Docket No. 2004N-0230
FDA Revision of Current Good Manufacturing Practice (CGMP)
Public Comment – Due Sept 10

In response to Question #7:

In today's food manufacturing environment, what are the principal contributors to the presence of undeclared allergens in food? For example, do labeling errors or cross-contamination contribute? Which preventive controls could help reduce, control, or eliminate the presence of undeclared allergens in food?

I. Introduction

The Food Allergy & Anaphylaxis Network (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.

FAAN is pleased that FDA has undertaken the task of revising its CGMP 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.

Eleven million Americans (or 1 in 25 persons) suffer from food allergy: approximately 6.6 million are allergic to seafood[1] (i.e., lobster, crab, fish), more than 3 million are allergic to peanut or tree nut[2] (i.e., walnuts, almonds, pecans). Milk, egg, wheat and soy are the other major food allergens.

[1] Scott H. Sicherer, Anne Muñoz-Furlong, and Hugh A. Sampson. Prevalence of seafood allergy in the United States determined by a random telephone survey. *Journal of Allergy and Clinical Immunology* 2004;114:159-65.
[2] 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.

2004N-0230 C9

The incidence of food allergy may not have peaked in the U.S. Peanut allergy in children doubled from 1997 to 2002.[3]

There is no cure for food allergy. Strict avoidance of the allergen is the only way to prevent a reaction. Consumers depend on accurate ingredient information for their health and safety. Trace amounts of allergens can cause severe or fatal reactions.

Severe allergic reactions (anaphylaxis) to food result in 30,000 Emergency Department visits and up to 200 deaths per year in the U.S.[4]

The presence of undeclared allergens in dozens of products suspected of causing reactions has been confirmed in testing by the Food Allergy Research and Resource Program (FARRP) of the University of Nebraska.

FARRP tested 177 food samples suspected of causing allergic reactions by consumers and/or allergists for the hidden presence of peanut, almond, walnut, wheat, soy, egg and milk (casein and whey). Of the 177 samples, 25% were positive for one or more hidden allergens including 28 of 72 for casein (milk), 2 of 9 for whey (milk), 8 of 190 for peanut, 2 of 47 for almond, 2 of 29 for walnut, 2 of 28 for egg, 0 of 7 for soybean, and 0 of 10 for wheat gluten.[5]

Recent passage of the Food Allergen Labeling and Consumer Protection Act (FALCPA) should yield improvements in the labeling of the eight major food allergens beginning in 2006; however, FALCPA fails to remedy both the problem of cross-contact during the food manufacturing process and the widespread use of precautionary i.e., "may contain" statements.

II. Principal Contributors

The principal contributors to the presence of undeclared allergens in food are: 1) cross-contamination (shared equipment), 2) lack of employee training, and 3) rework.

Cross-contamination (shared equipment)

---

[3] 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.

[4] 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.

[5] Taylor SL, Hefle SL, Lambrecht DM, Niemann LM, Muñoz-Furlong A. Immunochemical Analyses for Food Residues Can Be Used To Confirm Presence of Hidden Allergens in Food Implicated in Consumer Complaints. *American Academy of Allergy, Asthma & Immunology* Abstract #852, Annual 2004 Meeting.

One FAAN member informed us that his daughter had had a reaction to a cookie product. When he called the manufacturer, he was told that the item was made on shared equipment with nuts. The company acknowledged that **cross-contamination** was the problem, and when they order new packaging they would have a new warning on the label.

Another FAAN member informed us that her 6-year old peanut- and tree nut-allergic daughter had had a reaction after eating ice cream. According to the label, the product contained milk, and there was no mention of peanuts/nuts. However, halfway through the product she found a sliver of a nut. When she called the company, they informed her that all of their ice creams were made on **shared equipment**, yet none have a disclaimer for peanuts/nuts on their package.

After acknowledging **cross-contamination** as the result of an allergic reaction, a company told a FAAN member that when they order new packaging they would add a new warning to the label. *However, it might take several weeks.*

One FAAN member called 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 **shared equipment** and should all have a peanut warning. Clearly, such an inconsistent use of precautionary statements increases the potential for an allergic reaction.

Lack of employee training

Another FAAN member reported that her 16-month old son had had a reaction to a frozen fudge product. When she called the company she was told that there was a possibility it contained milk because it was made on the same equipment as milk and **"employees aren't careful these days"**.

Some companies think that peanuts and tree nuts are interchangeable. One FAAN member informed us in February, 2003 of a product label that stated it contained "traces of peanuts". Her tree-nut allergic daughter, however, had a reaction. When she called the company, she was told that the product was made on the same line as a product containing walnuts, and that was why the company indicated traces of peanuts on the label.

Some companies think that peanuts are the only allergen that warrants advisory labeling. Some will have a "Contains peanuts" statement even though other major allergens (milk, egg) are listed ingredients.

Rework

A prominent allergist with a known peanut allergy nearly died after ingesting ginger snap cookies. The product had undeclared allergens from **rework**. If not for his training, his ability to recognize the symptoms of anaphylaxis, and his quick access to epinephrine, he may not have survived.

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. The company's ignorance of the proper use of **rework** cost this individual his life.

III. Preventive Controls

In order to help reduce, control, or eliminate the presence of undeclared allergens in food, FAAN recommends the following preventive controls: 1) revision of current GMPs to include guidelines regarding rework and shared equipment, 2) guidance on the need for employee training regarding food allergies, and 3) guidance on the use of precautionary ("may contain") statements.

IV. Precautionary ("May Contain") Statements

Allergen advisory statements or "may contain" statements were developed by the food industry as a way to communicate additional allergen information to those with allergies. The 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.

FAAN has seen an increase in both the types of messages and the number of products that contain them. The increase has made label-reading even more time consuming and confusing.

More than two-thirds of those who responded to FAAN's 2002 Survey reported spending at least one hour per week reading food labels (N=398).

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.

More than 80% of those responding to the 2002, 2003, and 2004 FAAN surveys indicated that they had called a food manufacturer for more information about a product's ingredients (N=1,577).

Clearly, such a wide range of precautionary statements can only cause confusion to consumers affected by food allergy. One FAAN member, in a 2000 E-mail, asked, "Is there a big difference between 'may contain traces of peanuts' and 'manufactured in a facility that uses peanuts'? Should we follow the same precautions for both of these warnings?"

FAAN has good reason to believe that, In lieu of proper equipment cleanup, some companies are merely placing "may contain" statements on all of their food products. An October, 2000 E-mail from a FAAN member states, "Are companies just putting these warnings on everything to cover themselves or are there really risks?" An E-mail from 1999 to FAAN reads, "Clearly, it is easier for (food companies) to make the disclaimer about peanut traces, rather than make the effort to clean their equipment properly so that contamination with the peanut traces does not occur".

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.

V. Conclusion

Food allergy is an emerging food safety and public health issue, and millions of Americans affected by food allergy depend on the FDA to protect them. Their lives depend upon accurate, clear, and reliable labeling. The agency ***must*** take the lead in food allergen controls, especially as it related to labeling and GMPs.

It is imperative that any revisions made to address food allergens **must** be mandatory (i.e., "shall") as opposed to optional (i.e., "should"). Consumers' lives are dependent upon compliance, not guidance.

Resources exist that can help FDA with its CGMP revisions. The Food Allergy Research & Resource Program (FARRP) contains a wealth of information pertaining to allergen control and the food industry. FAAN, the largest nonprofit organization dedicated to food allergy, is also an available resource.