

# **Appendices**

to  
A Background Paper  
by the Organic Materials Review Institute

## **NOP Policy on Synthetic Substances used in Food Processing**

**May 07, 2003**

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## Appendix 1

### **Synthetic Substances Subject to Review and Recommendation by the National Organic Standards Board When Such Substances Are Used as Ingredients in Processed Food Products**

*From the USDA NOP website, at*

<http://www.ams.usda.gov/nop/NOP/PolicyStatements/SyntheticSubstances.html>

Accredited certifying agents, food processors, and food manufacturers have contacted the National Organic Program (NOP) regarding under what conditions synthetic substances used as ingredients in processed food products are subject to review and recommendation by the National Organic Standards Board (NOSB).

7 CFR 205.2 defines ingredient as “any substance used in the preparation of an agricultural product that is “still present” (quotations added) in the final commercial product as consumed.” This definition arose from an April 25, 1995, NOSB recommendation on good manufacturing practices in certified organic handling operations.

The NOP defines “still present” as those ingredients regulated by the Food and Drug Administration (FDA) as food additives permitted for direct addition to food for human consumption under:

1. 21 CFR Part 172, Food additives permitted for direct addition to food for human consumption.
2. 21 CFR Part 173, Secondary direct food additives permitted in food for human consumption: Except, That, substances classified by the FDA as food contact substances are not subject to this definition.
3. 21 CFR Part 180, Food additives permitted in food or in contact with food on an interim basis pending additional study: Except, That, substances classified by the FDA as food contact substances are not subject to this definition.
4. 21 CFR Part 181, Prior-sanctioned food ingredients: Except, That, substances classified by the FDA as food contact substances are not subject to this definition.
5. 21 CFR Part 182, Substances generally recognized as safe.
6. 21 CFR Part 184, Direct food substances affirmed as generally recognized as safe.

The NOP also defines “still present” as those materials approved by the Bureau of Alcohol, Tobacco and Firearms (ATF) as being acceptable for use by proprietors in the production of alcohol beverages under:

1. 27 CFR Part 24, Section 24.246, Materials authorized for the treatment of wine and juice: Except, That, substances classified by the FDA as food contact substances are not subject to this definition.

2. 27 CFR Part 24, Section 24.247, Materials authorized for the treatment of distilling material: Except, That, substances classified by the FDA as food contact substances are not subject to this definition.
3. The Brewers Adjunct Reference Manual: Except, That, substances classified by the FDA as food contact substances are not subject to this definition.

Accordingly, substances listed in 21 CFR Parts 172, 173, 180, 181, 182, and 184; 27 CFR Part 24; and the Brewers Adjunct Reference Manual, except those substances classified by the FDA as food contact substances, must be on the National List of Allowed and Prohibited Substances to be used in the production of an “organic” or “made with organic (specified ingredients or food group(s))” processed product.

Handlers must include in their organic systems plan a list of all synthetic substances to be used in the production of processed products. Each synthetic substance must be identified as an ingredient or a contact substance. Any substance identified as a contact substance must be accompanied by documentation that substantiates the claim.

## Appendix 2

### FDA 21 CFR Table of Contents

The URL for the relevant sections of 21 CFR is:

[http://www.access.gpo.gov/nara/cfr/waisidx\\_02/21cfrv3\\_02.html](http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfrv3_02.html)

Title 21--Food and Drugs

(This index contains parts 170 to 199)

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF  
HEALTH AND HUMAN SERVICES

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## Appendix 3

### Examples of Indirect Additives Permitted under NOP Policy

Government Printing Office's website containing the Code of Federal Regulations

[http://www.access.gpo.gov/nara/cfr/waisidx\\_02/21cfrv3\\_02.html](http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfrv3_02.html)

#### **PART 175--INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS**

**175.105 Adhesives:** including morpholine, o-phenylphenol, zineb (zinc ethylenebisdithiocarbamate), as well as rosins and shellac.

**175.125 Pressure-sensitive adhesives:** includes BHA and BHT, as well as rosins.

**175.210 Acrylate ester copolymer coating:** including formaldehyde, methyl cellulose, and potassium hydroxide.

**175.230 Hot-melt strippable food coatings:** including GRAS substances, acetylated monoglycerides, cellulose acetate butyrate, cellulose acetate propionate; and white mineral oil.

