



May 3, 2012

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2648-So, Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-12-0017

RE: CACC – Discussion Document on Use of Sanitizers on Eligibility for 100% Organic Claims

Dear Ms. Arsenault:

Thank you very much for this opportunity to provide comment on the NOSB Compliance, Accreditation, and Certification Committee's (CACC) Discussion Document on Use of Sanitizers on Eligibility for 100% Organic Claims.

OTA is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 49 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy.

OTA's position is that sanitizers used on **raw agricultural commodities** during pre- and post-harvest activities should not impact the 100% organic label claim. Any guidance issued on this topic should focus on the use of "processing aids" used on "processed" products as defined by FDA and USDA. Alternatively stated, sanitizers used in direct contact with an otherwise 100% organic raw agricultural product should not prevent the product from qualifying for the 100% organic label.

In summary:

- The discussion document is incorrect in stating that current guidance from NOP disallows using the '100% organic' label claim when organic goods come in contact with food contact or food contact surface sanitizers. NOP does not have a current policy on this topic in its NOP Handbook. NOP previously had a Q & A on its website that addressed the use of chlorine used on apples at 4ppm or below, but it was taken down when NOP created their formal NOP Handbook.
- The 100% organic label holds value, but it is also creates significant complexity to understanding organic claims on certified products. Most consumers equate the content or ingredient statement of a product to the certification claim on the label. If the product contains all organic ingredients, the product at face value is perceived to be 100% organic. Most

consumers are unaware of the subtle nuances in the regulations that prevent a product from being labeled as 100% organic.

- The 100% organic label creates an additional layer of time and resources for manufacturers using “organic” ingredients in further processed organic products. Certified operators commonly need to collect documentation to verify the actual percentage of an “organic” ingredient (defined as 95% +). Otherwise, it must be defaulted to and calculated into a multi-ingredient product at “95% organic” even though it may contain anywhere from 96% - 100% organic ingredients.
- It’s currently very difficult to label a product as “100 organic” due to the common use of allowed processing aids, or due to the hassle of obtaining documentation to verify the 100% organic status. Disallowing the use of the “100% organic” label when raw organic agricultural products come in contact with sanitizers, in effect, would prevent most products from qualifying for the “100% organic” label.
- The regulations at § 205.301(f)(4) specify that “processing aids” must be “organic” for a *processed* product to be labeled as “100% organic.” Similarly, the heading of § 205.605 specifies the substances that may be used in or on *processed* products labeled as “organic” or “made with.” This list includes sanitizers, leading some to believe that a sanitizer used directly in or on a processed product should restrict the labeling claim to either “organic” or “made with.” Additionally, the substances listed under § 205.605 are allowed in organic *handling* (as per § 205.271), which is understood to include post-harvest handling of raw organic agricultural products and further processing. This leads some to believe that a processing aid or a sanitizer used in direct contact with a ‘100% organic’ product anytime after harvest prevents the product from being labeled as “100% organic.”
- OTA is aware of three primary certification practices that emerge from the interpretations of § 205.301(f)(4) and § 205.605. One disallows the “100% organic” claim when “organic” **raw or processed** products come in contact with anything listed on § 205.605. The second disallows the “100% organic” claim only when a *processed* product comes in contact with a non-organic processing aid **OR** sanitizer. The third disallows the ‘100% organic’ claim *only* when a product, raw or processed, comes in contact with a *processing aid*.
- In addition to guidance, we believe, at a minimum, the heading of § 205.605 will need to be revised and/or the addition of sub-categories will need to be added to the § 205.605 (i.e., ingredient, processing aid, sanitizer, boiler chemical, pest materials, post-harvest materials). It appears the wording in the heading of § 205.605 and § 205.606 is the central factor that is resulting in differing interpretations between certifiers.
- OTA suggests that the CACC committee issue another more refined discussion document for the Fall 2012 meeting with two or three options as presented in our comments.

We offer the following more specific comments in context of the committee’s questions:

Does the 100% Organic label claim hold value for you?

