FOOD AND DRUG ADMINISTRATION

PUBLIC MEETING ON:

THE CHALLENGE OF LABELING FOOD ALLERGENS

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P R O C E E D I N G S

DR. FALCI: I want to say welcome to you all. I know some of you have come a long way and we're all glad you arrived safely. Let me give a special welcome to our panelists. We're very glad you're here today.

They've given me a few things to say as far as announcements and sort of housekeeping kind of things. Today is the FDA's Public Meeting on Labeling of Food Allergens, and I'd like to go over some of the administrative details.

Everyone should have picked up a packet, a registration packet, at the registration desk. In your packet, you'll see there is a list of restaurants. There is also a cafeteria. There are a lot of restaurants nearby here. There is also a cafeteria in this building downstairs. You have to go down one flight.

At the registration desk or a little bit off to the side, you'll be able to see various consumer and industry handouts. We hope you pick up a few of those. The guards, I believe, are requesting those of you that came through the I think this is the Third Street entrance, if you have your visitor's pass on you, that you keep that

with you when you enter and leave the building. Use that pass to come back in.

If you have any cell phones or beepers, would you just kindly take a look at them now and shut them off.

The bathrooms are located in the main hall of this building. When you leave this room, go to the right and you go to the main hallway and they're either on the right or the left-hand side, and if you think about, if you'll think about it, too, on the second floor, it's the same kind of configuration just in case they get a little crowded here on the first floor.

We have a sign language interpreter available today. If you know of anyone who needs sign language interpretation, please see the staff people. They'll be walking up and down the aisles.

Let's see. One more message for our panelists. The silver microphones are not to be moved. Those are the ones used for recording, and the black microphones are the ones you can move towards you to make any statements you wish.

The press has some area here in the front seats; if the press would like to come down and come up front, you certainly may.

And let's see, oh, yes, telephones. There are telephones in this building. You can walk out of this auditorium again and go to your right and you'll go past the guard station, and you'll see them right there by the guard station.

And I'd like to just do a little summary of where we've come as far as food allergens are concerned. It wasn't very long ago, actually in 1999, that FDA first thought about being and becoming more active with food allergens, and we did have discussions and we did formulate a plan of action as far as food allergens were concerned.

We formed an internal steering committee within the Center for Food Safety and Applied Nutrition, which is a center in FDA. And we also had a general committee on food allergens made up of a number of people within different offices that are in the Center for Food Safety. And at that time, one of the reasons for our action was because recalls of foods placed in the market, foods that contained undeclared food allergens were at high levels in the nation.

And in 2000, we followed that up. We went out with industry, we went out to industry and to consumers. We gathered data at that time. We were

seeking advice. We were trying to raise awareness of people in the industry as well as consumers as far as food allergens were concerned.

At that time, too, we were trying to decide on accomplishable tasks, those tasks that would make a difference as far as food allergens were concerned in the nation.

And in 2001, you see that we have our website established. You can turn to our website and see a variety of different actions that the agency has taken, examples of training as far as our inspectors are concerned, as far as food allergen control measures that are used in processing plants, how the inspector should go into processing plants and look for food allergin processing.

There is also a Compliance Policy Guide on our website as well, and we're actively training our inspectors over the next six months or so.

Today, we seek further information, and the kinds of things we'll talk about today, you will see eventually in our action plan for fiscal year 2002. So that's what we're trying to accomplish here today as well.

On our agenda, there are three subjects.

Dr. Christine Lewis, who is the Director of the Office of Nutritional Products and Labeling and Dietary Supplements, will be our moderator today at today's meeting. Dr. Lewis will give you an overview on the issues that we will be discussing here today and mention the agency's regulatory framework. And as your moderator, I'll turn this meeting over then to Dr. Lewis.

DR. LEWIS: Thank you, Dr. Falci. And I'd like to add my welcome to his welcome. We are looking forward very much to this meeting, and in our listening mode hope to be gathering a great deal of information today. I will be taking a few minutes to orient us by highlighting the challenges of labeling foods relative to allergens, but as Dr. Falci had some housekeeping rules to say, I have some ground rules to share with you.

The purpose of this meeting is to put forward and discuss information to help FDA determine what additional activities we should undertake vis-a-vis the issues surrounding the food label and allergens.

So our focus today is labeling. We're not addressing the technical aspects of food processing. More specifically our meeting will

address only the topics outlined in the Federal Register Notice, again plain English source labeling, advisory labeling, and labeling of ingredients exempted from declaration.

While we recognize there are other issues such as restaurant labeling and even latex glove allergies, these issues are beyond the scope of our discussions today.

In terms of ground rules for members of the press here, FDA staff will not be giving any interviews because we are in a listening mode. There are three FDA press officers here today, and they will stand right now. One is Ruth Welch, one is Kathleen Kolar, and Sebastian Cianci. Please see them if you have any questions or need assistance.

There will be some brief opportunities to ask written questions to panelists at the end of each panel session. A reminder: these are questions, not comments. And as we move through the presentations, please write your questions on the cards and give them to the ushers as soon as possible.

We will get to as many questions as time allows from you folks in the audience. I do need

to emphasize the questions from the public should be addressed to the panelists, not to FDA, as again we're in a listening mode.

