

**National Organic Standards Board  
Certification, Accreditation & Compliance Committee  
Discussion Document Proposal  
Use of Sanitizers on Eligibility for 100% Organic Claims**

**March 29, 2012**

## **Introduction & Background**

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:

- Products comprised of less than 70% organic ingredients
- Products comprised of at least 70% organic ingredients ( “made with”)
- Products comprised of 95% or more organic ingredients
- Products comprised of 100% organic ingredients.

All four categories may be produced using processing aids which are either removed prior to packaging or remain behind in “insignificant amounts,” and which do not have to be identified on the ingredient statement. (FDA regulations in 21 CFR Subpart F) However, under the NOP the use of such processing aids is restricted in the three highest categories:

- At least 70% - processing aids must be on National List
- 95% or more - processing aids must be on National List
- 100% - processing aids must be organic

From the beginning of NOP implementation, the use of food contact sanitizers did not impede a producers or handlers ability to make a 100% organic label claim on products coming in contact with them. This changed in early 2007, when certifiers were advised during ACA trainings that the use of these substances voided 100% organic label claims on processed products, but this was later retracted (though not formally) by NOP staff at that time, but in any event formal written guidance affirming the loss of 100% organic claim eligibility emerged from the NOP and continues in force presently. It is worth noting that several companies were forced to change packaging claims as a result to reflect the downgraded organic status.

In 2010 the NOSB deliberated on the use of inert gases in the packaging of organic products and how such use should or should not affect the eligibility for 100% Organic claims.

The 100% category has been marked by confusion since its inception by certifiers, consumers, producers, manufacturers, and by NOP staff at times. This category is not allowed by U.S. major trading partners the E.U. and Canada and the U.S. is the only jurisdiction to define it

## **Relevant areas in the Rule**

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 distinct 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.”

7 CFR 205.301 (f) (4) states:

“All products labeled as “100 percent organic” or “organic” .....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;

The definition of “processing aid” in the Rule is taken verbatim from the FDA definition found in 21 CFR Subpart F, below:

21 CFR Subpart F- Exemptions from Food Labeling Requirements comprehensively describes those things which do not need not appear on a product ingredient statement. Section 100.101 (a) (3) (i) and (ii).

§ 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”)

The definition of “processing aid” found in 7 CFR Part 205 is taken directly from the FDA definition of “processing aid,” which, in turn, makes a clear distinction between “processing aids” and substances such as some specific atmospheric gases which have no functional effect in the food or the processing of that food, but merely modify the environment in which the food is packaged. The Organic Rule – 7 CFR Part 205, by including separate definitions for “processing aid” and “ingredient” allows that not everything in a package labeled and sold as “organic” is an ingredient.

Sanitizers are defined and regulated by FDA (21 CFR Part 178) as “substances used to control the growth of microorganisms.” According to the FDA, these substances are classified as Food Contact Substances, not processing aids.

## **Discussion**

CACC members discussed the background and prior activity around this subject, referencing especially the 2009-2010 NOSB discussions around inert gas packaging aid use and the 100% Organic claim.

The current guidance from the NOP disallows using the 100% Organic label claim when organic goods come into contact with food contact or food contact surface sanitizers, even when the sanitizer is no longer present in the finished product prior to sale. This is consistent with the loss of 100% Organic eligibility when non-organic (but organic -compliant) processing aids are used in otherwise organic products. Of course, any such sanitizers or processing aids used must be included on the appropriate section of the National List, included as part of each operator’s Organic System Plan, and approved by the operator’s Accredited Certifying Agent (ACA).

This guidance leads to some interesting outcomes. For example, organic oranges are harvested into bins in the field and may be labeled with a 100% Organic claim. If and when those oranges are deposited into a wash tank at the pack shed and that tank has added chlorine in it, the oranges lose their 100% organic status. The chlorine is there to keep the water from becoming contaminated with pathogens or spoilage organisms. To think of an unprocessed orange as anything other than 100% is confusing for some consumers.

Beyond that, if and when that orange is sold, for juicing for example, the juice that comes from that orange cannot make a 100% Organic claim since the oranges it came from can't either. For the sake of example, assume that no filtering agents are used in the juicing process. If a beverage maker wants to use that organic juice in a 100% juice beverage, that operator would have to default to allowing only 95% of the orange juice to contribute to the organic percentage of the beverage as a whole. This can occur unless the organic certifier of the juice is willing and able to issue a letter of some sort to clarify the amount of the juice that may be used in excess of 95% toward finished goods percentage calculations.

Another example of confusion occurs when produce is field packed, such as celery hearts, which are typically cut, trimmed and placed on a mobile harvest machine in the field. The belt which conveys the produce to those who pack it into cartons is typically sprayed with chlorinated water to reduce the likelihood of contamination by pathogens or spoilage organisms. Once again, those celery hearts, 100% Organic after being cut from the stem and trimmed, are relegated to Organic status (with a presumptive 95% organic percentage) once they touch that belt.

Other options the Committee discussed were the concept of recommending the removal of the 100% Organic claim altogether and the concept of recommending the removal of the requirement that processing aids used in products making a 100% Organic claim be themselves organic. These concepts are more complicated and have intricate ramifications for the regulation and industry as a whole, and the Committee is not prepared to focus on those options at this time.

It is worth noting, as did the NOSB in 2008, that “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.”

The CACC believes that this issue deserves additional attention and community deliberation. The Committee does not feel that adequate information or dialogue has been had on the subject to propose a recommendation about guidance on the matter at this time, and we would like to promote community discussion. Accordingly, we ask for public comments in response to the questions posed below.

### **Requested Input from NOSB, NOP and Public Comment**

The CACC proposes to put forward the following questions to the NOSB and the organic community regarding the use of food contact or food contact surface sanitizers and the resultant ability to use labeling claims of “100% Organic”:

1. Does the 100% Organic label claim hold value for you?
2. Do you feel that contact with a non-organic processing aid should prevent an item from being 100% organic and why?
3. Do you feel that contact with a non-organic food contact sanitizer should prevent an item from being 100% organic and why?
4. How do you distinguish a processing aid from a food contact sanitizer?

5. Does your organic certifier provide guidance on what is a processing aid versus a food contact sanitizer? If so, what is that guidance?
6. If your certifier allows you to use a processing aid, how do you show that the processing aid “is present in the finished food at insignificant levels and does not have any technical or functional effect in that food?”
7. Should there be a category/list of NOP allowed food contact sanitizers and non-organic processing aids that are approved to be used in the 100% organic category? (e.g. Chlorine, peracetic acid, diatomaceous earth, etc.)
8. At what concentration, if any, do you consider a sanitizer/disinfectant to have disqualified an item from the 100% organic category?
9. Should food contact sanitizers be allowed in the 100% organic category if it is proven that no residue from the treatment remains in the finished good?
10. Do you certify items to the 100% organic category? If so, how many?
11. Do you feel that food contact sanitizers are necessary for food safety concerns?
12. If food contact sanitizers could be used while still allowing for a 100% organic claim would you certify more products with the organic claim? If not, why not?
13. Do you have customer requests/demand for products in the 100% organic category?

The CACC also welcomes comments and input in addition to answers to the questions above.

### **Committee Vote**

Motion: The CACC moves to accept this document and present it for full board discussion at the Spring 2012 NOSB meeting

Motion by: John Foster      Second: Calvin Walker

Yes: 7      No: 0      Absent: 1      Abstain: 0      Recuse: 0