**175.250 Paraffin (synthetic).**

**175.260 Partial phosphoric acid esters of polyester resins.**

**175.270 Poly(vinyl fluoride) resins**

**175.300 Resinous and polymeric coatings.**

**175.320 Resinous and polymeric coatings for polyolefin films.**

**175.380 Xylene-formaldehyde resins condensed with 4,4'-isopropylidenediphenol-epichlorohydrin epoxy resins.**

#### **PART 178--INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS**

**178.1010 Sanitizing solutions.** (46 listed), including potassium, sodium, or calcium hypochlorite; dichloroisocyanuric acid, trichloroisocyanuric acid or the sodium or potassium salts of these acids; potassium iodide, sodium p-toluenesulfonchloroamide; sodium lauryl sulfate; ethylene glycol monobutyl ether; hydriodic acid; isopropyl alcohol.

**178.3120 Animal glue.**

**178.3620 Mineral oil.- as a lubricant with food contact**

**178.3710 Petroleum wax.**

**178.3730 Piperonyl butoxide and pyrethrins as components of bags.** Piperonyl butoxide in combination with pyrethrins may be safely used for insect control on bags that are intended for use in contact with dried feed ...or that are intended for use in contact with dried food in compliance with Secs. 193.60 and 193.390 of this chapter.

**178.3800 Preservatives for wood,** including Pentachlorophenol and its sodium salt

## Appendix 4

### Examples of Food Contact Substances

Selected substances on FDA's food contact surface website:

<http://www.cfsan.fda.gov/~dms/opa-fcn.html>

FCN No.	Food Contact Substance (FCS)	Intended Use	Limitations / Specifications
2	GENOX™ EP, chemically identified as Amines, bis(hydrogenated rape-oil alkyl) methyl, N-oxides (CAS Reg. No. 204933-93-7)	An antioxidant and/or stabilizer	For use only at levels not to exceed 0.1 weight percent polypropylene complying with 21 CFR 177.1520. The finished copolymers may be safely used in single-use as well as repeated-use applications involving contact with food of types I, II, IV-B, VI, VII-B, and VIII, under Conditions of Use B through H, as described in 21 CFR 176.170(c), <a href="#">Tables 1 and 2</a>
11	4,5-dichloro- 2-n-octyl-3(2H)-isothiazolone	As a preservative and slimicide in the manufacture of paper and paperboard intended to contact aqueous and fatty food.	<ol style="list-style-type: none"> <li>1. As a slimicide, in compliance with 21 CFR 176.300, at a maximum level of 0.034 pound per ton of dry weight fiber.</li> <li>2. As a mold-proofing agent applied to the surface of uncoated paper and paperboard and in coatings for paper and paperboard, in compliance with 21 CFR 176.170(b), at a level not to exceed 100 parts per million (ppm) based on dry fiber weight.</li> <li>3. As a preservative in wet lap and sheet pulp, in compliance with 21 CFR 176.170(a) prior to repulping to produce paper and paperboard, at a level not to exceed 100 parts per million (ppm) based on dry fiber weight.</li> <li>4. As a preservative in pigment dispersions, in compliance with 21 CFR 176.170(b), at a level not to exceed 50 parts per million (ppm).</li> </ol>
18	Sodium acrylate/styrene sulfonate copolymer	As an antiscalant boiler water treatment where steam from treated boilers may contact food.	The food contact substance contains not more than 15% styrene sulfonate and has a molecular weight greater than 20,000 and a polydispersity of 2.0 - 3.3, as measured by a method entitled "Molecular Weight Distribution of Aqueous Anionic Polymers by Size Exclusion Chromatography (SEC) Using Synchropak GPC Columns". The substance must not exceed 20 ppm in feed water, must not be used in boilers at pressures above 1000 pounds per square inch gauge (psig), and must meet any applicable specifications prescribed in 21 CFR 173.310.