We request that the questions only be on the specific subject that the panel has just discussed.

The last part of the meeting will be devoted to public comment. For those of you who wish to make a public comment and have not preregistered, there are sign-up sheets at the registration desk, first come/first served, and these statements should be no longer than three minutes.

There will be a timer set up for the public presentations. We'll let you know if you're going beyond your three minutes and need to stop. In addition to the oral public statements at the end of the day, you and anyone else may also submit written comments. They should be sent to Dockets, and again that information is in the Federal Register notice, and if you picked up your package, there is a copy of the Federal Register in your package.

There will be a transcript of the meeting available approximately one month after the

meeting. The transcript will be available at FDA's website, again in your package, www.cfsan.fda.gov.

Before I turn to highlighting our challenges today, I'd like to introduce our panelists. In no particular order, we have sitting with us today Regina Hildwine, who is Senior Director, Food Labeling and Standards, Regulatory Affairs at the National Food Processors Association.

We have Dr. Michael Jacobson, Co-Founder and Executive Director of the Center for Science in the Public Interest.

With us also is Lisa Katic, Registered Dietician, and Director, Scientific and Nutrition Policy at the Grocery Manufacturers of America.

And also Anne Munoz-Furlong, President and Founder of the Food Allergy and Anaphylaxis Network.

We also will have with us John Hallagan, who is General Counsel of the Flavor and Extract Manufacturers Association, American Spice Trade Association, and also with the International Association of Color Manufacturers, who will participate on Panel III this afternoon.

We also will have with us Kate Winkler,

Legislative Assistant from the office of the Honorable Nita M. Lowey, who will give an update on congressional activities related to the labeling of food allergens. Ms. Lowey's office was invited today because she's initiated draft legislation on the labeling of food allergens.

I appropriately need to inform you at this point that the current administration has not taken a position on such labeling.

And finally, I'd like to introduce the FDA listening panel, which is directly on my left. First there is Dr. Ken Falci, from whom you've already heard.

We also have Felicia Satchell, who is Director of the Division of Standards and Labeling Regulations in the Office of Nutritional Products, Labeling and Dietary Supplements.

We have Kathy Gombas, who is Deputy Director of the Division of HACCP in the Office of Field Programs.

And Thomas Wilcox, who is a Medical Officer within the Office of Scientific Analysis and Support.

And finally, Theresa Dziuk, Consumer Safety Officer, FDA's Minneapolis District Office,

who will discuss the summary of inspectional findings from the FDA/Minnesota and Wisconsin Food Allergen Partnership.

So, at this point, I will take just a few minutes with the slides to highlight the challenges that we're facing relative to labeling of food allergens.

I believe I can do this; correct? There we go. Keep going. Technology will help us some day. We're just not there yet.

As I've already mentioned, the focus of the meeting today is threefold: source or plain English labeling; advisory labeling; and labeling of ingredients exempted from declaration.

And more specifically, our meeting will focus on the eight most common allergens listed here: peanuts, soy, milk, eggs, fish, crustacea, tree nuts and wheat.

Next. As a bit of background, our current regulatory framework is such that the labels of food made from two or more ingredients list each ingredient by its common or usual name in descending order of predominance by weight in the ingredient statement.

Thus, consumers can obtain information

about the foods that they eat by reading the ingredient list. There are, however, two exceptions.

The first is that the act provides that spices, flavorings and colorings may be declared collectively without naming each.

Second, FDA regulations exempt from ingredient declaration incidental additives such as processing aids that are present in a food at insignificant levels and that do not have a technical or functional effect on the finished food.

However, I need to point out that FDA's policy is that an allergenic ingredient is not insignificant and therefore is not exempt from labeling.

In terms of the current state of play, FDA has two petitions in-house regarding food allergens. One is from the Attorneys General from nine states and requests FDA require a variety of activities including allergen information on the label, an insignia, toll free telephone numbers, good manufacturing practices, and labeling of flavors and incidental additives.

The second is a petition from a consumer

addressing very similar issues.

Next. We also are aware of NFPA's Code of Practice on Managing Food Allergens. This code of practice is a voluntary program adopted by NFPA's members.

Most recently, we've received and are aware of guidelines from the Food Allergy Issues Alliance. The Food Allergy Issues Alliance is a private group comprised of industry and trade group representatives and a consumer group as well as a scientific advisor representing academia. In May, they submitted to us a consensus document on guidelines for food allergen labeling.

The questions on which FDA is seeking information are spelled out in detail in the Federal Register. So just very briefly, they are, first, questions on source labeling. We're asking what plain English terms would be understandable. That is terms such as "milk" instead of "whey." And we're asking about what formats would be most informative. The issues are things such as formats in the ingredient statement itself versus below the ingredient statement as one example.

Also, in terms of source labeling--next slide--we're asking about whether or not multiple

formats would be confusing and should source labeling be voluntary or mandatory?

Second, we have a set of questions on so-called advisory labeling, advisory labeling falling into the category of such things about "may contain" and its impact on consumers.

And, in the next slide, questions about the appropriateness of advisory labeling including questions should the recommendations in the State Attorneys General petition be adopted and what about the criteria in the Food Allergy Issues Alliance?

