



November 3rd, 2008

The National Organic Standards Board
c/o Valerie Frances, Executive Director, NOSB
1400 Independence Avenue, SW
Room 4008 – South Building, Ag Stop 0268
Washington D.C. 20250-0200

RE: Docket Number AMS-AMS-08-0083; TM-08-12

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

Oregon Tilth thanks the NOSB for their work on this very complicated issue. While it's apparent that guidelines are needed, we have concerns about the direction the recommended guidelines will take the organic community.

The Certification Accreditation and Compliance Committee (CACC) recommended guidelines largely do away with the regulatory language set forth in § 205.301 and the related definitions of 'ingredient' and 'processing aid' and 'processing.' Furthermore, they do not consider or distinguish between the requirements for labeling products vs. product composition and how the organic content of a product is determined.

On the first page of the CACC recommended guidelines the following is stated:

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.

Oregon Tilth strongly agrees with this statement therefore we are concerned to see the recommended guidelines diverge from this line of reasoning. With respect to labeling products and determining the organic content of a product, the regulation refers to 'ingredients' and 'processing aids' only.

Substances which fall outside of those definitions, such as post-harvest sanitizers used for washing raw agricultural products or pest control materials used on raw agricultural products, are neither ingredients nor processing aids therefore they should not affect the 100% organic labeling status or the organic content (organic ingredients) of the product in question.

The CACC conclusion is based on the presence of a substance in a finished product, never mind when or how the substance was used. This ignores definitions and classifications that are already established by the FDA, EPA, and USDA. Any guidance offered on this issue should be relevant to processed products and processing only and should 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.

In order to demonstrate Oregon Tilth’s position, please consider the following examples:

Apples

Suppose organically raised apples are harvested and trucked to the packinghouse where a chlorinated water flume is used to float apples onto the packing line. Chlorinated water contacts the apples before they are packed. The chlorine is used as an antimicrobial and is regulated by the FDA as a secondary additive at 21 CFR 173.315 for washing fruits and vegetables. There is a FDA requirement to rinse with potable water to remove "to the extent possible" the residues of allowed chemicals. In this application the use of the chlorine does not meet the definition of a processing aid because it is used on a raw agricultural commodity prior to processing. It is not regulated as an ingredient or a direct additive therefore it does not need to be included on the ingredient statement of the product. Yet on page 5 of the guidance document the CAC committee states:

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.

In other words the CAC committee is stating that chlorine used during washing should be treated like an ingredient if the chlorine is still present in the final product. Who determines whether an input is still present? If an antimicrobial used on a raw agricultural commodity is viewed as an ingredient and the product cannot be labeled as 100% organic, how is the *organic percentage* of that product determined?

There are hundreds of products on the market that do not qualify for the ‘100% organic’ label category due to the use of one or more non-organic processing aids. While the finished product cannot be *labeled* as ‘100% organic’, the product does contain *100% organic ingredients* and can be calculated as such when used in a product processed by others. This is an extremely important distinction, one that is used every day by certifiers and one that relies entirely on the regulatory text found in § 205.302 (Calculating the percentage of organically produced ingredients) and the terms ‘ingredient’ and ‘processing aid’ as defined in § 205.2.

It is recognized by the FDA and the USDA that certain processing aids are present in the finished food at insignificant amounts or they have been converted to constituents naturally found in that food. This allowance is provided for in NOP and FDA definition of a processing aid. If an input, such as chlorine used in wash water, does not meet the definition of processing aid, yet is considered to still be present in the final product, then it would need to be treated as an ingredient. If treated like an ingredient, the amount of residue on the finished product would need to be determined and calculated accordingly as the non-organic portion of the product. Short of all our clients purchasing gas chromatographs and testing each and every product, we fail to see how this guidance can be applied and enforced. Furthermore the NOP would be regulating antimicrobials as ‘ingredients’, which is not done by any other regulatory agency in the United States.

It must be noted that the NOP definition of ‘processing aid’ was taken directly from the FDA definition of processing aid therefore it is incorrect to say that the FDA definition for a processing aid does not correlate with the NOP definition. The CACC document states:

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.

The definition cited above is a term adopted from the National Academy of Sciences/National Research Council and describes the physical or technical functional effects for which direct human food ingredients may be added to foods. The FDA definition of 'processing aid' as it relates to labeling is found at 21 CFR 101.100(a)(3)(ii), and is identical to the NOP definition of processing aid found at 205.2. As per the Definitions Preamble pg. 80548 Federal Register / Vol. 65, December 21, 2000:

(9) Several commenters recommended that the final rule include a definition for "processing aid" that is consistent with the definition proposed by the NOSB and used by the Food and Drug Administration (FDA). We agree with these commenters and have included a definition for processing aid that is the same as the definition used by FDA and found in 21 CFR Part 101.100(a)(3)(ii).