The “100% organic” label is valuable for a number of reasons, but it also adds a great deal of complexity to the labeling of certified products. First and foremost, the ‘100% organic’ label sets apart a certified product that is composed of wholly 100% organic ingredients from an “organic” product

that may be composed of between 95% to 100% organic ingredients. This distinct labeling category gives the certified operator an opportunity to prominently display “100% organic” on the Principal Display Panel (PDP) of a label. This can offer a marketing advantage, and it provides an incentive for certified manufacturers to move to a higher level of organic ingredients so they may be able to make the ‘100% organic’ claim. At the same time, it’s likely that a large number of consumers do not understand the difference between multi-ingredient products labeled as ‘100% organic’ and products labeled as ‘organic.’

In order for a certified operator to qualify for the ‘100% organic’ claim, every ingredient in the product must be “100% organic” and any processing aid used must be “organic.” Most consumers are likely not aware of the nuances between an ingredient, processing aid, and sanitizer and how those differences would impact an organic claim on a label. It’s more likely that the average consumer will correlate “100% organic” and “organic” to the ingredient statement and the declaration of non-organic ingredients. At the same time, a consumer may find great value in knowing that a ‘100% organic’ claim means that the product and all ingredients contained within the product are ‘100% organic’ and have not come in contact with a non-organic processing aid.

Do you feel that contact with a non-organic processing aid should prevent an item from being 100% organic and why?

Based on the regulations under § 305.301(f)(4), the use of a *non-organic* processing aid prevents a product from being labeled “100% organic.” Although this has been the accepted requirement since the implementation of the Rule, it has created significant confusion and is arguably counter-intuitive in context with the NOP labeling claim scheme that focuses on product composition.

It’s likely that most consumers are unaware of the regulatory nuances surrounding processing aids. Consumers are more likely to equate the composition of a product to its actual content as declared by the ingredient statement. If the ingredient statement lists only organic ingredients, one would reasonably assume that the product is ‘100% organic.’ Similarly, if a label states ‘100% organic,’ one would expect all the ingredients listed in the ingredient statement to be organic. However, despite the reality of the general consumer’s understanding, once explained it’s reasonable to understand the expectation that a 100% organic product should not be processed with a non-organic processing aid.

The 100% organic label was designed to be a very restrictive labeling claim. In consideration of all factors, this should apply to the use of processing aids as long as our regulation includes the 100% organic label category.

Do you feel that contact with a non-organic food contact sanitizer should prevent an item from being 100% organic and why?

No, we do not believe the regulation intended for a food contact sanitizer to prevent the 100% organic claim. Based on the existing regulations, there are two primary considerations that need to be factored when answering this question: 1) The regulatory language in § 205.301(f)(4); and 2) the regulatory language in the heading of § 205.605 and § 205.606. The regulatory language with keywords is highlighted as follows:

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;**

7 CFR 205.605 states:

§ 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)).”

In consideration of the existing regulatory language in each section referenced above, two general options emerge. We recognize that variations of each could exist, but we believe that the two options below best describe the primary practices we are aware of. OTA is in support of Option #1:

Option #1

Focus on the language in § 205.301(f)(4) and the heading of § 205.605 and § 205.606, specifically the terms “processed” and “processing aid,” and the phrase “in or on.” Any substance on either list that is used “*in or on*” an otherwise “100% organic” product during “*processing*” would prevent the product from being labeled as ‘100% organic.’ Sanitizers used in direct contact with organic product during crop production or post-harvest handling would not prevent a product from being labeled as 100% organic.

With respect to labeling products and determining the organic content of a product, the regulation refers to ‘ingredients’ and ‘processing aids’ only. The language also specifies “if processed.” Substances that fall outside of those definitions, such as sanitizers used for washing raw agricultural products or equipment surfaces, are neither ingredients nor processing aids, and arguably should not affect the 100% organic labeling status.

Under this option, guidance would be relevant to processed products and *processing only*, and would strictly adhere to the regulatory language contained in § 205.301 and § 205.302 and the corresponding NOP definitions of ‘ingredient,’ ‘processing aid,’ and ‘processing’ as defined in § 205.2 as well as FDA definitions of antimicrobials, sanitizers, direct, 2ndary and indirect additives, and raw agricultural commodities.