Next slide. In terms of advisory labeling, we're also asking are there better alternatives to advisory label statements and do advisory statements adequately inform consumers? I should add that examples of current advisory labels in practice include, for instance, "may contain peanuts" or "manufactured in a facility that also processes peanuts."

Next slide. We are also asking should these advisory statements be prescriptive and what should be the location and prominence of these statements?

The third set of questions focuses on

flavorings, spices and colors. We're asking if FDA should continue to address the labeling of individual allergenic flavors, spices and colors on a case by case basis. We also raise the question of label location and the issue of mandatory versus voluntary labeling.

And in the next slide, we've also asked for comments on the labeling of incidental additives. What minor ingredients or processes would manufacturers be unlikely to recognize? And also when products are to be further processed or repacked, is better labeling on intermediate products necessary?

The questions on the labeling of incidental additives in terms of lastly, we're asking whether FDA should codify its policy that allergens cannot qualify as incidental additives that are exempt from labeling?

That basically highlights the purpose and issues we'd like addressed today during our meeting, and at this point, I think we will actually begin our program.

More or less without further ado, we'd like to turn to some remarks from Ms. Kate Winkler, who as we've mentioned before is from the Office of

Congressman Lowey. Ms. Winkler.

MS. WINKLER: Good morning. I'm delighted to be here today. It's also a pleasure to see so many people here that the Lowey office has worked so closely with. I too have to do a little good housekeeping before we start and say that I am Mrs. Lowey's legislative assistant. I handle her food safety and agricultural work. However, I'm not an official spokesperson for the congresswoman. If the press has any questions for the Lowey office, you can feel free to give us a call afterwards and speak with our press person. I'm just not at liberty to do so.

I'm here in my legislative capacity to talk about the work that my boss has been doing over the last year and a half on the food allergin issue and let you know where our piece of legislation stands at this point. Mrs. Lowey has a long record of achievement on food safety issues. She wishes she could be here today. She's actually up in New York catching up on a little district time, but Mrs. Lowey was formerly on the Agriculture Appropriations Subcommittee.

On that subcommittee, she took a strong interest in food safety issues. She's introduced

legislation that would require manufacturers to put a "best if used by" date on all perishable foods. She's also authored legislation that would require all fresh meat and poultry products to come with a nutrition label just as prepackaged food does, but her interest in the food allergy issue has taken her pro-consumer work to a new level.

I'd say about two years ago, we started to receive a number of mail and, you know, when she'd be in the grocery store making shopping visits--you know she's been a member of Congress now for more than ten years--people would come up to her and let her know their frustration with reading labels, and that's when she turned to me and said what can we do about those that have a food allergy and can't get the information that they need off of a food label?

So, you know, unfortunately, misleading and insufficient labels are not only a burden for some of us who look for expiration dates, but it's a serious health hazard for the millions of Americans with a food allergy. Food allergic consumers and the parents of food allergic children do not have a choice. Their health and lives depend on reading labels.

That's why Mrs. Lowey moved to introduce the Food Allergen Consumer Protection Act. An estimated 30,000 Americans suffer severe and even life-threatening reaction to foods each year and about 150 of them die. While we can't prevent allergic reactions, we can enact common sense food labeling requirements that will help consumers avoid allergen laced foods.

Currently, even those with a food allergy, even if they read labels for every food product they purchase every time they shop, they still cannot be assured that a product is safe.

For example, under current regulations, food manufacturers do not have to identify the products used in certain flavorings or additives. This exemption leaves critical health and safety information off our food labels. Although flavorings and additives are present in small quantities, for the millions with a food allergy no amount is irrelevant.

Furthermore, ingredient statements are written for scientists, not consumers. For example, how many people know that surimi is another term for egg. Food allergic children should not be expected to decipher terms like

"casein, albumin, or muso."

The bill that my boss has sponsored would require that food statements list in plain language what if any of the eight food allergens are contained in a product.

Beyond improving the readability of labels, it's time for manufacturers to clean up their acts. Too many manufacturers are preparing multiple products with the same cooking utensils or on the same production lines without properly cleaning the equipment. These practices must stop. A recent FDA study found that one-quarter of all manufacturers did not list ingredients that can cause potentially fatal allergic reactions and 47 percent of manufacturers did not check their products to ensure that all ingredients were accurately portrayed on the label.

There is no excuse when it comes to health and well-being of our children. Manufacturers should be taking every step possible to ensure their product safety. And as mentioned, the industry did recently propose voluntary guidelines, and my boss has worked very, very well with organizations like Grocery Manufacturers and National Food Processors Association, and she was

incredibly pleased that these guidelines were issued a couple months ago, and she has applauded the industry for taking to heart the seriousness of this health hazard.

But the fact is these are voluntary guidelines. The legislation will give some of the suggestions the weight of statutory law and ensure that every manufacturer abide by some of the suggestions made in the guidelines. Furthermore, it will provide the Food and Drug Administration with the resources to enforce the law.

As I said earlier, before we introduced the bill in the last Congress, and I should say that the bill introduced in the 106th Congress is very, very different than the one we'll be introducing in the 107th Congress. But before we introduced that bill, companies like Kraft and General Mills were already imposing stricter labeling standards, and we did use their labels as a model to work off of.

