

**National Organic Standards Board**  
**Certification, Accreditation and Compliance Committee**

**Recommended Guidelines for the Use of Packaging and Processing Aids**  
**with Products labeled and sold as “100% Organic”**

**September 15, 2008**

**Introduction**

Four labeling categories have been established for products intended for human consumption under the National Organic Program (7 CFR Part 205.301). From lowest to highest organic composition they are:

- Ingredient Panel Only; products comprised of less than 70% organic ingredients
- Made With Organic; products comprised of between 70% and 94% organic ingredients
- Organic; products comprised of 95% or more organic ingredients and
- 100% Organic; products comprised of 100% organic ingredients

7 CFR § 205.301 (a) Product Composition states: “Products sold, labeled, or represented as “100 percent organic.” A raw or processed agricultural product sold, labeled, or represented as “100 percent organic” must contain (by weight or fluid volume, excluding water and salt) 100 percent organically produced **ingredients**. If labeled as organically produced, such product must be labeled pursuant to § 205.303.”

7 CFR § 205.301 (f) (4) states: “All products labeled as “100 percent organic” or “organic” and all ingredients identified as "organic" in the ingredient statement of any product must not: (4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: Except, That, products labeled as 100% organic,” if processed, must be processed using organically produced processing aids.:

Potentially, products in all four labeling categories, including the “100% organic” category could be produced using processing aids that comply with the NOP 205.2 definition of a processing aid.

However, the regulations under NOP are clear that in the 100% category, all ingredients and processing aids **MUST** be organic. The question then becomes that of defining “ingredient” and “processing aid” and then, whether there are other substances being used in organic handling which fall outside of the definition of either of these. Finally, should the use of such substances negate a claim of 100% organic that the finished product may otherwise have been able to make?:

The following recommendation focuses three areas in the evaluation of how best to preserve the 100% organic claim. These areas include:

- A. Processing aids and ingredients
- B. Sanitizers and anti-microbials
- C. Packaging materials and modified atmosphere packaging aids

Note: In this recommendation, the CAC Committee identifies specific materials which illustrate different types of materials used which may fall outside the statutory and regulatory definitions of “ingredient” and “processing aid.” The Committee recognizes that there may be other handling

materials in use of which we are not aware, and which similarly fall outside those definitions. Such materials may or may not be listed on 205.605. It is the hope of the Committee that such materials will be brought to the attention of the Board during the public comment period.

## **Background**

### **A) Processing aids and ingredients**

There are no references to processing aids in OFPA. Potentially relevant Statutory citations pertain to use of synthetic ingredients are found in Sec 2111 - HANDLING

- (a) IN GENERAL – 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 postharvest 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

In NOP 205.2 Terms Defined, the following definitions can be found for “ingredient” and “processing aid:”

*Ingredient.* Any substance used in the preparation of an agricultural product that is still present in the final commercial product that is consumed

*Processing aid.*

- (1) A substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form;
- (2) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and
- (3) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.

The NOP 205.2 and FDA’s definition for processing aid do not correlate. The FDA definition for processing aid is found in: 21 CFR 170 Sub-Part A (3) Definitions

(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, flocculents, filter aids, and crystallization inhibitors, etc.*

FDA’s list of Food Contact Substances, found in 21 CFR Part 175-178. Food Contact Substances, fall within two categories: Direct Food Contact Substances and Indirect Food Contact Substances.

- 1). Indirect Food Additives includes such things as components of packaging materials, substances such as ion exchange resins, components of conveyors that contact food, components of food-grade

equipment and contact surfaces, inert ingredients in hand sanitizers used in food handling establishments. Also included in Part 178 are sanitizers, defined by FDA as “Substances Used to Control the Growth of Microorganisms.”

2). Secondary Direct Food Additives have a technical effect in food during processing but not in the finished food. Secondary Direct Food Additives include such things as carcass sanitizers, fresh produce dips, adjuvants, and production aids. Some secondary direct food additives also meet the definition for a food contact substance.

NOP and FDA definitions for Processing Aids do not correlate. In fact, a majority of the NOP 205.2 definition for processing aid directly correlates to, and therefore falls within, FDA’s regulation for Food Contact Substances, as Indirect Food Additives under 21 CFR Part 175-178 or as Secondary Direct Food Additives under 21 CFR Part 173.

