



Asthma and Allergy
Foundation of America

Before the Department of Health and Human Services
Food and Drug Administration
[Docket No. FDA-2008-N-0429]

Food Labeling; Current Trends in the Use of Allergen
Advisory Labeling: Its Use, Effectiveness, and Consumer
Perception

Statement of the Asthma and Allergy Foundation of America

September 16, 2008

Recommendations on the Usefulness of Allergen Advisory
Labels to Consumers

The Asthma and Allergy Foundation of America (AAFA) is the leading nonprofit consumer and patient organization fighting asthma and allergic diseases. AAFA provides free information to the public, offers educational programs to consumers and health professionals, leads advocacy efforts to improve patient care and supports research to find better treatments and cures.

On behalf of AAFA, I am pleased to offer this statement. My name is Charlotte W. Collins, and I am Director of Public Policy & Advocacy.

Food allergies have grown in prevalence in the United States. About four million people have food allergies. People with food allergies have reason to be concerned about what they eat. Food allergies can kill and severely injure, causing about 30,000 cases of anaphylaxis, 2,000 hospitalizations and 150 deaths each year. Avoiding food allergens is the best strategy for people who are affected. Having a food allergy means a life of constant vigilance against unintentional exposure to the eight most common food allergens responsible for 90% of all food-allergy reactions – peanuts, tree nuts, fish, shellfish, eggs, milk, wheat and soy.

Unfortunately, for millions of food allergy patients, even the smallest trace-amount exposure to certain allergens may be enough to trigger a life-threatening allergic, “anaphylactic” reaction. Although many foods do not have main ingredients that are allergenic, many of them are processed in facilities that cause cross contamination with allergens, or include spices, flavorings or colorings derived from food allergens. This risk alone makes the current “ingredient-only” labels incomplete and dangerously irresponsible. Short of restricting their diets to what they produce themselves, allergic consumers need better food packaging labels to assist them. AAFA is pleased that the Food and Drug Administration (FDA) is considering a long term strategy for food allergen labeling at this hearing today.

Labeling can be a powerful tool to help people avoid their allergic triggers. Widespread labeling went into effect in 2004 with the enactment of the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004. Producers are required to label ingredients. However, this current “ingredient-only” labeling does not go far enough to let consumers know that a product may actually expose them to allergens that inadvertently contaminate a product due to cross contact during the production process.

AAFA stands for a labeling system that gives people with food allergies a fair chance to avoid potentially deadly allergens in the food products they consume, either as ingredients or as contaminants. In addition, this type of labeling should be uniform on all food products to inform consumers from product to product no matter the brand or producer.

Some manufacturers, while adhering to the new FALCPA rules, also voluntarily add “allergen advisory labels” on some products to warn consumers about these other contaminants. Advisory labeling can be helpful, but is insufficient and problematic as currently practiced.

First, the current advisory labeling scheme is voluntary, not mandatory. This loophole must be addressed.

Second, current advisory labels may cause confusion for some consumers. Advisory language is not consistent and may evoke different levels of concern in consumers. A 2007 study reported in the *Journal of Allergy and Clinical Immunology* suggested that the number of parents who heed the advisories is dropping. (We are conducting a survey of people with allergies about ingredient and advisory labeling consistent with the questions posed in the FDA's request for comments. We plan to report our findings from the survey as we develop the comments for submission to this agency in January 2009.)

Third, people whose English-language skills are limited may not fully understand written advisory label warnings. This includes people who are illiterate, have low literacy or have limited English-language proficiency. While an estimated 99% of Americans are literate, according to the National Adult Literacy Survey, about 21% have reading skills that are too limited to read a food label. Growing numbers of U.S. residents do not use English primarily. Labeling should take into account wide and expected variations in literacy levels, including language differences, by using symbols and images as well as words to convey warnings. Labeling should also consider those who are visually constrained in reading small print, like "Baby-Boomers" who are experiencing age-related vision loss.

While labeling is an important line of defense, it should not stand alone. AAFA believes that consumers need to know that they can rely on the integrity of the products that they consume, and the accuracy of labels. Even if clear, uniform and mandatory, advisory labels are no substitute for sound manufacturing practices that minimize the risk of unintentional cross contact with known allergens. The FDA ought to pursue the uniform adoption of standards for food processing that is consistent with this goal. Protecting the integrity of foods is vital for those who do not understand written messages because of low literacy or limited English proficiency.

Recommendations:

1. Establish regulatory authority for the FDA to compel food manufacturers to use clear, uniform labeling for advisories to warn consumers of the risk of inadvertent cross contact with major allergenic substances.
2. Extend mandatory ingredient labeling to flavorings, spices and colorings.
3. Collaborate with stakeholders from patient groups, food industry and researchers to develop allergen advisories that use terms and simple, evocative symbols or images that convey meaning intuitively, like "Mr. Yuk".
4. Collaborate with food industry and patient groups to develop minimum standards for manufacturing and processing food to reduce chances of cross contact with the major classes of known allergens.
5. Support these actions with a robust public awareness campaign.