In addition, we enlisted the help of NFPA and GMA to help us raise awareness of the problem in the industry, and I think their guidelines show that they really have taken to heart some of the work that my boss has done and others.

To go point for point exactly what our bill does is again it requires that food ingredient statements identify in common language what if any of the eight main allergens are in a product. It closes the food additive loophole which requires that on the ingredient statements if an allergen is used in any of the spices or natural or artificial flavorings that it be labeled as such.

It preserves the Food and Drug Administration's authority to regulate the safety of certain bio-engineered products. It requires food manufacturers to include a working telephone number, including one for deaf persons in case a family has an emergency and they'd like to contact the actual manufacturer themselves to have questions answered.

It requires food manufacturers to better prevent cross-contact between food products that are produced in the same facility or on the same production line. It also would disallow the use of "may contain" language except for those that the Food and Drug Administration would allow. So that would put the FDA in charge of deciding in what instances a "may contain" language label is appropriate.

It would allow the Food and Drug Administration to assess civil penalties against processes and plants that are in violation of the labeling manufacturing requirements for food allergens. Furthermore, it would require the Center for Disease Control to attract food allergic related deaths. Fortunately, we don't have reliable and accurate statistics right now.

And lastly, it would direct the NIH, National Institutes of Health, to convene a panel of experts to develop a plan for research activities concerning food allergens. So that's the bill in sum.

In closing, I'd like to say that the bill will probably be introduced just after August recess. The bill will be introduced in both chambers. Part of the hold-up has been we've been working with Senator Kennedy on creating a bill that is suitable for both chambers so that we can have the same bill introduced on both sides of the Hill.

We've also been trying to educate other offices about the bill, let them know what we're looking to achieve, and in doing so, we've held a briefing where we had Dr. Sampson, one of the

leading doctors on food allergens, from Mount Sinai come down to the Hill and brief staff.

We've also been working very closely with some organizations like Food Allergy Initiative, FAAN and CSPI, and let them activate their base so that like the constituents who reached out to my boss to say that this is something that is needed, we need to have accurate, reliable, readable labels, that they can let their members of Congress know that this is important to them, and that they should get on board with Mrs. Lowey, Senator Kennedy, and cosponsor our legislation.

The only way this legislation is going to move is if we show that we have bicameral, bipartisan support, and I believe we do. But the only way that message is going to be made clear is if people contact their members and let them know. So it's very important that some of the groups here today, some of the families and children that are here today, get in touch with their members of Congress and let them know what's important to them and how a labeling law like this could make their daily lives easier.

I'd also like you to know that earlier this year the House passed the agriculture

appropriations bill and in that bill was report language that asked the Food and Drug Administration to act on the Attorney General petition that put forward to them suggestions on how to make labels more readable and how to address some of the concerns for food allergic families and their children.

In closing, I'd like to say I'm so pleased that FDA is having this public forum, as is Mrs. Lowey. I think this is a step in the right direction. I also think we need to get moving now. The voluntary guidelines were a huge, huge first step, but we need to ensure that every product on our shelves is readable, accurate and reliable so that families can feel confident about the food on their tables.

Thank you.

[Applause.]

DR. LEWIS: Thank you, Ms. Winkler. We'll now turn to our first panel today which addresses the source or plain English labeling. We have with us four panelists who will each make brief five minute comments on this topic, which will be followed by a discussion among the panelists themselves with input from our own FDA listening

panel.

We'll begin with Dr. Michael Jacobson, followed by Ms. Anne Munoz-Furlong, Ms. Regina Hildwine, and then Ms. Lisa Katic. Dr. Jacobson.

DR. JACOBSON: Thank you very much, Dr. Lewis, and I must say that I really appreciate the FDA holding this important meeting, the first one I can recall on food allergies. I think it indicates that the FDA is taking this issue very seriously.

Ingredient statements on food labels should be printed in a readable typeface and should clarify which ingredients might cause allergic reactions. Unfortunately, all too many ingredient lists are unreadable due to the small size and style of typeface used. Consumers shouldn't have to play the game of "Where's Waldo" when they're shopping to find the ingredients they're concerned about.

I have two examples here of some basically unreadable ingredient lists. The first one is a Stovetop Oven classic pasta--I guess it's pasta; I don't know what it is--for your inspection. And another one is a Hormel Kid's Kitchen product--the next slide, please--that really challenges people to read ingredients.

Labels such as these make a mockery of the FDA's requirement that ingredient lists shall appear prominently and conspicuously. Also, ingredient labels typically give the chemical names of additives such as sodium caseinate, lactose, albumen or gluten. That's enough of that slide, please.

This Quaker product, for instance, includes whey and sodium caseinate without disclosing that they are milk derivatives.

It can be tough for the average person to memorize all the possible derivatives of foods to which they're allergic. To help people who are sensitive to the eight major allergens and the raft of less common but sometimes no less severe allergens as well as for consumers who use ingredient lists for other purposes, the FDA should require all products to bear an entirely redesigned ingredients level which is on the poster in front of you.

