National Organic Standards Board
Certification, Accreditation and Compliance Committee

Guidance Recommendation

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

January 25, 2010

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, many Accredited Certifying Agent (ACA)s have used the NOP Policy on Food Contact Substances to allow the use of "packaging aids" for both raw agricultural products; and retail products, which are labeled and sold as 100% Organic, containing only organic ingredients and that are made with organic processing aids.

Historically, there have been two other classes 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 allowed by the NOP. T 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 can be added to the head space of a bottle of organic olive oil or in a vacuum packed coffee bag to prevent oxidation, and therefore rancidity[1]*. The use of these substances or packaging aids 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 certifiers 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.

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.

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[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.

The 100% category has been marked by confusion since its inception by certifiers, consumers, producers, manufacturers, and even the national organic program. 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.

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 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")

(See Appendix 1 Below)

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.

Discussion

This document focuses on the use of inert atmospheric gases as a packaging aid in organic processed products. The purpose of this narrow focus is to address a discrete problem that was created for food manufacturers when an interpretation was given by the NOP that disallowed the 1005 claim on products that utilized inert atmospheric gases in organic product. 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. This discussion document will not address the broader issue of Food Contact Substances. Neither is it the intent of the CACC to examine post-harvest handling practices. We recognize the importance of these issues however it is not the intention of the CACC to resolve them within the framework of this recommendation.

Please note that it is the CACC's intent that this recommendation allows only for 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.

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.

In addition the CACC re-affirms that 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

Recommendation

The CACC is recommending that the use of inert atmospheric gases as packaging aids can be allowed in the 100% Organic labeling claim.

Moved: Joe Smillie Second: Barry Flamm

Committee vote: 4 Yes 0 No 0 Abstain 1 Absent

APPENDIX 1

FDA definition from the Food Code, http://www.cfsan.fda.gov/~dms/fc01-1.htm
U. S. Department of Health and Human Services
Public Health Service
Food and Drug Administration
2001 Food Code (**Updated April 2004***)
Supplement to the 2001 Food Code

Title
1-101.10 Food Code. These provisions shall be known as the Food Code, hereinafter referred to as "this Code."

Intent
1-102.10 Food Safety, Illness Prevention, and Honest Presentation. The purpose of this Code is to safeguard public health and provide to CONSUMERS FOOD that is
safe, unADULTERATED, and honestly presented.

Scope
1-103.10 Statement. This Code establishes definitions; sets standards for management and personnel, FOOD operations, and EQUIPMENT and facilities; and provides for FOOD ESTABLISHMENT plan review, PERMIT issuance, inspection, EMPLOYEE RESTRICTION, and PERMIT suspension.

Applicability and Terms Defined

1-201.10 Statement of Application and Listing of Terms.
(A) The following definitions apply in the interpretation and application of this Code.
(B) Terms Defined.
(71) **Reduced Oxygen Packaging.**
(a) **"Reduced oxygen packaging"** means:
(i) The reduction of the amount of oxygen in a PACKAGE by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the surrounding, 21% oxygen atmosphere, and
(ii) A process as specified in Subparagraph (a)(1) of this definition that involves a FOOD for which ***Clostridium botulinum*** is identified as a microbiological HAZARD in the final PACKAGED form.
(b) **"Reduced oxygen packaging"** includes:
(i) Vacuum PACKAGING, in which air is removed from a PACKAGE of FOOD and the package is HERMETICALLY SEALED so that a vacuum remains inside the PACKAGE, such as sous vide;
(ii) Modified atmosphere PACKAGING, in which the atmosphere of a PACKAGE of FOOD is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the PACKAGING material or the respiration of the FOOD. Modified atmosphere PACKAGING includes: reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen; and (iii) Controlled atmosphere PACKAGING, in which the atmosphere of a PACKAGE of FOOD is modified so that until the PACKAGE is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food, and impermeable packaging material.

Regulations - Title 21 part 170.3 defines a *food contact substance* as, “any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food”.

A *processing aid* is any substance used 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.