A resulting policy would read as follows:

- NOP-approved sanitizers used on farm or in post-harvest facilities to wash and sanitize fruits and vegetables to be sold in their raw form* will NOT affect the 100% Organic status of the agricultural product. Sanitizers used in this way fall under EPA jurisdiction. Therefore, the use of these sanitizers is not considered to be food additives or processing aids.
- NOP-approved no-rinse sanitizers used on post-harvest handling equipment or food contact surfaces, including milking equipment (CIP lines or bulk tanks, etc.) or in milk haul-tankers, will NOT affect the 100% Organic status of the agricultural product.
- NOP-approved no-rinse sanitizers used on food processing equipment or food contact surface in food manufacturing operations will NOT affect the 100% Organic status of the agricultural product. Sanitizers used on equipment are deemed by the FDA as ‘indirect food additives’ and are not considered ingredients or processing aids in the product being handled on such equipment.
- A NOP-approved sanitizer (referred to by FDA for this use as an “antimicrobial”) used to

wash/disinfect meat carcasses or fruits and vegetables that are NOT raw agricultural commodities* **DOES** affect the 100% Organic status of the agricultural product. Antimicrobials used in this way are considered food additives (e.g., processing aids) under FDA and NOP.

*The FDA defines a raw agricultural commodity as: “any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.” 21 U.S.C. 321 (r)

Under this option, a change to the language in § 205.605 is likely needed and/or the addition of sub-sections to distinguish ingredients and processing aids from sanitizers/disinfectants and other non-ingredient/non-processing aid categories (pest materials, boiler chemicals, etc.).

Post-harvest materials continue to be problematic because they are used during the “handling” of certified product yet often prior to “processing.” In some cases, post-harvest materials are placed on § 205.605 of the National List. At other times, they are allowed as non-synthetic post-harvest crop production aids. We urge NOSB to recommend the designation of a specific section of the National List for post-harvest materials along with a definition of “post-harvest handling.” Please see comments on Gibberellic Acid for a current and relevant example.

Option #2

Focus on the language in § 205.605 and § 205.606, specifically the reference to “organic” or “made with organic” (NOTE: 100% organic is not an option) and the list of allowed substances. Any substance on either list used in or on a product during handling (post-harvest or processing) would prevent the product from being labeled as “100% organic.”

This approach focuses on “handling” in general and does not make a distinction between post-harvest and processing, just as the regulations currently do not make a distinction between the two. Under this option, if a substance is listed on § 205.605 or § 205.606 and it comes in contact with a “100% organic” product during post-harvest handling activity, the product could no longer be labeled as 100% organic. This is perhaps the most straight-forward approach because it does not involve various FDA definitions, and it may not involve any change to the regulation. However, realistically very few products will ever qualify for the 100% organic product as a result. Any fruit or vegetable washed after harvest would not qualify for the 100% organic product. This would have a significant impact on the 100% organic label for all downstream processed products that utilize organic fruits and vegetables.

Other options to consider

As a third option, NOSB might want to consider the elimination of the ‘100% Organic’ claim entirely. While it is understandable why many would want a label to identify products that are purely organic, the reality is that such a claim adds to the complexity of organic labels and consumer confusion. The European Union organic food regulation does not provide for such a label, and neither does the Canadian organic food regulation. Not only are the production and handling standards difficult to interpret, a ‘100% Organic’ claim raises serious questions about the incidental or unavoidable contamination of organic product. If a product is contaminated by pesticides or other prohibited substances, the ‘100% Organic’ claim could be considered empirically false.

A fourth option to be considered would be striking the language under § 205.301(f)(4) that requires a processing aid to be organic.

7 CFR 205.301 (f) (4):

“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;~~

Given the reference to “ingredients” in the heading of § 205.605 and § 205.606, under this option a product could be labeled “100% organic” if it contained 100% organic ingredients. Any processing aid or sanitizer used in direct contact with a certified product would need to be on the National List. However, their use in direct contact would not prevent that product from being labeled as “100% organic.”

How do you distinguish a processing aid from a food contact sanitizer?

Processing aids can be distinguished from sanitizers by using the existing USDA NOP and FDA definitions for “sanitizers,” “processing aids,” and “processing.”

The NOP definition for processing aid is derived from FDA labeling requirements at 21 CFR 101.100(a)(3)(ii).

*Processing aid. (1) 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.*

FDA also provides a functional definition of processing aid at 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.