Pear Juice Concentrate

In this example, pear juice concentrate is formulated using 100% organic pears, enzymes, and diatomaceous earth (filtering aid). This product, as currently evaluated by Oregon Tilth, could not be labeled as '100% organic pear juice concentrate' due to the use of enzymes and diatomaceous earth, both of which are used as processing aids. For calculation purposes however, the organic percentage of the product is 100% organic because all of the **ingredients** are '100% organic'. The product therefore can be labeled 'Organic Pear Juice' but also include a percentage statement of '100% organic ingredients'.

The enzymes and the diatomaceous earth do not remain in the final product as consumed. Although both materials meet the NOP *and* FDA definition of a processing aid, the Pear Juice Concentrate would be eligible for the '100% organic' label claim according to the logic of the CAC committee recommended guidance. Oregon Tilth assumes that the CAC committee did not intend for materials clearly meeting the definition of a processing aid to fall under the "still present" litmus test. Our point however is that we need guidance that can be equally applied to any material in question, and that guidance must directly relate to the definitions provided in the regulation.

Whole Grain Wheat

In this example, organically grown hard red winter wheat is harvested, stored in a grain silo on-site of the farm, and treated with diatomaceous earth to control flour beetles. The diatomaceous earth (DE) product is registered with the EPA and regulated as an insecticide. It does not appear on the National List at § 205.605 or § 205.606; it is allowed as a non-synthetic post-harvest material. It does not meet the definition of a processing aid because it's used during storage, prior to the processing of the grain. It is not regulated as an ingredient or direct additive and therefore the DE does not have to appear on the ingredient statement of a food label. The CACC guidelines however state the following:

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.

According to the CACC guidelines, Oregon Tilth would issue a certificate to Company ‘A’ representing the wheat as ‘organic’. Company ‘A’ sells the wheat to Company ‘B’ who is making an organic wheat baby cereal. Company ‘B’ is certified by QAI. The cereal product contains organic wheat, organic maple syrup, enrichment vitamins, and salt. In order for Company ‘B’ to label the cereal product as organic, the wheat must be at least 97 % organic. QAI contacts Oregon Tilth in order to determine the organic percentage of the wheat. We have no way of determining this information since the use of the diatomaceous earth was not factored into the formula as either an ingredient or processing aid. Company ‘B’ in turn must default to 95% organic and label their baby cereal as a “made with” product, or test the wheat for any remaining content of diatomaceous earth. After careful examination of the regulation, Company ‘B’ cannot understand how a post-harvest pest control material used during the storage of their wheat resulted in a 95% organic product.

Raw Beef Cuts

An organically raised steer is sent to the slaughterhouse. The hide is removed and the carcass is treated with either lactic acid or peroxyacetic acid after trimming but prior to chilling to reduce levels of bacteria.

In this application, both the peroxyacetic acid and lactic acid are used **during processing**. They have a technical effect during processing but they do not have a lasting effect in the treated food. Any residuals that may carry over to the final product do not exhibit a technical effect. Thus they would be considered processing aids under the NOP definition and the FDA definition. Under the USDA FSIS regulation of meat, the FDA definition of a processing aid is deferred to.

In this situation the meat could not carry the 100% organic claim because a non-organic **processing aid** is used. The meat, if used as an ingredient in a multi-ingredient product however, could be calculated in at ‘100% organic’ since the only non-organic input used is a processing aid.

IQF Strawberries

Organic strawberries are pulled from segregated storage and dumped into a wash tank containing 15ppm of sodium hypochlorite. As the berries are conveyed out of the tank they pass under two fresh water spray bars to rinse the berries after the sanitizing step. Following the rinse operations the berries are transported into a tunnel freezer where liquid nitrogen is sprayed directly onto the food surface of the strawberries carrying out freezing operations. The strawberries are then sized, sent through the metal detector and gravity fed into poly lined corrugated boxes.