Last month, CSPI formally petitioned the FDA to provide an ingredient facts label that is consistent with the nutrition facts label. The ingredients label should be printed in clearer larger type using upper and lower case letters,

major and minor ingredients should be separated out, and a clear allergy information section should alert sensitive consumers.

That section would include such statements as contains milk, soy and wheat or may contain peanuts. This particular label was designed by the same firm, Greenfield-Belser, that designed the nutrition facts label for the FDA about ten years ago. The wording and location of such information should be as standardized as possible on all packages.

It has been suggested that the sources of various food additives such as whey and albumen be declared after the names of the additives in the ingredient lists. So labels would state "whey (a milk derivative). "

If a clear ingredient facts label with an allergy information section is adopted, I'm not sure whether that redundancy is needed, whether the sources of the major allergens need to be stated in the ingredient list.

Focus groups could explore that matter and the request by the attorneys general that an "A" in a circle be printed on the front label to alert consumers about the presence of allergens.

While the FDA has focused on the eight most common allergens, I urge you to at least add sulfites to that list. Sulfites are not allergens but still cause life threatening anaphylactic reactions and must be listed on labels when present at 10 ppm, ten parts per million, or more.

Finally, the FDA should prevent consumer confusion about products that claim to be non-dairy or wheat-free or vegetarian when they actually contain additives from derived from milk, wheat or animals.

The front label of this product, for instance, says "vegetarian and soy cheese," but the manufacturer told us that the natural flavoring is actually skim milk, and the ingredient listed discloses calcium caseinate, both of which ingredients people with milk allergies and strict vegetarians would avoid. That kind of misleading labeling should simply not be allowed.

In sum, people with allergies and the rest of consumers need a clear legible ingredient fact statement with an allergy information section. That would do wonders to help people avoid the major allergens as well as other ingredients about which they're concerned. Thank you very much.

[Applause.]

DR. LEWIS: Thank you, Dr. Jacobson. Before we turn to Ms. Anne Munoz-Furlong, I'd like to remind the audience that you do have the opportunity to write questions on cards. We have several ushers who will be walking among you to pick these up. So as questions arise, please feel free to write them on the cards.

Go ahead, please.

MS. MUNOZ-FURLONG: Thank you. I have some slides. Shall I ask you to change them or do I--okay--fine. As we bring up these slides, I want to make the point that FAAN is a nonprofit organization. Our mission is to increase awareness, provide education and advance research into the conditions under which reactions and fatalities occur. We have 23,000 members. Most of these are parents of children with food allergies. Can we flip the slide and go on to the next one?

My objectives this morning--you can flip to the next one--thank you--are to give you information about the size of this problem, who is affected, and what the confusion is with the current labels. Next slide, please.

Currently, food allergies affect about

seven million Americans. About three million Americans are allergic to peanuts and tree nuts, and study after study continues to show that peanuts and tree nuts are the leading cause of severe or fatal reactions in this country.

Children are the largest group affected by food allergy. Up to six percent of children have a food allergy and eight foods account for 90 percent of the allergic reactions.

Next slide, please. Now, we know this list. The point I want to make here is that almost all of these foods have caused a fatal reaction to a child or an adult in this country.

Next slide. There is no cure for food allergies. Strict avoidance is the only way to avoid a reaction. That means the individuals must read the label for every product every time they go to the store.

Next slide. Food allergy is the leading cause of anaphylaxis. This is a larger problem than insect sting and medication allergy combined. There are about 30,000 emergency room visits a year and tens of thousands of reactions that are taken care of at home. Additionally, about 150 to 200 people die from these reactions.

Next slide. Okay. This is it. The symptoms can occur within minutes, and in every case the individual is eating something they believe is safe. So we're not talking about risk takers.

Next slide. Now let's talk about the confusion with the current labels. The first stop is when we go to the doctor and get a diagnosis, the doctor makes a diagnosis and tells the patient go home and avoid milk or eggs or wheat. They don't know that they're not going to see those names on very many products until they get to the grocery store.

If I could have the next slide, please. Now, this is just a sampling of what we call milk words. When someone has a milk allergy, they need to learn casein, caseinates, lactalbumin. These are the types of terms that they need to become familiar with, yet they're looking for the word "milk."

Then there is a whole host of situations under which the product may contain milk depending on the product, and that will change. They need to learn this as well.

Next slide. When we look at eggs, you can

see that some of these terms are very scientific and they certainly aren't consumer friendly.

Next slide. When we look at wheat, again the individual is going to the store expecting to see "wheat," but they're going to have to learn that semolina and durum and some of these other terms are what they need to avoid.

Next slide. Now, we have conferences across the country. Last year, there were 760 attendees. We conducted a survey looking at labeling and had 550 respondents.

Next slide. We asked them when they see a label, do they consider that the food labels currently on the market are easy to understand? 88 percent disagreed. 98 percent told us that the information on the label is not enough regarding allergens. 99 percent disagreed with the statement that the current labels can be understood by a seven year old. A seven year old would be about the first age that you can expect a child to start to learn to look for milk or eggs or some of the words that they're allergic to.

And 98 percent told us that the current labels are not easy to be understood by a new babysitter, a teacher, scout leader, anyone else

who is giving information or food to a child.

