

Docket # 1998N-0359

Program Priorities in the Center for Food Safety and Applied Nutrition

Due August 9, 2004

Written comments from The Food Allergy & Anaphylaxis Network

The Food Allergy & Anaphylaxis Network (FAAN) is pleased to submit the following comments regarding new program areas or activities that CFSAN should add as high priorities for FY 2005 (Oct 1, 2004 thru Sept 30, 2005).

FAAN is a nonprofit organization whose mission is to raise public awareness, provide advocacy and education, and to advance research on behalf of all those affected by food allergies and anaphylaxis. Currently, FAAN has more than 26,000 members, the majority of whom have family members (children) who suffer from food allergies.

As always, FAAN is available to partner with FDA/CFSAN in increasing public awareness, and providing food allergy education and training to consumers and industry.

In this written comment, FAAN will make the following nine suggestions for FY 2005:

1. Increase Consumer Awareness and Industry Outreach.
2. Develop a Food Allergen Training Module for ORA University
3. Revise GMPs
4. Clarify Allergen Recall Policy
5. Standardize Allergen Advisory (“May Contain”) Labeling
6. Eliminate “Non-Dairy” from Foods Containing Milk
7. Develop a Milk Assay
8. Report to the Public of Allergen Adverse Events
9. Implement Section 203 of The Food Allergen Labeling and Consumer Protection Act

1) Increase Consumer Awareness and Industry Outreach

1a) Consumer awareness

FDA/CFSAN must continue to assign Priority Level A to efforts aimed at educating consumers about food allergy, an increasing public health and food safety issue.

Eleven million Americans (or 1 in 25 persons) suffer from food allergy: 6.5 million are allergic to seafood (i.e., lobster, crab, fish), and 3.1 million are allergic to peanut or tree nut (i.e., walnuts, almonds, pecans). Peanut allergy, in fact, doubled in children from 1997 to 2002¹, and the incidence of food allergy may not have peaked in the US.

¹ Scott H. Sicherer, Anne Muñoz-Furlong, and Hugh A. Sampson. Prevalence of peanut and tree nut allergy in the United States determined by means of a random digit dial telephone survey: A 5-year follow-up study. *Journal of Allergy and Clinical Immunology* 2003;112:1203-7.

Severe allergic reactions (anaphylaxis) to food result in 30,000 Emergency Department visits and up to 200 deaths per year in the US.²

There is no cure for food allergy. Strict avoidance of the allergen is the only way to prevent a reaction. As a result, individuals affected by food allergies rely on food labels as a first line of defense. Virtually 100% of individuals affected by food allergy always/frequently read ingredient statements before purchasing packaged food. As the federal agency that oversees the integrity of our nation's food labels, FDA must strive toward the clear, accurate, and consistent display of allergen information on all food products. The lives of millions of Americans depends on it.

Although FDA has taken affirmative steps toward clear and consistent allergen labeling, there is much work that still needs to be done.

The majority of food-allergic consumers report having called food manufacturers for more information about ingredients; spend at least one hour per week reading food labels; feel that labels are not simple enough, not easy to understand, and do not give enough information about allergens.

1b) Industry outreach

FDA/CFR should assign Priority Level A to helping to guide the food industry on the serious nature of food allergies, and the ways to avoid cross-contamination and errors in food labeling.

One method by which FDA can help industry in this capacity is by inspections of randomly selected manufacturers, similar to the inspections conducted in 1999 of bakery, ice cream, and candy manufacturers in Wisconsin and Minnesota. This type of study highlights the weaknesses in the food manufacturing process.

Clearly, the results of such inspections are invaluable to members of the food industry, and can help reinforce that food allergy management (i.e., equipment cleaning, employee training, labeling) is a constant endeavor, and that trace amounts of an allergen can trigger a life-threatening reaction.

2) Develop a Food Allergen Training Module for ORA University

FAAN strongly encourages the assignment of Priority Level A to the development of a "Basic Food Allergen" training module for ORA in order to enhance and improve the Agency's knowledge base.

² Michael W. Yocum, Joseph H. Butterfield, Joel S. Klein, Gerald W. Volcheck, Darrell R. Schroeder, and Marc D. Silverstein. Epidemiology of anaphylaxis in Olmstead County: A population-based study. *Journal of Allergy and Clinical Immunology* 1999;104:452-6.

Clearly, food allergy is an increasing public health and food safety issue, with seafood allergy affecting an estimated 6.5 million Americans. It is critical that FDA inspectors possess the education and awareness necessary to keep our food supply safe.

FAAN has numerous resources that can help CFSAN in this endeavor, especially our comprehensive website (www.foodallergy.org), and our training tools for schools and food service establishments.

Moreover, the Food Allergy Research & Resource Program (FARRP) of the University of Nebraska contains a wealth of information pertaining to allergen control and the food industry.

3) Revise GMPs

FDA/CFSAN must assign Priority Level A to the inclusion of food allergies in its revisions of GMP regulations (CFR Part 110). Since the last revision, in 1986, food allergens have emerged as a public health and food safety issue, one that must be addressed by FDA in order to protect millions of Americans.

FDA held a series of public meetings on proposed revision of GMPs, and FAAN presented at two of these meetings (College Park and Chicago). FAAN will also be submitting comprehensive written comments on the topic.

Revising GMPs to include food allergies will go a long way toward eliminating the ways in which foods, during manufacturing and processing, are unintentionally contaminated with major food allergens. This is especially crucial when considering the fact that trace amounts of an allergen are enough to cause a fatal reaction. To illustrate, a 21-year-old man with a known peanut allergy died after purchasing chocolate chip cookies from a vending machine. Peanuts were not listed in the ingredients, nor was there a precautionary statement. Package testing revealed 3,000 PPM of peanut, enough to trigger the anaphylactic reaction.

4) Clarify Allergen Recall Policy

FDA/CFSAN must assign Priority Level A to establishing a clear recall policy, and aggressively pursuing any credible consumer reports of undeclared allergens.

FAAN is aware of several recent instances when the FDA has been informed that a food-allergic individual has had an allergic reaction to a food, analytical testing has confirmed the presence of an undeclared allergen in the food, yet FDA has refused to classify the incident as a recall.

By not having a clearly defined recall policy, FDA is putting millions of food-allergic Americans at risk.

5) Standardize Allergen Advisory (“May Contain”) Labeling

Allergen advisory (“may contain”) statements are voluntary, and as a result, there is no standardization of messages and no rules for when these messages can or should be used. Some companies use them, others don’t; some use them sparingly, others put them on all their products. FDA/CFSAN must assign Priority Level A to the development of standardized guidelines for the use of these advisory statements. Without consistency, individuals affected by food allergy are forced to: 1) avoid the product altogether even though the product may be safe; 2) spend more time reading and interpreting food labels; or 3) purchase the product, placing their lives and/or the lives of their food-allergic family members at risk.

Unfortunately, FAAN has seen an increasing number of both the types of messages and the number of products that contain them. To illustrate, in December 2002, a FAAN volunteer went to one supermarket in the northern Virginia area and reviewed the allergen messages on four product categories: candy, cookies and crackers, snack foods (chips, snack bars), and other (i.e., cereal, bread, baked goods, etc. She found **28** varieties of these messages.

Clearly, such a wide range of precautionary statements can only cause confusion to consumers affected by food allergy. How is the consumer to know the difference in risk between “may contain traces of peanuts” and “manufactured in a facility that uses peanuts”?

Precautionary statements are also being used in an inconsistent fashion. One product may have an advisory statement on its label; however, an identical product on the same shelf may not. Precautionary statements are sometimes inconsistent, thereby increasing the risk of a reaction. To illustrate, one FAAN member called in April, 2003 to tell us that a chocolate bunny product she had purchased listed no peanut or tree nut ingredients and no allergy warning. However, other identical products had a “may contain peanut” warning on the label. When she called the manufacturer she was told that all the bunnies are made on the same equipment and should all have a peanut warning.

The ultimate example of a confusing precautionary statement is one recorded by a FAAN staffer in 2003: ***“May contain peanuts and other allergens not listed on the label”***. It is apparent that interpreting such a statement is nearly impossible.

FDA/CFSAN must provide clear guidance on the use of precautionary statements, for the benefit of the food manufactures along with the 11 million Americans affected by food allergy and their families.

6) Eliminate “Non-Dairy” from Foods Containing Milk

FDA must place Priority Level A on rescinding the law/regulation that allows food items that contain milk-derivatives to be marked and advertised as “Non-Dairy”. From the perspective of consumers affected by milk allergy, this is clearly a form of false advertising.

Under current food labeling laws, casein or caseinates are considered chemical additives. As a result, foods that contain these ingredients can be legally advertised as “non-dairy” products. However, milk is one of the 8 major food allergens, and is most common among young children, with an estimated 2.5% of children under the age of 2 affected.

Many of our members have told us they have purchased “non-dairy” products for their milk-allergic children because they believed these items to be safe. Individuals often interpret “non-dairy” to mean “no dairy” and therefore do not feel it necessary to read the ingredient statement on the back of the package. In fact, doctors often advise parents of milk-allergic children to avoid “milk”, without informing the patient/parent of technical ingredient names such as casein.

However, FAAN has learned of situations in which “non-dairy” items (such as whipped toppings, imitation cheeses, and soft-serve frozen desserts) have caused milk-allergic reactions in children because it was later discovered that the item contained a milk-derived protein. Sometimes, this discovery was not made until *after* the child had ingested the food, suffered an allergic reaction, and was treated by 911 rescue personnel.

Clearly, this is a situation that no parent should have to face. However, until the confusion between *non-dairy/casein* is settled, this scenario will continue to play out in the future.

7) Develop a Milk Assay

FAAN believes that a milk assay should be assigned Priority Level A for FY 2005. Milk allergy is most common among young children, with an estimated 2.5% of children under the age of 2 affected. This represents the most vulnerable group of our population. A review of cases of undeclared allergen that caused injury to a consumer indicates that milk is the leading cause of these reactions.

8) Report to the Public on Allergen Adverse Events

FDA/CFSAN must assign Priority Level A to improving the collection and publication of the incidence of clinically significant or serious adverse events related to food allergies.

FDA recalls due to undeclared allergens continue to occur, with the major causes including ingredient statement omissions and errors, manufacturing equipment cross-contact, and errors by ingredient suppliers or manufacturing firm employees.

If FDA discovers the presence of an undeclared allergen, the food-allergic public must be notified as soon as possible, as lives are clearly at stake.

There is no cure for food allergy; strict avoidance is the only way to prevent a reaction, and a trace amount of the offending allergen has been known to cause near-fatal

reactions. As a result, the health and safety of food-allergic individuals depend on reading food labels and knowing when to avoid a product.

Upon discovery of an undeclared allergen, the food plant in question must be inspected so that mistakes during the manufacturing process can be identified, and the potential for future undeclared allergens is eliminated.

9) Implement Section 203 of The Food Allergen Labeling and Consumer Protection Act (FALCPA)

With the passage of FALCPA, FDA/CFSAN must issue a rule pertaining to the labeling of the most common allergens. Although the law has been passed, FAAN has reason to believe that some food companies will not change their labeling practices until FDA instructs them (via rule) regarding FALCPA compliance. Since the provisions of FALCPA are to apply to food manufactured on or after January 1, 2006, FAAN should assign it “A” level priority.