



# Association of Food and Drug Officials

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Dockets Management Branch (HFA-305)  
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**RE: Docket No. 00P-1322  
Food Safety and Food Labeling; Presence and Labeling of  
Allergens in Foods**

For over 105 years, the Association of Food and Drug Officials (AFDO) has endeavored to create uniformity among government regulatory agencies at all levels. By building consensus with program managers at the state and local levels, AFDO is able to establish united positions on national food safety matters that affect all of us. It is in this spirit of uniformity that AFDO is pleased to offer our comments on the labeling of food products containing allergens.

Some state food safety programs currently have active allergen surveillance programs. These agencies collect food product samples and labels at food manufacturing facilities. Labels are reviewed and products are analyzed to assure that all food allergens contained in the food products are appropriately listed on the product labels. Some of these programs are conducted within the framework of partnerships with FDA Districts or Regions.

The results of these surveillance programs reveal a need for government and industry to improve manufacturing and labeling practices. The objective is to provide consumers who experience adverse reactions to food allergens with complete and accurate label information so that they can avoid those specific food allergens. Surveillance sample analyses frequently reveal small amounts of allergenic material, which suggests cross contamination from foods that contain allergens to foods that are not intended to contain allergens. Inadequate equipment cleaning between processing of allergen-containing and non-allergen-containing foods, or improper sequencing of allergen-containing foods ahead of non-allergen-containing foods without an effective intervening cleaning step are the most likely causes of these inadvertent, but potentially harmful cases of cross contamination. Sample results that reveal significant levels of undeclared food allergens in a food product, whether due to labeling errors or improper handling of allergen-containing foods, have resulted in costly product recalls.

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To make the regulation of the labeling and handling of food allergens both effective and practical AFDO believes that human threshold levels must be established for specific food allergens. Precisely, what is the threshold level for peanut, egg and other allergen material in foods which will cause adverse reactions in consumers? While this debate continues, however, AFDO supports a continued dialogue such as occurred at the August 13, 2001 public meeting and the voluntary guidance which has been developed for and employed by food manufacturers to assist them in producing foods that are safe for consumers with food allergies.

Our specific comments regarding the labeling of food products containing food allergens are as follows:

- AFDO applauds the Food Allergy Issues Alliance (FAIA) for their development of the Food Allergen Labeling Guidelines and the National Food Processors Association (NFPA) for their development of the Code of Practice on Managing Food Allergens. These guidance materials and others will be included in a prominent manner at an educational program for managing food allergens that AFDO is holding in Washington, D.C. on November 8, 2001.

#### Balance Issues

- Common sense must remain an integral component of any food allergen control practice.
- Decisions must be made along the lines of providing the best possible public health protection while taking into consideration industry concerns over available labeling space and consumer perceptions of various foods.
- Advisory labeling cannot be a substitute for adhering to Good Manufacturing Practices, but regulators must be cautious about discouraging allergen labeling in the "labeling vs. GMP" struggle.
- Allergen advisory labeling cannot appear unnecessarily - its presence must have a clear and significant meaning. The use of standardized language for a standardized situation could be utilized.
- Voluntary vs. mandatory labeling:
  - Mandatory labeling certainly levels the playing field, if FDA and the states enforce rules, but mandatory labeling probably puts the small company at a disadvantage initially because they do not hear about labeling rules or read the Federal Register.
  - Voluntary labeling allows for the development of well thought out consensus guidelines like the FAIA document, but opens the door to less responsible members of the industry.

- AFDO supports uniformity through a national preemption process for any mandatory labeling proposal that may arise in a jurisdiction where non-uniformity could result.

#### Education and Training Issues

- NFPA's Code of Practice on Managing Food Allergens and FAIA's Food Allergen Labeling Guidelines will serve as the nucleus of the November 8, 2001 AFDO training initiative to educate both regulators and the industry.
- Training of regulatory and industry personnel on allergen issues will certainly benefit the ultimate consumer and hopefully build more confidence in product labels.
- As part of any educational effort, it is critical to specifically identify and communicate a full list of known allergens, including their numerous derivatives, to all stakeholders.

#### Labeling Issues

- Encourage voluntary allergen labeling. Voluntary labeling may be the most appropriate route to pursue so that FDA can gain more experience concerning the results and effectiveness of the voluntary approach. Appropriate adjustments can then be made as necessary.
- Increase emphasis on compliance with existing labeling requirements.
  - Labeling information must be conspicuous.
  - Minimum type size must comply with existing requirements.
  - Labeling information must appropriately contrast with the label's background.
  - Pictorial backgrounds must be avoided on areas of the label that contain important labeling information.
- Plain English descriptions should be used in the ingredient statement. For example, the declaration of casein should be "casein (milk ingredient)." Consumers and regulators must easily understand labeling words and phrases.
- Allergy statements should be located immediately following or adjacent to ingredient statements. Allergy advisory information should be readily discernible to the consumer. This could be done by a variety of labeling methods such as bolding, color differences or italics.
- For advisory labeling, the number of phrases used should be kept to a minimum and should be uniform throughout the industry. Too many phrases will only cause confusion for consumers and regulators.

- Consideration should be given to "prescribed" advisory labeling to promote uniformity and understanding.
- Before advisory labeling choices, wordings and styles become limited, regulated or endorsed, there must be clear understanding by industry, regulatory agencies and consumers of what the statements mean. This includes what the manufacturer means about the manufacturing and the product itself and what the statements mean to the consumer. This understanding is still evolving.
- FDA should address labeling of individual allergenic flavorings, spices and colors with a generally applicable policy, not on a case-by-case basis.
- For individual flavorings, spices or colors that contain one of the eight most common allergens, listing of the common or usual name, in plain English, should be mandatory.
- Special efforts should be made to address allergens in imported foods. This could be accomplished by:
  - Including imported foods as a priority item for food safety contracts with states.
  - Expanding contracts/partnerships with states to specifically target imported foods for labeling, microbiological and filth issues.
- Foods for institutional use and food ingredients supplied by manufacturers to retailers and small specialty food processors must have full ingredient labeling.

AFDO wishes to thank FDA for conducting a public meeting regarding the presence and labeling of allergens in foods and for allowing us to share our thoughts on this very important issue.

Sincerely,



Doug Saunders  
President  
Association of Food and Drug Officials

cc: AFDO Board of Directors  
AFDO Regional Affiliate Presidents



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