Now, the top three concerns--this was a write-in section to the survey--were "may contain," natural or artificial flavoring, and non-dairy. I know we have other panels to discuss "may contain" and non-dairy so I'm not going to stop here. The "non-dairy" bears mentioning for another discussion at a future meeting. This is certainly a big issue for our families.

Next slide. So when we're talking about labels, there is no cure for food allergy. Strict avoidance is the only way these people can avoid a reaction. Therefore, the labels must be clear and easy to understand. They must be consistent and reliable.

And the next slide. We recommend that these labels state in simple English terms adjacent to the ingredient panel what that product contains; that the allergens be identified when they're in these products at all times; and that there be a phone number so that the individual can contact the manufacturer whenever they have a question and we'll talk more about that as we go forward.

I want to sum up with one of the comments from our members is that we are not food

scientists, we're just mom and dad. Thank you.

[Applause.]

DR. LEWIS: Thank you. Regina Hildwine.

MS. HILDWINE: NFPA thanks FDA for the opportunity to participate in these panels today, and we will also be filing written comments. The National Food Processors Association is the voice of the $460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs.

My remarks today are all based on the Food Allergen Labeling Guidelines issued by the food allergy issues alliance. NFPA is a member of the Food Allergy Issues Alliance, and NFPA members support the Food Allergen Labeling Guidelines. NFPA believes that it is important to present information on the major food allergens in terms commonly understood by consumers. NFPA believes that plain language presentation options should not replace but should rather augment current ingredient labeling requirements.

NFPA also believes that the approaches outlined in the Food Allergin Labeling Guidelines are sufficiently flexible to suit various

situations and serve as a useful start for this discussion.

NFPA believes that plain language labeling options should be voluntary. To require such declaration would necessitate rulemaking on several standards of identify and other existing rules, and this is an unnecessary complication.

Food allergen information presented in plain language terms will help food allergic consumers including children and other challenged readers to recognize the foods they must avoid. Plain language labeling also makes it easier for the caregivers of food allergic children to recognize the food allergens to which their charges are sensitive.

The major food allergens as defined by FDA are not all single foods. Crustaceans, fish and tree nuts represent classes of foods. Within these classes of foods, food allergen information must be presented as the common or usual name of the individual food in the ingredient declaration.

For example, for crustaceans, crab, crayfish, lobster and shrimp are the terms that would be used. For fish, the common or usual name of the fish species must be declared in the

ingredient list. Likewise, for tree nuts, the individual types of allergenic nuts must be declared.

Other foods that contain allergenic proteins should include the plain language name of the allergen. In many cases, the plain language name of the allergen is used within the ingredient declaration as the common or usual name of the food ingredient or its standardized name.

For example, hydrolyzed soy protein, buttermilk, peanut butter, cracked wheat and milk chocolate all include the plain language names of major food allergens as part of their common or usual names or standardized names. In these instances, food processors declare the plain language names of food allergens through ingredient declaration.

When the plain language name of the allergen is not declared in the ingredient list, food processors should ensure that plain language terminology is present in association with the ingredient list.

Now, standards of identity can complicate the issue of declaring plain language names for food allergens, but these complications can be

resolved.

For example, the standardized food egg albumin specifies egg, and that's required in the standard. Dried yolks, a name permitted by that standard, should be supplemented with the term "egg." The ingredient would be dried egg yolks, a name permitted by the standard, which could be declared on the ingredient list as egg yolks.

Now, despite what you heard earlier, you would not see the word "surimi" to represent egg. Surimi is derived from fish and on the ingredient list of a surimi product, you are likely to see the term "fish protein."

With respect to wheat, semolina, farina, durum flour, graham flour, and white flour, all standardized names, should include the term "wheat" and the dozens of standardized cheeses all declare "milk" as a sub-listed ingredient.

Plain language terms for the major food allergens should appear within, at the end of, or in immediate proximity to the ingredient declaration. One option is to place at the end of the ingredient declaration a statement such as "contains peanuts." It could be prefixed by a phrase that highlights attention of the food

allergic consumers such "allergy information: preceding contains peanuts."

The same effect could be accomplished with the use of a reference mark, such as an asterisk next to the name of the ingredient whose common or usual name does not include the plain name of the allergen, such as farina or casein, each followed with a reference mark. That would then refer to a corresponding notation at the end of the ingredient list that would say "wheat" or "milk ingredient." This option takes up very little space and could be useful for long ingredient declarations.

Another alternative is to use within the ingredient declaration a parenthetical statement that follows the ingredient name such as "farina (wheat)." Any of these options, "contains," reference mark, parentheses, could use bold in their other highlighting to feature the information about food allergens.

NFPA does not believe that multiple format options should be confusing to consumers provided the food allergen information is always presented in association with the ingredient declaration. This is where food allergic consumers are instructed to look for information about the

allergens in food.

Finally, plain language labeling for food allergens should be permitted on a voluntary basis. A mandatory approach would necessitate FDA revising a number of rules for standards of identity and other labeling rules. This would complicate a labeling approach that can be done, and it is now being done on a voluntary basis. Thank you very much.

[Applause.]