### **B). Sanitizers and Antimicrobials:**

It is important to note that sanitizers and antimicrobials have two differing definitions under FDA, and are regulated by differing US governmental agencies:

1). Sanitizers are defined and regulated by FDA (21 CFR Part 178) as “substances used to control the growth of microorganisms.” As such these substances are classified as Food Contact Substances, are not processing aids, and do not have to be reviewed and approved by NOSB to be placed on the National List to for use in organic products.

*Synthetic Substances Subject to Review and Recommendation by the National Organic Standards Board when such Substances are used as Ingredients in Processed Food Products*

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

2). Antimicrobial agents are defined by FDA as, “Substances used to preserve food by preventing growth of microorganisms and subsequent spoilage, including fungistats, mold and rope inhibitors, and the effects listed by the National Academy of Sciences/National Research Council under “preservatives.” *21 CFR Part 170.3 Definitions*

Antimicrobials are regulated by EPA as, “substances used to preserve food by preventing growth of microorganisms and subsequent spoilage.” Under EPA jurisdiction, antimicrobial pesticides are substances or mixtures of substances used to destroy or suppress the growth of harmful microorganisms whether bacteria, viruses, or fungi on inanimate objects and surfaces. Antimicrobials are not exempted by the NOP Policy statement because they are not regulated by FDA as Food Contact Substances; therefore they must be considered to be processing aids as defined by the NOP and must be reviewed by NOSB for addition to the National List for use in organic products.

### **C). Packaging Materials and Modified Atmosphere Packaging Aids**

Due to rising concerns about Food Safety and to the increased HACCP requirements for harvesting and packaging raw agricultural products such as fresh fruits, vegetables, and eggs, producers are frequently utilizing sanitizing agents as packaging aids: 1). Sanitizers (Chlorine, Peracetic Acid) in direct contact with fresh vegetable and fruit wash water prior to processing 2). Modified atmosphere gases, such as carbon dioxide, carbon monoxide, or nitrogen gases added to prevent oxidation in vegetable and fruit clam shells; and 2).Ozone gases shot in egg cartons as a sanitizing agent.

MAP (Modified Atmosphere Packaging) is defined as packaging of a product in an atmosphere which has had a one-time modification of gaseous composition so that it is different from that of air (Carbon Monoxide, CO<sub>2</sub>, or Nitrogen).

These sanitizers whose use is often required, in many cases, by State and Federal Health regulations on Food Safety, can broadly be described as packaging aids under 21 CFR 170(3)(25) Definitions:.

*21 CFR 170(3)(25) ‘‘Propellants, aerating agents, and gases’’: Gases used to supply force to expel a product or used to reduce the amount of oxygen in contact with the food in packaging.*

Diatomaceous earth is another substance that has historically been added as direct food contact capping of grain stored in grain silos for pest control.

According to 21 CFR Subpart F, ‘‘Exemptions from Food Labeling Requirements’’, none of these categories of Food Contact Substances have to be identified in the ingredient statement of the product packaging. Determining the addition of these substances can be problematic for the certifying agents without the producer providing full disclosure because they are not listed in the ingredient statement.

21 CFR Subpart F- Section 101.100 (a)(3)(i)(ii); Exemptions from Food Labeling Requirements comprehensively describes those things which do not need not appear on a product ingredient statement.

*§ 101.100 – Food; exemptions from labeling.*

*(a) the following foods are exempt from compliance with the requirements of section 403(i)(2) of the act (requiring a declaration on the label of the common or usual name of each ingredient when food is fabricated from two or more ingredients).....*

*(3) incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. For the purpose of this paragraph (a) (3), incidental additives are: (ii) Processing aids, which are as follows:*

*(a) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.*

*(b) Substances that are added to food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of those constituents naturally found in the food.*

*(c) Substances that are added to a food for their functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.*

*(iii) Substances migrating to food from equipment or packaging or otherwise affecting food that are not food additives as defined in section 201 (s) of the act; or if they are food additives as so defined, they are used in conformity with regulations pursuant to section 409 of the act. (‘‘Food and Drugs Sub Chapter B-Food for Human Consumption’’)*

Historically, from the NOP’s inception to the present, many organic certifiers have used the NOP Policy on Food Contact Substances to allow the use of these sanitizers, antimicrobials and packaging aids for raw agricultural products without the product losing its 100% Organic labeling category.