NOP regulations provide a definition of “processing” at 205.2 (Terms defined):

Processing. Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

FDA defines a raw agricultural commodity as:

“any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.” 21 U.S.C. 321 (r)

Sanitizers are regulated by FDA at 21 CFR Part 178.

Sanitizing solutions, as defined in 21 CFR 178.1010, are substances regulated by FDA as Indirect Food Additives. These substances may come in direct contact with a food substance, and may reasonably become a component of the food directly or indirectly.

FDA's list of Indirect Food Additives is found in 21 CFR Part 175-178.

Indirect Food Additives include 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, identified by FDA as "Substances Used to Control the Growth of Microorganisms."

Secondary Direct Food Additives are listed at Part 173.

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.

In terms of figuring out when a substance would prevent a product from being labeled as "100% organic," the following logic can be followed based on the definitions above. Anything that meets the definition of a "processing aid" and is used during "processing" would NOT be a considered a sanitizer. Similarly, indirect additives that are used on raw agricultural products would NOT be considered processing aids. The FDA definition of raw agricultural commodity in combination of the NOP definition of "processing" provides sound guidance for distinguishing a processing aid from a sanitizer. It can also be noted that FDA does not require processing aids to be listed on an ingredient statement.

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.)

No, this is unnecessary. The best option is to use existing definitions and draw a line between post-harvest handling, processing and raw agricultural products.

At what concentration, if any, do you consider a sanitizer/disinfectant to have disqualified an item from the 100% organic category?

We do not believe a sanitizer used in direct contact with a certified raw agricultural product should prevent it from being labeled as 100% organic provided the sanitizer is on the National List of approved substances and it is used according to its approved label rate and any other FDA limitation or requirement.

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?

First, any sanitizer that would prevent a product from being labeled as 100% organic should be limited to its use during "processing" and the sanitizer must be on the National List and approved for such use. This keeps us within our regulatory requirements. Basing a label claim on the presence of a residual sanitizer is completely outside the scope of the regulations, and it's too complicated because we get into measuring residues and their detection limits. This is too cumbersome and completely beyond the regulations as written. If we decide that a sanitizer listed on § 205.605 prevents a product from being labeled as 100% organic, we should treat it the same way as a processing aid. The determination

should be according to the “in or on” language. Residual allowances should be kept separate and based on FDA or USDA requirements. Any sanitizer that is allowed to come in direct contact with an organic product has already undergone NOSB review.

Do you feel that food-contact sanitizers are necessary for food safety concerns?

Absolutely, they are critical, and we would hate to see an operator decide to forego using a sanitizer in order to attain the 100% organic label.

Conclusion

Again, OTA thanks the CACC committee for its time on this complicated topic. First and foremost, OTA supports the following position:

Sanitizers used on **raw agricultural commodities** during pre- and post-harvest activities should not impact the 100% organic label claim. Any guidance issued on this topic should focus on the use of “processing aids” used on “processed” products as defined by FDA and USDA. Alternatively stated, sanitizers used in direct contact with an otherwise 100% organic raw agricultural product should not prevent the product from qualifying for the 100% organic label.

We believe this position reflects the intent of the regulations and will best support the survival and promotion of the “100% organic label.” Overall, we believe it will also help minimize further confusion surrounding organic label claims.


Although OTA strongly supports the above position, we feel that a subsequent discussion document may be needed in order to get all NOSB members and stakeholders up to speed. We recommend that the committee present two or three options, as presented in our comments, in a discussion document for the Fall 2012 meeting. This will allow the public to spend additional time analyzing the pros and cons of two or three specified scenarios.

While not specifically addressed in the April 2012 discussion questions, OTA would like to see the following points emphasized in the next discussion document:

- In all cases, **agricultural** processing aids used in or on processed products must be organic or listed on § 205.606 and commercially unavailable in organic form.
- Sanitizers used on food contact surfaces should never prevent a product from being labeled ‘100% organic’.
- Sanitizers and processing aids should not impact the organic **percentage** of a product. They may impact the **label claim**, but they should not impact the calculation made to determine the organic percentage of the product. It’s possible to have a product that can only be labeled as “organic” due to the use of a processing aid, but it still contains 100% organic INGREDIENTS for further calculation purposes.

Again, on behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment and for your time and dedication to upholding the organic standards.

Respectfully submitted,



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