In this application the chlorine material is used prior to processing therefore its use would *not* prevent the strawberries from being labeled ‘100% organic’. The liquid nitrogen however is used to **freeze** the strawberries. Nitrogen is regulated as a direct food substance under 21 CFR 184.1540. Flash freezing is one of four applications listed. **Freezing** is included in the NOP definition of ‘processing’ therefore the nitrogen is used as a processing aid and the strawberries could not be labeled as ‘100% organic’. The strawberries, if used as an ingredient in a multi-ingredient product, could be calculated in at ‘100% organic’ since the only non-organic input used is a processing aid.

Bananas

Organically grown and harvested bananas are exposed to ethylene gas for post-harvest ripening. Ethylene is listed on the National List at § 205.605(b). It’s regarded legally as a pesticide for regulatory purposes. It must be registered with the EPA and appropriate state agencies. In this application the ethylene is used for post-harvest applications prior to packaging or further processing. In line with the examples provided thus far, use of the ethylene gas would not prevent a product from being labeled as ‘100% organic’. The ethylene is not regulated as a direct additive or ingredient, and it’s not used during processing therefore it does not meet the definition of

Use of nitrogen (or other allowed inert gases) for storage and packaging applications

Oregon Tilth agrees with the CAC committee recommendation on the use of inert gases for packaging applications. Nitrogen is regulated as a direct food substance under 21 CFR 184.1540. It is not regulated as an additive, it does not need to be labeled, and it's not "added to a food during processing" as described in the NOP definition of a processing aid. The CFR listed use is as follows:

Nitrogen is a relatively inert gas and helps to enhance product stability by displacing oxygen and thus reducing oxidation. Under pressure, it is a superior propellant without ozone-depleting properties.

The use of nitrogen in this application is reducing the amount of oxygen in contact with the food in packaging rather than having a technical effect on the product during processing. In support of this reasoning, the FDA defines the technical functional effect of oxygen displacement under 21 CFR 170(3)(25) whereas the technical functional effect of a processing aid is described under 21 CFR 170(3)(24).

In conclusion, the examples above represent three fundamental areas that should guide the discussion on the use of the 100% organic label claim:

1. Production inputs used on **raw agricultural commodities** during pre- and post-harvest activities should not impact the 100% organic label claim.
2. As supported by the regulatory language in § 205.301, loss of the 100% organic label occurs when a non-organic substance listed under § 205.605 or § 205.606 is used during **processing** and functions as a **processing aid** or an **ingredient**.
3. The organic content of a product is based on the percentage of **organic ingredients**. The use of a non-organic processing aid prevents a product from being labeled as 100% organic, but the product continues to contain 100% organic ingredients.

Oregon Tilth believes that the CAC committee recommendation #2 and #3 will have a significant financial impact on certifiers and operators due to the time and money needed to review and revise labels and formulations. Furthermore we are concerned the guidance could lead to compromised food safety.

Page 3 of the CACC document states that antimicrobials regulated by the EPA must be considered processing aids. Oregon Tilth strongly disagrees with this statement. A large number of the antimicrobials regulated by the EPA are applied in the field and/or at facilities that are dedicated to washing raw agricultural commodities. Farmers and handlers strive to achieve the 100% organic claim, and if a sanitizer used in the field or in wash water is the one barrier to marketing their product as 100% organic, we are concerned they may forfeit appropriate food safety steps.

From a certifier's perspective, we are in the daily grind of reviewing ingredient certificates and verifying the organic percentage of ingredients that will be used for further processing. If an ingredient used in an organic product formula is not listed on a certificate as 100% organic, the operator can either default that ingredient to 95% organic or chase down the actual percentage of the ingredient. It's generally understood that products listed on farm certificates are '100% organic'. The CACC guidance would require thousands upon thousands of farm and post-harvest handling facility certificates to be adjusted to specify a '100% organic' or 'organic'

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category, and a large majority of the products would be listed as 'Organic'. The organic community throughout the supply chain will be significantly burdened by the process of trying to determine the organic percentage of a product that lost its 100% organic status at the beginning of the supply chain due to the use of a material that is neither an ingredient nor a processing aid. This is a significant divergence from the understanding and practices the industry has built itself around for the last ten years. The CACC recommendation is leading industry towards consideration of residues or presence of substances in products as a determining factor for decisions about product labeling and composition. This approach is largely out of line with the concept that organic certification is "process-based" and not "product based".

In closing, we urge the CACC committee to reconsider their guidance on this extremely important issue and give close consideration to the examples and points we have presented.

Once again, thank you for receiving our comments.

Oregon Tilth, Inc.

Oregon Tilth, Inc. is a non-profit 501(c)(3) organization that supports and promotes biologically sound and socially equitable agriculture through education, research, advocacy, and product certification.