In the January 23 and February 15, 2007 NOP Accredited Certifying Agent Training, NOP stated that use of all processing aids not certified as organic would lower the 100% labeling claim to Organic. NOP interpreted 205.301 processing aids to include sanitizers and packaging aids. They reinforced this interpretation in the 2008 Accredited Certifying Agents Trainings. As a result of that NOP directive enforced by the certifying agents, a number of companies have had to change their packaging, at considerable expense to reflect the downgraded organic status.

In 2008, NOP issued an informal statement, released over the ACA List-Serve, stating that the use of approved sanitizers did not impact the 100% Organic status. Not all certifying agents have received that new interpretation statement which creates unequal interpretation and enforcement.

There is clearly a need to review all relevant statutory and regulatory citations as well as any previous Board recommendations so that a clear guideline will be on record.

## **Discussion**

It is understood by members of the CAC Committee that many certifiers have been and currently do view substances such as sanitizers, antimicrobials and packaging aids to fall outside the definition of “ingredient” or “processing aid” discussed above, and therefore have been allowing the use of these substances in products labeled as 100% organic. Consequently, there are numerous products in the marketplace carrying a claim of “100% organic” which have been:

- processed on equipment cleaned with sanitizers;
- stored in grain silos with diatomaceous earth added as an insect inhibitor; or
- packaged in containers in which nitrogen has been pumped into the headspace to prevent oxidation.
- exposed to CO<sub>2</sub> or other inert gases

In considering the use of sanitizers on processing equipment, the committee appreciates the fact that sensitive, simple-to-use tests are widely available and a standard part of the Organic Handling Plan of processing operations that utilize sanitizers on their equipment and do not see that the use of sanitizers on processing equipment would disallow the 100% organic claim.

In considering the use of sanitizers in hydro-cooling and rinse water of produce, the CAC committee feels that the residue of the sanitizer remaining on the produce is consumed as part of the final product and it is, in effect, an ingredient and therefore these products would not be eligible for the 100% organic claim.

Anti-microbials, although seen clearly by the CAC committee as falling outside the definition of “processing aid” and also meeting the FDA definition of a “food additive,” are less clearly distinguishable from other ingredients. They are present in the finished product and are consumed along with it. The committee views the use of diatomaceous earth in grain silos in the same way because it cannot be removed from the grain prior to consumption and therefore these products would not be eligible for the 100% organic claim.

Atmospheric gases such as CO<sub>2</sub>, Ozone, Nitrogen and other inert gases present a situation which is different than those presented above. They do come into contact with the food, but do not become incorporated into the food and are no longer present by the time the food is consumed. At this time the committee does not see that the use of CO<sub>2</sub> and Nitrogen would disallow the 100% organic claim.

The committee is also seeking public input regarding other items on the National List that should be considered and evaluated under the 100% claim. The committee is also interested in knowing how this recommendation might impact the current market of products labeled under the 100% claim.

### **Recommendation**

The CAC committee strongly recommends that:

Sanitizers used:

1. On processing equipment are not processing aids and are not present in the finished food. Their use should not impact the 100% organic labeling category of the organic processed product with which it is used.

In addition, the CAC committee recommends that:

2. Sanitizers used in produce rinses and hydro-cooling of produce, as well as anti-microbials do remain on the final product and are consumed along with it. The CAC committee recommends that the use of this substance in or on a processed product, precludes that product's being labeled as "100% organic."

3. Diatomaceous earth when used in grain silos similarly remains on final product and is consumed along with it. The CAC committee recommends that the use of this substance in or on a processed product, precludes that product's being labeled as "100% organic."

4. Nitrogen, Ozone, Carbon Dioxide and other inert atmospheric gases, are not incorporated into organic foods and do not resemble ingredients because they are no longer present by the time the food is consumed. Their use should not prevent a food product from being labeled "100% organic: if that food meets the criteria for such labeling in all other ways.

### ***Committee vote:***

***Moved:*** *Bea James*                      ***Second:*** *Joe Smillie*

*Yes- 6      No- 0      Absent- 0      Abstain- 0*