annotation

Magnesium silicate – prohibited

Ascorbic acid – allowed w/annotation

Sulfur dioxide - allowed w/annotation

Tocopherols - allowed w/annotation

Sodium phosphate - allowed w/annotation

Monobasic calcium phosphate

Disodium phosphate

Tetra sodium pyrophosphate - allowed w/annotation

21 CFR 184 Direct Food Substances affirmed as generally recognized as safe

***Examples of materials reviewed by NOSB:***

Acetic Acid – currently petitioned

Alginic acid – allowed

Enzymes – allowed w/annotation

Citric Acid – allowed w/annotation

Lactic Acid – allowed w/annotation

Lecithin – allowed

Potassium acid tartrate – allowed

Tartaric acid – allowed

Agar-agar – allowed

Ammonium bicarbonate – allowed w/annotation

Ammonium carbonate – allowed w/annotation

Bentonite – allowed

Calcium carbonate – allowed

Calcium chloride – allowed  
Calcium citrate – allowed  
Calcium hydroxide – allowed  
Calcium stearate – prohibited  
Carbon dioxide – allowed  
Beta carotene – allowed  
Ferrous sulfate – allowed  
Glucono delta-lactone – allowed  
Gums – allowed w/annotation  
Hydrogen peroxide – allowed  
Magnesium carbonate – allowed w/annotation  
Magnesium chloride – allowed w/annotation  
Magnesium stearate – allowed w/annotation  
Nitrogen – allowed w/annotation  
Nitrous oxide – currently petitioned  
Ozone – allowed  
Pectins – allowed  
Potassium carbonate – allowed  
Potassium citrate – allowed  
Potassium hydroxide – allowed w/annotation  
Potassium iodide – allowed w/annotation  
Sodium citrate – allowed  
Vitamins – allowed w/annotation  
Carnauba Wax – allowed

The production of wine labeled as “organic” and “made with organic” represents a sector affected by several CFR’s. It is included in this guidance document because the NOP and NOSB have received several petitions regarding materials used in the production and handling of organic wine. Many of these materials do not appear in 21 CFR, consequently the NOSB offers the following recommendation for materials included in 27 CFR part 24 (wine) section 246 (materials authorized for treatment).

**The NOSB Processing Taskforce recommends that all nonagricultural (nonorganic) substances that are classified 27 CFR part 24 (Wine) section 246 (Materials authorized for treatment) be subject to the National List Material Review Process.**

**Section 24.246 CFR 27 Wine Materials authorized for treatment**

***Examples of materials reviewed by NOSB:***

Gums – allowed w/annotations  
Activated Carbon – allowed w/annotations  
Albumen – currently petitioned  
Bentonite – allowed  
Kaolin – allowed  
Ammonium phosphate – prohibited  
Ascorbic acid – allowed w/annotation  
Calcium Carbonate – allowed  
Calcium Sulfate – allowed  
Carbon dioxide – allowed  
Citric Acid – allowed  
Enzymes – allowed w/annotation  
Ferrous sulfate – allowed

Gelatin – allowed  
Isinglass – allowed  
Lactic acid – allowed  
Nitrogen - allowed  
Oxygen – allowed  
Potassium Carbonate – allowed  
Potassium citrate – allowed  
Sorbic acid – prohibited  
Sulfur dioxide – allowed w/annotation  
Tartaric acid – allowed  
Yeast – allowed

**The NOSB Processing Taskforce recommends that all nonagricultural (nonorganic) substances that are classified as indirect food additives (21 CFR 174 through 178 & 186) are exempt from the National List Material Review Process.**

21 CFR 174 Indirect food additives: General  
21 CFR 175 Indirect food additives: Adhesives and components of coatings  
21 CFR 176 Indirect food additives: Paper and paperboard components  
21 CFR 177 Indirect food additives: Polymers  
21 CFR 178 Indirect food additives: Adjuvants, production aids, and sanitizers  
21 CFR 179 Indirect food additives: Affirmed as generally recognized as safe

Indirect food additives are substances for which their primary intended use is in food packaging. The NOSB does not recommend that substances that have indirect food contact be subject to material review. This is validated by OFPA and NOP rule:

OFPA Sec. 211 6510 Handling- For a handling operation to be certified under this title, each person on such handling operation shall not, with respect to any agricultural product covered by this title

(a)(5) use any packaging materials, storage containers or bins that contain synthetic fungicides, preservatives, or fumigants.

