

CPG Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens

This update to the Compliance Policy Guides Manual (August 2000 edition) is a new CPG. This update will be included in the next printing of the Compliance Policy Guides Manual. The statements made in the CPG are not intended to create or confer any rights for, or obligations on FDA or any private person, but are intended for internal guidance.

BACKGROUND:

Each year the Food & Drug Administration (FDA) receives reports of consumers who experienced adverse reactions following exposure to an allergenic substance in foods. Food allergies are abnormal responses of the immune system, especially involving the production of allergen specific IgE antibodies, to naturally occurring proteins in certain foods that most individuals can eat safely. Frequently such reactions occur because the presence of the allergenic substances in the foods is not declared on the food label.

To combat this problem, the agency issued a letter titled "Notice to Manufacturers," dated June 10, 1996, which addressed labeling issues and Good Manufacturing Practices (GMPs). This letter is available on FDA's website, <http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/ucm106546.htm>.

FDA believes there is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies.^{2, 3, 4}

Peanuts
Soybeans
Milk
Eggs
Fish
Crustacea
Tree nuts
Wheat

Note: For other foods that may cause an allergic response in certain individuals, the appropriate FDA Field Office should contact CFSAN/Office of *Compliance* for guidance.

Manufacturers are responsible for ensuring that food is not adulterated or misbranded as a result of the presence of undeclared allergens. Therefore, the districts should pay particular attention to situations where these substances are added intentionally to food, but not declared on the label,

or may be unintentionally introduced into a food product and consequently not declared on the label. When an allergen, not formulated in the product, is identified as likely to occur in the food due to the firm's practices, (e.g., use of common equipment, production scheduling, rework practices) then the field office should determine if a manufacturer has identified and implemented control(s) to prevent potential allergen cross-contact, e.g. dedicated equipment, separation, production scheduling, sanitation, proper rework usage (like into like).

POLICY:

Direct addition as ingredients or sub-ingredients

Products which contain an allergenic ingredient by design must comply with 21 U.S.C. 343(i)(2). Where substances that are, bear, or contain allergens are added as ingredients or sub-ingredients (including rework), the Federal Food, Drug, and Cosmetic Act (the Act) requires a complete listing of the food ingredients (section 403(i)(2); 21 U.S.C. 343(i)(2); 21 C.F.R.101.4) unless a labeling exemption applies.

Exemptions from Ingredient Labeling

Section 403(i)(2) of the Act provides that spices, flavors, and certain colors used in a food may be declared collectively without naming each one. In some instances, these ingredients contain sub-components that are allergens.⁵

FDA's regulations (21 CFR 101.100(a)(3)), provide that incidental additives, such as processing aids, which are present in a food at insignificant levels and that do not have a technical or functional effect in the finished food are exempt from ingredient declaration. Some manufacturers have asserted to FDA that some allergens that are used as processing aids qualify for this exemption. FDA, however, has never considered food allergens eligible for this exemption. Evidence indicates that some food allergens can cause serious reactions in sensitive individuals upon ingestion of very small amounts; therefore, the presence of an allergen must be declared in accordance with 21 CFR 101.4. The exemption under 21 CFR 101.100(a)(3) does not apply to allergenic ingredients.

Practices Used to Prevent Potential Allergen Cross-contact

Allergens may be unintentionally added to food as a result of practices such as improper rework addition, product carry-over due to use of common equipment and production sequencing, or the presence of an allergenic product above exposed product lines. Such practices with respect to allergenic substances may be insanitary conditions that may render the food injurious to health and adulterate the product under section 402(a)(4) of the Act [21 U.S.C. 342(a)(4)].

REGULATORY ACTION CRITERIA:

The following represents criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN*:

1. The appropriate FDA *Field Office within the Human and Animal Food Program* obtains inspection evidence showing that a food was manufactured to contain an allergenic ingredient as a primary or secondary ingredient, but the food's label does not declare such allergenic ingredient,

and

2. The allergenic ingredient is one of the eight (8) ingredients listed in this guide,

and

3. The allergenic ingredient was not used as a processing aid in the production of the food,

and

4. The inspection of the firm was conducted consistent with the Guide To Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients.

The following represents the criteria for recommending legal action to CFSAN/Office of *Compliance/Division of Enforcement* (HFS-605):

1. The food contains an undeclared allergenic ingredient that is a derivative of one of the eight (8) ingredients listed in this guide.
2. The food contains an undeclared allergenic ingredient that was used as a processing aid in the manufacture of the product.
3. The food contains an undeclared allergenic ingredient, but the ingredient is not one of the eight (8) allergens listed in this guide.
4. The food is not labeled as containing an allergen, but inspection of the firm shows that it was manufactured under conditions whereby the food may have become contaminated with an allergen.
5. The inspection of the firm was conducted consistent with the Guide To Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients.

Specimen Charges:

Misbranding due to an undeclared allergen:

The article was misbranded when introduced into and while in interstate commerce and is misbranded while held for sale after shipment in interstate commerce, within the meaning of the Act, 21 U.S.C. 343(i)(2), in that it is fabricated from two or more ingredients, and its label fails to bear the common or usual name of each such ingredient, namely (specify the undeclared allergenic ingredient).

Adulteration due to food contamination with an allergen:

The article was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce, within the meaning of the Act, 21 U.S.C. 342(a)(4), in that it has been prepared, packed and held under insanitary conditions whereby it may have been rendered injurious to health.

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 2. Food and Agriculture Organization of the United Nations, Report of the FAO Technical Consultation on Food Allergies. Rome, Italy, November 13 to 14, 1995. [Back to ref.]
 3. Hefle, S.L., et al. Allergenic Foods. Critical Reviews in Food Science and Nutrition, 36(S); S69-S89 (1996). [Back to ref.]
 4. Sampson, H.A. Food Allergy, JAMA (278), pp.1888-1894, 1997. [Back to ref.]
 5. As noted in the 1996 letter, FDA is exploring whether allergenic ingredients in spices, flavorings, or colors should be declared, 21 U.S.C. 343(i) notwithstanding. In the meantime, FDA strongly encourages the declaration of an allergenic ingredient of a spice, flavor, or color by either:
 - o declaring the allergenic ingredient by its common or usual name in the ingredient list as a separate ingredient or parenthetically following the term spice, flavor, or color

or

- o as a declaration attached at the end of the list of ingredients indicating the presence of a specific allergen. [Back to ref.]
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Material between asterisks is new or revised

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