National Organic Standards Board

Certification, Accreditation and Compliance Committee

Discussion Document
Guidelines for the Use of Inert Atmospheric Gases
With Products labeled and sold as "100% Organic"

March 30, 2009

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:

- Products comprised of less than 70% organic ingredients; products comprised of between 70% and 94% 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 two highest categories:

- 95 % - must be on national List
- 100% - must be all organic

Historically, from the NOP's inception to the present, most Accredited Certifying Agent (ACA)s have used the NOP Policy on Food Contact Substances to allow the use of these packaging aids for both raw agricultural products and retail products containing only organic ingredients and made with organic processing aids which are labeled and sold as " 100 % Organic" without the product losing its 100% Organic labeling category. There have also been two other classes of substances used in organic processing which are not ingredients, but have not been considered "processing aids" either. The first is sanitizers whose use is required, in many cases, by FDA regulations on Food Safety) and the second is what many in the organic industry think of as packaging aids.

Packaging aids, while not legally defined, has generally included substances such as nitrogen or argon gas which is added to the head space of a bottle of organic olive oil to prevent oxidation, and therefore rancidity[1]. The use of these substances or packaging aids for lack of a better term was not seen as affecting the organic labeling claim that could be made by the finished retail product in which it was being used.

This changed in early 2007, when were advised during ACA trainings that the use of these substances voided 100% organic label claims on processed products. As a result, a number of companies changed their packaging at considerable expense to reflect the downgraded organic status.

Since that time, that interpretation has been questioned, including by NOP staff, which could result in a justification for a second packaging change. When interpretations vary in such a short period of time about issues which must be resolved by expenditure of time and financial resources, it is certainly an obstacle to commerce.

[1] Rancidity, while not an acute food safety issue, is a food quality issue with implications for longer term human health. Rancidity in oils is caused by the breakdown of longer chain fatty acids into shorter and mid- chain fatty acids, resulting in the formation of free radicals which are considered to be carcinogenic.

There is clearly a need to review all relevant statutory and regulatory citations as well as any previous Board recommendations so that clear guidelines will be on record. In this way, future processors can be spared the expense of unnecessary changes in either packaging or product formulation, and consumer are not confused by the continual change in label claims.

Background

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 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 it's 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 FDA distinguishes a processing aid from a packaging material such as an inert atmospheric gas. However, it does not clearly distinguish categories and FDA's GRAS Notifications are not consistent with FDA's "EAFUS" (Everything Added to Food in the US) listings For instance, EAFUS includes listings for Carbon Dioxide and Nitrogen, but not Argon. On the other hand, GRAS includes listings for Argon, but not Carbon Dioxide and Nitrogen.

There is a history of some use of inert gases in packaged fresh products – typically meat, and these have been controversial -- to keep red meat looking bright red even while being in a package in a retail case. This procedure might be considered contradictory to organic consumer expectations which historically have been to rely on truth of product quality based on appearance, even if those appearances may be imperfect.

Discussion

This document focuses narrowly on the use of inert atmospheric gases as a packaging aid in organic processed products. The purpose of focusing this narrowly is to address a discrete problem that was created for food manufacturers when widely differing interpretations were delivered by the NOP within a short period of time. The CACC acknowledges that several other issues were raised during the consideration of inert atmospheric gases. For example, discussion of inert gases led quickly to the subject of Food Contact Substances. Also, the idea of dropping the 100 % claim altogether, as a labeling category for processed product was discussed at length. In addition, an earlier version of this document included within it's scope the post- harvest handling of raw agricultural products.

This discussion document will not address the broad issue of Food Contact Substances. Neither is it the intent of the CACC to broadly examine post-harvest handling practices. And although their may be merit to the idea of eliminating "100 % Organic "as a labeling category for organic processed products, this document will not be the vehicle to address it. We recognize the importance of these issues; however, it is not the intention of the CACC to resolve them within the framework of this discussion.

Please note that it is the CACC's intent that this discussion and any guidance recommendations that may follow from it, address the use of gases that are both inert **AND** atmospheric. During the course of our deliberations the CACC discovered that it was not sufficient to refer simply to "atmospheric" gases, because some atmospheric gases are not inert. We did not want to allow the use of a substance in packaging that could react with the organic product it contained. On the other hand, we were concerned that relying on the phrase "inert gases" to define the category, would extend use to materials beyond those occur naturally in the earth's atmosphere. For example, carbon monoxide could not be allowed as a material under the framework now being considered. It is not inert and it's presence in the earth's atmosphere is due primarily to the combustion of petroleum products.

Seeking Public Comment

The CACC is considering that the use of inert atmospheric gases should not down-grade the labeling category of a processed organic product. 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.

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.

In addition the CACC re-affirms the restrictions on the use of processing aids in the 95% and 100% labeling categories: 95% - must be on the NL; 100% must be organic

The CACC is seeking public comment on:

1) The specific inert atmospheric gases and other possible substances used as packaging aids in organic food including those than those listed below.
   Nitrogen
   Argon
   Carbon Dioxide

2) The specific types of packaging under which these atmospheric gases and other substances are used (bottles, cans, fresh meats…..)

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Motion: Julie Weisman *Second: Joe Smillie*

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