NOP – Sec. 205.272 Commingling and contact with prohibited substance prevention practice standard.

(b) The following are prohibited for use in handling..... (1) Packaging materials, and storage containers, or bins that contain a synthetic fungicides, preservatives, or fumigants.

Finally, the task force would like to address indirect food additives used as sanitizers for food contact surfaces. Historically, the NOSB has reviewed at least one sanitizer (chlorine), and issued an annotation pertaining to its use on food contact surfaces, as shown below:

§ 205.605(9) 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.

(i) Calcium hypochlorite  
(ii) Chlorine dioxide  
(iii) Sodium hypochlorite

**The NOSB Processing Taskforce recommends that the annotation referencing the use of chlorine on food contact surfaces is beyond the scope of NOSB review. The use of chlorine in water used as an ingredient, however, is within the scope, and is subject to the National List review process. Therefore, the taskforce recommends that the words, “disinfecting and sanitizing food contact surfaces, Except, That,” be deleted from the annotation.**

Rationale: As stated above, indirect additives, including surface sanitizers should not require National List approval before they can be used to remove pathogens from surfaces that may contact organic food products. First, Congress distinguished between "ingredients" and food-contact materials in Section 6510 of the OFPA and chose to treat them differently. "Ingredients" are subject to National List review (Sec. 6510(4)); food packaging materials are not (Sec. 6510(5), (6).)

Second, Section 6512 states that all production or handling practices that are not prohibited or restricted under the OFPA are permitted. OFPA does not address the use of sanitizing solutions; accordingly, the practice of applying sanitizing solutions for food safety purposes is permitted.

Third, Section 6519(f) states that the OFPA does not alter the authorities of USDA under the meat or poultry inspection acts or FDA under the FD&C Act. The FMIA, PPIA and FD&C Act, as well as the Model Food Code, all prohibit the adulteration of food and require the use of basic sanitation practices.

The Model Food Code requires food-contact surfaces and utensils to be sanitized before use in contact with food and after cleaning. (The Food Code distinguishes between cleaning, which is intended to remove particulate matter, and sanitizing, which is intended to "destroy organisms of public health importance.") Specifically, after being cleaned, equipment food-contact surfaces and utensils must be sanitized in a specified manner, such as by chemical, manual or mechanical operations, including the application of sanitizing chemicals by immersion, manual swabbing, brushing or pressure spraying methods for a minimum period of time, followed by draining of the solution and air drying.

The use of cleansers and sanitizers is regulated by the Model Food Code and Good Manufacturing Practices (GMPs). As such, prevention of contact with organic products must be adhered to by following GMPs, such as rinses and/or products purges, as described in an operation's Organic Handling Plan and verified by certification.

In conclusion, the NOSB Processing Taskforce does not interpret the OFPA as requiring sanitizers to be listed on the National List before they may be used to sanitize food contact surfaces that may contact organic products. Steps must be taken, however, following GMPs and Model Food Code requirements, to prevent contamination of organic products, and these steps must be verified through the Organic Handling Plan and certification process.

**Processing Taskforce Addendum 10.19.02**

On October 15, 2002 new FDA regulation was implemented concerning food contact substances. This may impact the use of secondary direct food additives (21 CFR 173) in the organic industry and consequently the current recommendation of this taskforce. For example, materials currently considered secondary direct food additives could be recognized as food contact substances, which would impact the NOSB's authority to review these materials. The taskforce recognizes this new regulation. However, the taskforce will further research this regulation and determine its relevance to the processing taskforce recommendation. The following language represents pertinent findings to date.

Section 409(h)(6) of the FFDCFA (21 U.S.C. 348(h)(6)) defines a food contact substance as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food." The premarket notification process for food contact substances in section 409(h) of the FFDCFA is the primary method by which the Food and Drug Administration (FDA) authorizes the use of food additives that are food contact substances.

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| For use in demineralizing sugar solutions prior to recrystallization, and to soften water for food and beverage production. | The ion-exchange resin must comply with all the applicable specifications prescribed in 21 CFR 173.25(b). |
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