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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 –Use of Sanitizers on Eligibility for 100% Organic Claims

Dear Ms. Arsenault:

Thank you for the opportunity to provide comments to the National Organic Standards Board.

QAI appreciates the work done by the NOSB Compliance, Accreditation, and Certification Committee (CACC) in presenting the discussion document Use of Sanitizers on Eligibility for 100% Organic Claims.

Our input regarding the questions posed by the CACC is as follows:

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

As an organic certification agency QAI benefits minimally from the 100% Organic label claim. The CACC discussion document points out the advantage of using the 100% organic claim for informational purposes to calculate the organic content of ingredients being used in other organic products.

QAI currently certifies 5,651 products making a 100% organic claim which indicates it must have value to our certified organic clients.

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

Yes, but it is necessary to look at the definition of “processing aid” versus “sanitizer” as described further in this document. 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.”

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

No, the FDA definition of a sanitizer and processing aid are not synonymous. Please see the next question.



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

QAI's current interpretation is based on whether or not the organic product is a raw agricultural commodity or whether it is being further processed. Our interpretation is based upon FDA and EPA definitions and jurisdiction.

- If the product is a raw agricultural commodity, antimicrobial use is covered under the EPA. The antimicrobial (referred to as sanitizer in this paper) is considered a pesticide under the EPA, not a food additive. It does not meet the definition of processing aid under the NOP. Therefore, a raw agricultural commodity that is sanitized with an NOP approved sanitizer, would not lose its 100% organic status.
- An antimicrobial used in direct contact to wash produce or meat that are to be further processed (ie, fruits, vegetables, meat that are not raw agricultural commodities) would meet the definition of a processing aid under the NOP and therefore, would knock the produce out of the 100% organic claim. This use of an antimicrobial (sanitizer) on meat and fruits and vegetables that are not raw agricultural commodities is regulated by the FDA and FSIS.
- We also take into consideration the FDA definitions of indirect and secondary food additives. See regulatory references below. NOP approved sanitizers used on equipment would not affect the 100% organic status.

Below is a summary of how the use of a sanitizer/antimicrobial will or will not affect the 100% Organic status of an agricultural product:

1. 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 are not considered to be food additives or processing aids.
2. 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.
3. 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.
4. A NOP-approved sanitizer (referred to by the FDA for this use as an "antimicrobial") used to **directly wash/disinfect** meat carcasses or fruits and vegetables that are **NOT** raw agricultural commodities* **DOES** affect the 100% Organic status of the agricultural



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product. Antimicrobials used in this way are considered **food additives** (e.g., processing aids) under the 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)

The Regulatory Framework :

Pursuant to section 2120(f) of the OFPA (7 U.S.C. 6519(f)), this regulation would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspections Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), nor the authority of the Administrator of the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.)..

As a consequence, at least four (4) federal agencies regulate the processing and handling of organic foods, including post-harvest handling. These ‘agencies’ are:

- The U.S. Department of Agriculture, National Organic Program (“NOP”)
- The Food and Drug Administration (“FDA”)
- The Environmental Protection Agency (“EPA”)
- The Food Safety and Inspection Service of the U.S. Department of Agriculture (“FSIS”)

The National Organic Program of the U.S. Department of Agriculture (“NOP”)

The current National Organic Program (NOP) regulation on the use of sanitizers/antimicrobials (peracetic acid, chlorine, ozone) in processed foods labeled as “organic” is codified at 7 CFR 205.605(b). §605 covers 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 Food and Drug Administration (“FDA”)

FDA is responsible for exercising the authority of the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act. FDA regulations relating to the use of sanitizers or antimicrobials for the uses allowed in 7 CFR 205.605(b) are codified in Title 21, Code of Federal Regulations, Parts 173 and 178. Part 173 of Title 21 is entitled “Secondary direct food additives permitted in food for human consumption”.

Part 178 of Title 21 is entitled “Indirect food additives: adjuvants, production aids, and sanitizers”

The Environmental Protection Agency (“EPA”)

EPA administers the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”). Sanitizers used directly on food are antimicrobial substances and thus are “pesticides” as defined by FIFRA.



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EPA and FDA issued a Memorandum of Understanding effective November 10, 1971, and amended August 28, 1973, giving primary responsibility for pesticide chemicals used on raw agricultural commodities to EPA. The primary responsibility for pesticide chemicals on food-contact surfaces and in processed food (such as “fruits and vegetables that are not raw agricultural commodities”) was given to FDA.

The Food Safety and Inspection Service (“FSIS”) of the U.S. Department of Agriculture

FSIS administers the Federal Meat Inspection Act and the Poultry Products Inspection Act. FSIS permits various antimicrobial solutions for direct food contact with red meat and poultry.

Does your organic certifier provide guidance on what is a processing aid versus a food contact sanitizer? If so, what is that guidance?

Yes, QAI offers guidance which was described above and is available at http://www.qai-inc.com/media/docs/CN_04212008.pdf

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?”

QAI assesses the purpose of the processing aid, obtains specification sheets and as necessary requests additional information from the manufacturer of the processing aid.

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.)

The National List 205.605 already contains materials that are neither ingredients nor processing aids. Some materials listed, such as citric acid, may serve a dual purpose as a processing aid or a sanitizer. It may be more practical to amend the title and introductory text of 205.605 and 205.606 to encompass food contact materials and materials specifically allowed for post harvest handling.

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

Not applicable. Sanitizers must be used according to label use directions or per NOP requirements (e.g. chlorine). Determining if the material has direct food contact is the critical issue rather than concentration levels.

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?

Establishing detection limits and testing for residue is very complicated. Sanitizers that are allowed to come in direct contact with food products have already been evaluated by other regulatory agencies to ensure optimal food safety. Encouraging organic operators to use materials outside their prescribed label usage requirements, including adding fresh water rinses or other mechanisms to reduce residuals, is outside the purview of the NOP. Any sanitizer that is allowed to come in direct contact with an organic product has already undergone NOSB review



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and should be allowed for any label claim. We do not wish to see operators forgoing proper sanitation in search of a coveted 100% Organic label claim.

Do you certify items to the 100% organic category? If so, how many?

Yes, 5,651. Some of these are the same product with different labels or the same product handled by several companies in the certified supply chain. Never the less we have reviewed and certified each one individually.

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

Yes, this has been established by the FDA and organic products should meet the same food safety requirements as conventional foods.

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?

QAI currently allows the 100% Organic claim for NOP Approved food contact sanitizers as described above. Clarification in this area could increase certification of additional products to this claim.

Do you have customer requests/demand for products in the 100% organic category?

QAI certified operators request certification of products to this claim.

In summary:

- The discussion document incorrectly states that “formal written guidance affirming the loss of 100% organic claim eligibility emerged from the NOP and continues in force presently.” There is presently no such policy in the NOP Handbook.
- QAI encourages the NOSB to consider the regulatory authority of all agencies that oversee the processing and handling (including post-harvest handling) of food products while deliberating further on this discussion document.
- We support the use of established definitions from other federal agencies when drafting guidance or regulations for the National Organic Program.

QAI thanks the National Organic Standards Board for considering our comments.

Sincerely,
Alexis Randolph
Technical and Regulatory Advisor
QAI, Inc.