MS. KATIC: Good morning. My name is Lisa Katic and I am the Director of Scientific and Nutrition Policy for the Grocery Manufacturers of America. GMA is the world's largest association of food, beverage and consumer products and works at the federal, state and local level on regulatory and scientific issues.

GMA member companies are committed to meeting the needs of the food allergic community. And I'd like to commend FDA for holding this public meeting to collect information on this very important issue.

GMA along with numerous trade associations formed the Allergy Issues Alliance several years ago because the food industry wanted to be

proactively out front of and address this allergy issue.

The Food Allergy and Anaphylaxis Network is an integral part of the Allergy Issues Alliance and as the association that represents food allergic consumers, FAAN is best positioned to provide insight into the labeling practices that would be of most use to the subset of the population. We really appreciated their input and work in developing our guidelines.

As Regina has already mentioned, the voluntary program has been developed by the Alliance and was released this spring. It's a culmination of several months of work by the Alliance including FAAN and some other, as was mentioned earlier, food allergy scientific experts. Unlike a regulatory process that will take several years to develop and implement, the Alliance's voluntary program is now in the implementation stage.

GMA's Board of Directors has adopted the Alliance's labeling programs and the CEOs of each of our member companies have asked their companies to implement the program. We fully expect widespread adoption and implementation of our

labeling programs by our companies in the very near future and as was already mentioned, some companies have been actively making changes since the adoption of this program.

With regard to the plain English labeling, the Alliance's labeling program specifically addresses this issue and requires the use of plain English names on the label of foods that contain an allergenic protein that is derived from one of the major allergens.

We recognize that it can be daunting for the food allergic consumer to learn the names of all of the ingredients that may be derived from an allergin. Milk is a classic example. As Anne showed earlier, there are numerous ingredients derived from milk.

In accordance with FDA's regulations, each of these milk-derived ingredients must be declared in the ingredient statement by a different name. Casein, sodium caseinate and whey are just a few examples of the milk-derived ingredients that must be avoided by a consumer with a milk allergy.

The Alliance's labeling program makes it easier for the milk allergic consumer to identify products that he or she needs to avoid by requiring

the use of the common term "milk" in addition to the name of the ingredient on the label of foods that contain an allergenic protein from milk.

As the agency is well aware, we have a tremendously diverse food supply that uses a wide variety of ingredients. Packaging materials are different as well as packaging sizes. Given this variety, there must be flexibility in presenting the common names of the allergens. The Alliance's labeling program provides this flexibility by offering options for presenting the major allergen's common name.

For example, a manufacturer could use parenthetical statements that identify the plain English name of the allergen in the ingredient statement after the ingredient. An allergen information statement could also be highlighted or used in the ingredient declaration panel and then it would list the common name of each of the major allergens in the food.

The Alliance's program provides other means of presenting the name of the common allergen as I think Regina has already laid out. The plain English name would appear either in the ingredient statement or in immediate proximity to the

ingredient statement.

In summary, we support the use of common and plain English names on labels of foods that contain major allergens, and we believe that the Alliance's labeling program sufficiently addresses how this information should be presented.

Because we anticipate widespread adoption of this program by the food industry, we believe that the allergen-labeling regulations are unnecessary. Thank you.

[Applause.]

DR. LEWIS: Thank you very much to members of our panel, and as scheduled on the agenda, we will now begin a 15 minute discussion among members of the panel as well as with the FDA listening panel. Let me remind you that that will be followed by the opportunity for us to address the questions you may be writing down on your cards, and again there are people walking the aisles so please do take advantage of that.

Relative to source or plain English labeling, are there particular issues anyone among our panelists would like to address? Dr. Jacobson.

DR. JACOBSON: I'd just like to ask Lisa how you could rely upon that voluntary flexible

labeling when there are thousands of food producers that are not members of NFPA and GMA? Many companies have never heard of these trade associations and things can change from one management to another management. I think the consumer needs to be assured that the clear English, the labeling will always be there.

MS. KATIC: Well, no doubt I appreciate that as a definite challenge. I would say that NFPA and GMA members represent a majority of food products on the shelves. So certainly we have the bulk of what we're talking about covered within our membership.

We've talked about--through Alliance outreach we certainly plan on doing a lot of education amongst our own industry, our own industry reaching out to other smaller manufacturers that potentially are not amongst our membership. We've got some discussions already underway on how to do that as well as educating. You know we have lots of large and small and medium-sized companies within our own memberships and we think that it's imperative that some of the larger manufacturers that have long-term experience with how to make changes on labels would be best

served by educating some of our medium and smaller sized companies. So it's really all about education and outreach and we have plans underway to do that.

DR. LEWIS: Other questions? Kathy Gombas.

MS. GOMBAS: Yes. This is Kathy Gombas with FDA. I'd like to ask a question of NFPA, Regina. You had indicated that source or plain English labeling should be voluntary versus mandatory because there are a lot of manufacturers currently using voluntary labeling. Do you have a prospective on how many manufacturers are doing this today?

MS. HILDWINE: I can tell you that at the present time, the Food Allergy Issues Alliance, and NFPA, of course, is a member of the Food Allergy Issues Alliance, is developing a survey so that we can collect some baseline data from the food industry regarding their awareness of the Food Allergen Labeling Guidelines and their use of various presentation techniques. We expect to field this survey, you know, the individual associations in the Alliance to our various members probably in the next month or so.

