

New Challenges in Managing Food Allergens in the US Food Industry

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Outlines

- US Food Allergen Labeling and Consumer Protection Act (FALCPA)
- Unintended consequences
- USDA FSIS Notice 45-05, 72-05
- What the future holds

Food Allergen – Unique Features

- No hazard to majority of population
- No effective treatment or cure (avoidance)
- Unexpected component in certain foods (labeling issue)
- Cross-contact (GMP/ compliance issue)
- Psychosocial impact – consumer fears

Labeling Challenges for Allergic Consumers

- Common or usual names of some allergenic ingredients are unfamiliar technical terms
- Collective terms for flavors and & non-certified colors do not identify their food sources
- Some ingredients that contain a food allergen and are used as processing aids or are present in spice blends are not declared

Food Allergen Labeling and Consumer Protection Act (FALCPA)

- Pub. L. 108-282 Title II
- Enacted August 2, 2004
- Effective January 1, 2006

<http://www.cfsan.fda.gov/~dms/allrgact.html>

Intent of FALCPA

Assist food allergic consumers to identify more easily when a packaged food was made using an ingredient (including a coloring, flavoring, or incidental additive) that contains a “major food allergen” so that they can avoid consuming it.

Essence of FALCPA

- Amends the FD&C Act to require that food labels disclose ingredients that are “major food allergens”
 - Requirement applies to products labeled after January 1, 2006
- Requires FDA to issue a regulation to define and permit use of “gluten free”
- Requires a Report to Congress focused on cross-contact with food allergens

FALCPA

- Food allergen labeling requirements for all packaged foods regulated by FDA
 - Do not apply to raw agricultural commodities
- Definitions of terms
 - “major food allergen”
 - “name of the food source from which the major food allergen is derived”

Definition of “Major Food Allergen”

- Milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans

AND

- A food ingredient that contains protein derived from one of these foods, except:
 - A “highly refined oil” derived from one of these foods or an ingredient derived from such oil
 - Food ingredient exempt from labeling via the petition process or the notification process specified in the law

Definition of Food Source of a Major Food Allergen

- Same as the name for the major food allergen (i.e., milk, egg, wheat, peanuts, & soybeans) **EXCEPT**
- Tree nuts must identify type (e.g., almonds, pecans, walnuts)
- Fish must identify species (e.g., bass, flounder, cod)
- Crustacean shellfish must identify species (e.g., crab, lobster, shrimp)

Ingredients subject to law

- Eight major food allergens
- A food ingredient that contains protein derived from major food allergens
- Includes incidental additives, flavors, spice blends
- Exceptions:
 - Highly refined oil
 - Food ingredient exempt from petition or notification process

Two ways to label products containing major food allergens

1 Within the list of ingredients:

The common or usual name of the major food allergen immediately followed parenthetically by the name of the food source

e.g.whey (milk)

.... Natural flavors (peanut, almond)

Two ways to label products containing major food allergens

2 In a separate summary statement:

The word “contains” followed by the name of the food source from which the major allergen is derived, immediately after or adjacent to the list of ingredients

e.g. Contains: peanuts, milk, and soy

FALCPA Exemption Processes

- Two ways a food ingredient containing protein from a major food allergen can be exempt from the labeling requirement
 - Notification process
 - Petition process

Notification Process

- Notification must contain scientific evidence (including method) that demonstrates an ingredient does not contain allergenic protein
 - e.g. highly refined oil exemption
- 4 notification requests filed to date
- No action yet by FDA

Petition Process

- Petitioner must provide scientific evidence (including a method) that demonstrates that the ingredient does not cause an allergic response that poses a risk to human health
- no petitions filed yet

FDA Threshold Meeting

- Draft Report on “Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food”
- Food Advisory Committee Meeting, July 13-15, 2005
- <http://www.cfsan.fda.gov/~dms/alrgn.html>

FDA Gluten Free Meeting

- Gluten Free Labeling public meeting, July 19, 2005
- Celiac disease, industry perspective, analytical methods, consumer perspective
- Transcript of the public meeting:
<http://www.cfsan.fda.gov/~dms/glutran.html>

Good Manufacturing Practices

- Can current food GMP be revised to more effectively deal with cross-contact and mis-labeling issues?
- GMP currently being reviewed throughout FDA
- Last time food GMPs revised: 25 yr ago
- Report to Congress, due Feb 2006

FDA Guidance

- Clarifies that FALCPA does not address advisory labeling, such as “may contain”
- FDA position remains that
 - advisory labeling is no substitute for GMPs
 - must be truthful and non-misleading

FDA Guidance

- FDA has issued guidance to address certain issues, such as unintentional cross contact
- Latest guidance (Edition 2) was issued in December 2005
- <http://www.cfsan.fda.gov/~dms/wh-alrgy.html>

FDA Guidance

- FALCPA provisions do not apply to allergens unintentionally added as a result of cross contact
 - e.g., soy in wheat flour
- FALCPA contains no requirement for FDA to establish threshold levels for allergens
- However, FDA acknowledges that this could occur as a result of addressing petition or notification requests

Unintended Consequences

- Zero tolerance is unrealistic and not achievable
- Unnecessary burden to food industry
- Leads to over labeling
- Labeling of incidental additive and processing aids, e.g. soy lecithin, fish gelatin, wheat starch

Unintended Consequences

- Soy in wheat flour; wheat in corn flour
- Confuses consumers, encourages risk taking
- Encourages “harmonization” for some food processors

FSIS Approach to Allergens

- Meat, poultry and egg products not directly addressed by FALCPA
- Indirect impact of allergens in meat and poultry product ingredients
- In interest of reducing allergen related recalls, FSIS issued Notice 45-05 July 2005

FSIS Notice 45-05

- Problems as issued
 - “substances of public health concern”
 - Little distinction between allergens and other ingredients of potential public health concern, e.g., sulfites and MSG

http://www.fsis.usda.gov/regulations_&_policies/Notice_45-05/index.asp

FSIS Activities

- Notice 72-05, November 2005, clarified some matters arising from 45-05
 - No basis for treating MSG as a public health concern
 - No requirement to list each allergen on a flow chart

http://www.fsis.usda.gov/regulations_&_policies/FAQs_for_Notice_45-05/index.asp

FSIS Activities

- FSIS approach to cross-contact grains addressed in Notice 72-05
 - The Grain Inspection, Packers and Stockyards Administration (GIPSA) has jurisdiction over the inspection
- New concerns
 - Must carry forward “may contain” labeling
 - Raised possible concern about allergen cross contact from reused deep fryer oil

What the Future Holds

- Further guidance from FDA
 - Regulatory discretion for processing aids?
- Report to Congress will be of interest
 - Could signal new expectations within the food plant
- Interesting to see if and when petitions for exemption will be filed

What the Future Holds

- FSIS will propose rules and follow FDA lead
- Alcohol & Tobacco Tax and Trade Bureau: anticipating mandatory regulations on allergen labeling for alcoholic beverages