30	Copolymer of the sodium salt of acrylic acid with polyethyleneglycol allyl ether(CAS Reg. No. 137898-98-7)	For use in boiler water additives complying with 21 CFR 173.310.	The mole ratio of the sodium salt of acrylic acid to polyethyleneglycol allyl ether in the copolymer must not exceed 2.5 to 1. In addition, the additive must not exceed 200 parts per million (ppm) in boiler water. Further, this product must meet any applicable specifications under 21 CFR 173.310.
31	Fluorescein, disodium salt or dipotassium salt (CAS Reg. No. 518-47-8) and (CAS Reg. No. 6417-85-2)	For use in boiler water additives complying with 21 CFR 173.310.	For use only as an inert tracer chemical in boiler systems and must not exceed 900 parts per billion (ppb) in boiler water. In addition, this product must meet any applicable specifications under 21 CFR 173.310.
35	Dimethyl dicarbonate	As a microbial control agent in non-carbonated juice beverages containing up to and including 100 percent juice.	No more than 250 ppm of DMDC may be added to non-carbonated juice beverages containing up to and including 100 percent juice. The DMDC complies with the requirements listed in 21 CFR 172.133(a) and (c). The beverages must be produced under good manufacturing conditions and their microbial load must first be reduced by current technologies such as heat treatment, filtration, etc., prior to the addition of DMDC.
45	Two quaternary amine (QAE) cellulose ion exchange resins (IXRs): (1) high substitution QAE cellulose IXR (1.5-2.5 milliequivalents quaternary ammonium per dry g of resin); and (2) high protein capacity QAE cellulose IXR (1.0-1.5 milliequivalents quaternary ammonium per dry g resin). Both IXRs consist of a base matrix of regenerated cellulose, cross-linked and alkylated with epichlorohydrin and propylene oxide. Dimethyl hydroxyethyl ammonium groups are added to the polymer to provide binding sites.	For use in the isolation and purification of protein concentrates and isolates from aqueous process streams for food processing.	The amount of epichlorohydrin plus propylene oxide employed in manufacture of the resins does not exceed 400 percent by weight of the starting quantity of cellulose. The resins comply with the requirements listed in 21 CFR 173.25(c) and 21 CFR 173.25(d)(2)(ii). The resins shall be used only in the pH range from 2 to 10. The temperatures of water and food passing through the resins shall not exceed 50°C.
55	Ion exchange resin which is a terpolymer of styrene, divinyl benzene and ethylvinyl benzene, aminomethylated, then quarternized with methyl chloride (CAS Reg. No. 113114-05-9).	For use in treating aqueous sugar solutions and hydrolyzed starch solutions.	The temperature of the sugar solution or hydrolyzed starch solution passing through the resin bed is maintained at 80°C (176°F) or less. The flow rate of the sugar solution or hydrolyzed starch solution passing through the bed is not less than 50 liters per cubic meter (0.37 gallons per cubic foot) of resin bed volume per minute.

74	Completely hydrolyzed tetra-polymer of divinyl benzene, ethyl vinyl benzene, acrylonitrile, and 1,7-octadiene as an ion exchange resin. (CAS Reg. No. 130353-60-5).	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).
98	2-Propenoic acid, 2-methyl, monoester with 1,2-propanediol, polymer with methyl 2-propenoate, 2-propenoic acid and sodium 2-propenoate (CAS Reg. No. 117675-55-5), manufactured and characterized as described in the notification.	As a fluid absorbent in food-contact materials.	The cross-linked polyacrylate copolymer may contain optional adjuvant substances that are required in its production. The optional adjuvant substances may include substances permitted for such use by regulation in 21 CFR Parts 170 through 179. The polyacrylate copolymer must meet the extractives limitations in 21 CFR 177.1211(c) and is limited to use as a fluid absorbent in food-contact materials used in the packaging of poultry, meat and fish at refrigerated and frozen temperatures.
100	Polyvinyl alcohol (CAS Reg. No. 9002-89-5), manufactured as described in the FCN.	As a component of coatings applied to fruits and vegetables with inedible peels, excluding citrus fruits.	The FCS will be used at levels not to exceed 5 percent of the coating formulation.
104	Hydroxymethyl-5,5-dimethylhydantoin (DMDMH) (CAS Reg. No. 27636-82-4), mixture with 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin (MMDMH) (CAS Reg. No. 6440-58-0).	As preservatives for mineral (pigment) slurries (clay, kaolin clay, calcium carbonate or titanium dioxide) that are used as components of paper coatings used in the manufacture of food-contact paper and paperboard and as preservatives in mineral slurries of calcium carbonate or titanium dioxide that are used as fillers in the manufacture of food-contact paper and paperboard.	1. The subject methylhydantoins may be used as intended, at a combined level not to exceed 1200 parts per million (ppm) in the slurry. 2. Paper and paperboard manufactured with DMDMH and MMDMH can be used under Conditions of Use D through H as described in 21 CFR 176.170(c), Table 2.
111	2-Methyl-4-isothiazolin-3-one (CAS Reg. No. 2682-20-4) as a 20 percent solution.	As an antimicrobial agent in adhesives and in components of adhesives for food-contact articles. As an antimicrobial agent in coating formulations and in additives used in the manufacture of paper and paperboard intended for use in contact with all food types.	2-Methyl-4-isothiazolin-3-one is not to exceed 150 mg/kg in the coating formulations and additives; except for use as an antimicrobial agent for polymer latex emulsions in paper coatings, 2-methyl-4-isothiazolin-3-one shall not exceed 250 mg/kg. The use of 2-methyl-4-isothiazolin-3-one in adhesives shall be in accordance with 21 CFR 175.105.