§ 170.39 Threshold of regulation for substances used in food-contact articles.
(a) A substance used in a food-contact article (e.g., food-packaging or food-processing equipment) that migrates, or that may be expected to migrate, into food will be exempted from regulation as a food additive because it becomes a component of food at levels that are below the threshold of regulation if:
(1) The substance has not been shown to be a carcinogen in humans or animals, and there is no reason, based on the chemical structure of the substance, to suspect that the substance is a carcinogen. The

substance must also not contain a carcinogenic impurity or, if it does, must not contain a carcinogenic impurity with a TD50value based on chronic feeding studies reported in the scientific literature or otherwise available to the Food and Drug Administration of less than 6.25 milligrams per kilogram bodyweight per day (The TD50, for the purposes of this section, is the feeding dose that causes cancer in 50 percent of the test animals when corrected for tumors found in control animals. If more than one TD50value has been reported in the scientific literature for a substance, the Food and Drug Administration will use the lowest appropriate TD50 value in its review.);

(2) The substance presents no other health or safety concerns because:

(i) The use in question has been shown to result in or may be expected to result in dietary concentrations at or below 0.5 parts per billion, corresponding to dietary exposure levels at or below 1.5 micrograms/person/day (based on a diet of 1,500 grams of solid food and 1,500 grams of liquid food per person per day); or

(ii) The substance is currently regulated for direct addition into food, and the dietary exposure to the substance resulting from the proposed use is at or below 1 percent of the acceptable daily intake as determined by safety data in the Food and Drug Administration's files or from other appropriate sources;

(3) The substance has no technical effect in or on the food to which it migrates; and

(4) The substance use has no significant adverse impact on the environment.

§ 174.5 General provisions applicable to indirect food additives.

(a) Regulations prescribing conditions under which food additive substances may be safely used predicate usage under conditions of good manufacturing practice. For the purpose of this part and parts 175, 176, and 177 of this chapter, good manufacturing practice shall be defined to include the following restrictions:

(1) The quantity of any food additive substance that may be added to food as a result of use in articles that contact food shall not exceed, where no limits are specified, that which results from use of the substance in an amount not more than reasonably required to accomplish the intended physical or technical effect in the food-contact article; shall not exceed any prescribed limitations; and shall not be intended to accomplish any physical or technical effect in the food itself, except as such may be permitted by regulations in parts 170 through 189 of this chapter.

(2) Any substance used as a component of articles that contact food shall be of a purity suitable for its intended use.

(b) The existence in the subchapter B of a regulation prescribing safe conditions for the use of a substance as an article or component of articles that contact food shall not be construed to relieve such use of the substance or article from compliance with any other provision of the Federal Food, Drug, and Cosmetic Act. For example, if a regulated food-packaging material were found on appropriate test to impart odor or taste to a specific food product such as to render it unfit within the meaning of section 402(a)(3) of the Act, the regulation would not be construed to relieve such use from compliance with section 402(a)(3).

(c) The existence in this subchapter B of a regulation prescribing safe conditions for the use of a substance as an article or component of articles that contact food shall not be construed as implying that such substance may be safely used as a direct additive in food.

(d) Substances that under conditions of good manufacturing practice may be safely used as components of articles that contact food include the following, subject to any prescribed limitations:

(1) Substances generally recognized as safe in or on food.

(2) Substances generally recognized as safe for their intended use in food packaging.

(3) Substances used in accordance with a prior sanction or approval.

(4) Substances permitted for use by regulations in this part and parts 175, 176, 177, 178 and §179.45 of this chapter.

(5) Food contact substances used in accordance with an effective premarket notification for a food contact substance (FCN) submitted under section 409(h) of the act.

[42 FR 14534, Mar. 15, 1977, as amended at 67 FR 35731, May 21, 2002]

§ 174.6 Threshold of regulation for substances used in food-contact articles.

Substances used in food-contact articles (e.g., food-packaging or food-processing equipment) that migrate, or that may be expected to migrate, into food at negligible levels may be reviewed under §170.39 of this chapter. The Food and Drug Administration will exempt substances whose uses it determines meet the criteria in §170.39 of this chapter from regulation as food additives and, therefore, a food additive petition will not be required for the exempted use.

[60 FR 36596, July 17, 1995]

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

Subpart B—Listing of Specific Substances Affirmed as GRAS
§ 184.1540 Nitrogen
§ 184.1540 Nitrogen.: (a) Nitrogen (empirical formula N2, CAS Reg. No. 7727–37&ndas
§ 184.1540 Nitrogen.: (a) Nitrogen (empirical formula N2, CAS Reg. No. 7727–37–9) is a colorless, odorless gas
(a) Nitrogen (empirical formula N2, CAS Reg. No. 7727–37–9) is a colorless, odorless, flavorless gas that is produced commercially by the fractionation of liquid air.
(b) The ingredient must be of a purity suitable for its intended use.
(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a propellant, aerating agent, and gas as defined in §170.3(o)(25) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.
[48 FR 57270, Dec. 29, 1983, as amended at 73 FR 8607, Feb. 14, 2008]

§ 570.3 Definitions –

(e) *Food additives* includes all substances not exempted by section 201(s) of the act, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. *Affecting the characteristics of food* does not include such physical effects, as protecting contents of packages, preserving shape, and preventing moisture loss. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive. A substance that does not become a component of food, but that is used, for example, in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive.