



8/26 02 15 22 11:15

August 20, 2002

Docket No. 98N-0359
Public Comments

The Food Allergy & Anaphylaxis Network
10400 Eaton Place, Suite 107
Fairfax, VA 22030-2208
Tel: (800) 929-4040
Fax: (703) 691-2713
E-mail: legisl@foodallergymail.org

I. FAAN

The Food Allergy & Anaphylaxis Network (FAAN) is submitting the following comments regarding CFSAN program priorities for FY2003. FAAN is a nonprofit organization dedicated to raising public awareness, providing advocacy and education, and advancing research on behalf of all those affected by food allergy and anaphylaxis.

On behalf of 25,000 members nationwide, FAAN strongly urges that CFSAN and FDA continue to consider food allergy a major priority as part of its planning, budgeting, and resource allocation process for FY2003.

II. Food Allergy Facts

Food allergy affects an estimated six to seven million Americans (up to 2.5% of the population). Allergic reactions cause an estimated 150 to 200 American deaths annually, and 30,000 emergency room visits.

III. The Importance of Labeling Integrity

Currently, there is no cure for food allergies. The only way to prevent an allergic reaction is strict avoidance of the offending allergen. **Reading food labels** is the only means of avoiding food allergens in packaged foods.

98N-0359

C 87

IV. The Problem

Unfortunately, many reactions occur when individuals eat a food they thought was safe but that contained an allergen either not listed on the food label or “hidden” by scientific terms or confusing terminology.

There are three crucial areas of food allergen labeling:

- 1) **source or plain-language labeling** Currently, ingredient labels are written for food scientists, not consumers. They include technical or scientific terms that are foreign to many of us (e.g., *ammonium caseinate* for *milk*).
- 2) **advisory labeling** Companies use advisory statements, such as *may contain (name of allergenic ingredient)* on the labels to warn consumers of the potential presence of allergens. However, there are no standard definitions for these statements, and no common understanding among consumers as to what these statements mean. What is more, a growing number of companies use these statements indiscriminately on their products; this not only limits the food supply of food-allergic consumers, but also casts a doubt about the potential risk to the food-allergic consumer.
- 3) **labeling of ingredients exempted from declaration** Current regulations allow companies to list ingredients which appear in low levels under collective names like *natural flavors*, *spices*, or *colors*. However, allergens may be present in these flavors, etc., and even at these low levels, have caused reactions. Manufacturers *may* declare an allergenic ingredient of a color, flavor, or spice in the ingredient list; however, this decision is a voluntary one. This lack of a standard rule causes needless confusion and introduces an avoidable element of risk into the purchase of food items.

V. Evidence

- 1) A recent study¹ demonstrates how complex ingredient terminology (eg, *casein* and *whey* for milk) and label ambiguities (eg, *natural flavor* and *may contain peanut*) might compromise the ability of parents to determine the safety of particular products. Only 7% (4 of 60) of parents correctly identified labels that indicated milk; only 22% (6 of 27) of parents correctly identified soy protein; and just 54% (44 of 82) of parents correctly identified peanuts. What is clear from this study is that, with current labeling practices, most parents are unable to identify common allergenic food ingredients. These results strongly support the need for improved labeling with plain-language terminology and allergen

¹ Interpretation of commercial food ingredient labels by parents of food-allergic children. Preeti Joshi, MD, FRACP, PhD, Shideh Mofidi, MS, RD, CSP, and Scott H. Sicherer, MD. *J Allergy Clin Immunol* 2002;109:1019-21.

warnings as well as the need for diligent education of patients about reading labels.

- 2) FDA's 1999 study of food manufacturers indicated that a significant percentage of food products were recalled because they contained one or more undeclared allergen. Three principal factors contributed to the presence of undeclared allergens in the recalled products: ingredient-statement omissions and errors, manufacturing equipment cross-contact, and errors by ingredient suppliers or manufacturing firm employees.²
- 3) The number of FDA Food Allergen recalls due to undeclared ingredients has steadily increased over the last decade.

Recent Strides

Over the last few years, CFSAN and FDA have taken positive steps on the issue of food allergy and food labeling: a public meeting, a field allergen inspection guide, food inspector training, the incorporation of the eight most common food allergens into broader food safety programs, the creation of an allergen-related web site, and inspections of food firms that produce foods susceptible to contamination with allergenic ingredients.

Voluntary Food Allergen Labeling Guidelines are currently being revised by the Food Allergy Issues Alliance, a group of food trade associations and other interested organizations that convene to discuss issues related to food allergy. However, these trade associations encompass only a small percentage of food manufacturers nationwide, and it is unclear precisely how many manufacturers plan to follow the Guidelines once they are released. What is more, a number of food companies have told FAAN staff that they will do nothing until *required* to do so.

Despite these efforts, much work still needs to be done in order to ensure that food-allergic consumers are not susceptible to inadequate food labeling.

Food processors **must** be diligent in informing food-allergic consumers about the presence of food allergens in their products. Without ingredient labels that are clear, consistent, and reliable, food-allergic consumers are unable to make a valid decision about whether or not a food is appropriate for them to eat. Even the most diligent label-readers and ingredient-checkers run the risk of being inadvertently exposed to allergens due to today's problematic standards and regulations governing food labeling.

FAAN urges CFSAN to continue to make the issue of food allergy and food labeling a top priority for FY2003. Specifically, CFSAN should continue to increase consumer and industry awareness to the presence of allergens in food; develop and implement an

² Recalls of foods containing undeclared allergens reported to the US Food and Drug Administration, fiscal year 1999. Katherine Vierk, MPH, Kenneth Falci, Ph.D., Cecilia Wolyniak, and Karl C. Klontz, MD, MPH. J Allergy Clin Immunol 2002;109:1022-1026.

allergen enforcement strategy for cross-contamination; conduct training of field investigators on food allergens; and develop standards in labeling. Most importantly, however, is the need for **100% participation** by the food industry in order to assure the integrity of food labels and protect all food-allergic consumers.