156	Cellulose, regenerated polymer with epichlorohydrin, carboxymethyl 2-hydroxypropyl ether (CAS Reg. No. 343844-23-5). The FCS is also referred to as carboxymethyl (CM) ion exchange cellulose resin.	The CM ion exchange cellulose resin is used to isolate and purify soluble protein from aqueous process streams for food processing.	The temperature of water and food passing through the CM ion exchange cellulose resin should not exceed 40°C. The operating pH of the column is between a pH of 2 and 10. The columns should be washed and preconditioned prior to use according to the manufacturers specifications as described in detail in the notification.
157	1. Cellulose, regenerated, polymer with epichlorohydrin, 2-(diethylamino) ethyl 2-hydroxypropyl ether, (CAS Reg. No. 343845-30-7) (High Capacity). The FCS is also referred to as diethylaminoethyl (DEAE) ion exchange cellulose resin (High Capacity). 2. Cellulose, regenerated, polymer with epichlorohydrin, 2-(diethylamino) ethyl ether, (CAS Reg. No. 343846-01-5) (Medium Capacity). The FCS is also referred to as diethylaminoethyl (DEAE) ion exchange cellulose resin (Medium Capacity).	The DEAE ion exchange resins are used to isolate and purify soluble proteins from aqueous process streams for food processing.	The temperature of water and food passing through the DEAE ion exchange cellulose resin (High and Medium Capacity) should not exceed 50°C. The operating pH of the columns are between a pH of 2 and 10. The columns should be washed and preconditioned prior to use according to the manufacturers specifications as described in detail in the notification.
163	A mixture of ca. 49 percent by weight of polyethylene glycol (400) monooleate and ca. 34 percent by weight of polyethylene glycol (400) dioleate.	The FCS will be used as an anti-corrosive agent in the steam header and steam lines of boiler systems where the steam will contact food.	The FCS is to be continuously added into the steam header to maintain a maximum concentration of 2 ppm in the steam. The FCS shall contain no more than 1 ppm and 10 ppm residual ethylene oxide and 1,4-dioxane, respectively, and must meet any applicable specifications prescribed in 21 CFR 173.310.
175	2-Pyridinethiol-1-oxide, sodium salt (CAS Reg. No. 3811-73-2).	To be used as an antimicrobial agent in adhesives and in components of adhesives in paper towels for use in contact with aqueous and fatty foods.	The FCS will be used as a 40 percent aqueous solution added to the adhesives at a level of 1000 ppm (wet/wet). The maximum level of the FCS in paper towels (on average) will not exceed 10 nanograms/cm <sup>2</sup> .

254	Methyl acrylate-divinylbenzene-diethylene glycol divinyl ether terpolymer, aminolyzed with dimethylaminopropylamine and partially quaternized with methyl chloride. (CAS Reg. No. 65997-24-2).	For use in treating water and aqueous food only of the types identified under categories I, II, and VI-B in <a href="#">Table 1</a> of 21 CFR 176.170(c).	a) The temperature of the water or food passing through the FCS must be maintained at 50°C or less, and the flow rate of the water or food passing through the FCS must not be less than 0.5 gallon per cubic foot per minute; or b) Extracts of the FCS will be found to contain no more than 1 mg/kg dimethylaminopropylamine in each of the food simulants, distilled water and 10 percent ethanol, when, following washing and pretreatment of the resin in accordance with 21 CFR 173.25 ( <i>Ion-exchange resins</i> )(c)(1), the resin is subjected to the test described in 21 CFR 173.25(b)(2)(ii)(B).

## Appendix 5

### NOSB Recommendation for Technical Correction, adopted unanimously 6/7/01

**§ 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))."**

The following nonagricultural substances may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

And

**§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as organic or made with organic ingredients.**

The following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

Delete the words "as ingredients" in 205.605 and 205.606 to read:

**§ 205.605 Nonagricultural (nonorganic) substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."**

The following nonagricultural substances may be used in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

**§ 205.606 Nonorganically produced agricultural products allowed in or on processed products labeled as organic or made with organic ingredients.**

The following nonorganically produced agricultural products may be used in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

**Rationale:** Deleting the words "as ingredients" from 205.605 and 205.606 clarifies that all substances used in or on organic products, including ingredients and processing aids, must appear on the National List. It also makes 205.605 and 205.606 consistent with 205.105(c) and (d), which read:

**§ 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.**

To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of:

- (c) Nonagricultural substances used in or on processed products, except as otherwise provided in § 205.605;
- (d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in § 205.606;

**Action: Adopted unanimously.**

## Appendix 6

### NOSB Processing Task Force Recommendation October 20, 2002

FINAL DRAFT

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 its 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  
***Carnuba 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.

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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