Now, there are many more food trade associations besides NFPA and GMA and the Food Allergy Issues Alliance, and many of these are specialized food trade associations that are focused on various sectors of the food industry, and we are going to be going out to our members collecting information from food companies both large and small to get a sense of how many have now begun to use the plain language labeling that was advocated along with other things that were advocated in the Food Allergen Labeling Guidelines.

DR. LEWIS: Felicia Satchell.

MS. SATCHELL: My name is Felicia Satchell and I'm with FDA. My first question is to Ms. Katic. You had indicated that the voluntary program is currently being implemented, and I understand from Regina's last response that you are beginning to work with the industry. Is there any plan for follow-up, say, six, eight, ten months down the road to see if all of your members are implementing this, if they are complying with the program? How do you plan to track follow-up?

MS. KATIC: Well, as Regina just mentioned, we are developing, in the process of developing a survey that will give us a baseline of

awareness and use of the program now, and we plan on reinstituting that survey in the spring and then obviously probably next fall to track the changes in usage and awareness.

MS. SATCHELL: What type of incentive, if any, for voluntary compliance? I mean I can appreciate your doing a survey, but let's say that you have manufacturers that for financial reasons find it too costly to relabel, what are your plans for addressing members that may not be following the guidance?

MS. KATIC: Well, I think, first of all, the incentive is that no manufacturer wants to harm any consumer, first and foremost. They take this very seriously. Secondarily, there are legal issues that certainly no company wants to, you know, have an issue with again harming a consumer. So this is something that the industry has been working on for decades, for a long, long time. This is nothing new. This is something that the industry continues to look at and refine and redevelop.

So, you know, as I said in my comment, this is something that has gotten to the highest levels within our member companies. It's been

presented to our board of CEOs. Our CEOs are on board and have given their support obviously and encouragement for use of the program.

And I think through the survey, you know, we're really going to have some understanding of-- the trade associations within the Alliance will have some understanding of how it's being used and obviously if it's not, then that will modify or adjust our education and outreach efforts.

MS. SATCHELL: Thank you.

DR. LEWIS: Other questions? Dr. Falci.

DR. FALCI: This is Dr. Falci of the Food and Drug Administration. I think there is a lot of agreement that we have here and I'm pleased with that. I'm trying to turn my head around so I can see your format of ingredients that you have there, Dr. Jacobson. And I think that's a very interesting idea about having different kind of formats for ingredients in the ingredient statement.

But my question has to do a little bit with consumer education. Maybe you could think about that as I continue on here. That is consumer education as far as the formats are concerned. One of the things that I've seen is that there's a

large percentage of the population that are unfortunately not interested in food allergens because they don't have that problem, they don't have to deal with it.

So when you sit down and you think about trying to educate the consumer, it's hard to try to think of maybe the appropriate way of approaching people that might not be interested in it and to try to get them more interested in that. So my question again is how would you really begin to try to educate the consumer?

I know that Lisa Katic had mentioned that you're discussing that now. I'd be interested just maybe if you could elaborate more on it, but some of the things that came to my mind, of course, were TV advertisements, of course, which are very expensive, but maybe once you get into the school programs about potential new formats as well. So would anybody like to field that?

DR. JACOBSON: Well, I don't think we could expect any kind of well-funded government educational program that lasts for any significant period of time. Measures should be self-actuating and that's what a clear ingredient label is. It makes it possible for consumers to actually read

the label as the law suggests.

Look at some of those products in front of you. Tom, could you pass that thing over there? These labels are designed not to be read. You'll definitely need your glasses and a magnifying glass, too.

[Applause.]

DR. JACOBSON: It's all upper case, skinny little print, very small writing that may be inevitable, but it goes--there are textbooks on how to print things legibly. This violates every precept in those textbooks, and if the information is clear, it would make it a lot easier for consumers to read the label whether it's for food allergens or sugars or heart disease or hydrogenated fat or whatever people are concerned about.

DR. FALCI: Just as a follow-up to that, I think one of the reasons why such a package is created like that is unfortunately there is not a lot of food in the particular containers, not enough space on the container to have a large letters, but I don't know how you'd overcome that.

DR. JACOBSON: Well, I think there's certainly a variety of products. We found very

small print on very large packages also. But even an example like that one before you, upper and lower case printing would be a lot easier to read. You know designers can make labels that are easier to read or harder to read. Unfortunately, many companies are choosing the latter.

DR. LEWIS: One more brief comment before we move on.

MS. MUNOZ-FURLONG: In response to Dr. Falci's question about how to educate the consumers, if we're talking strictly about the simple language labeling, they are already reading labels, those that are affected, the food allergic population. The problem is they can't understand what they're reading. What we need to do is simplify the labels so that when the children and the adults and the teachers and so forth read them, they'll understand what they're reading, and also when that doctor makes a diagnosis and tells that patient to read the label, they will then be able to read it.

So in this issue I don't think it's such a concern for education as it will be in some of the other panels.

DR. LEWIS: We'll take one more brief

question from Felicia Satchell and then we'll move to the cards.

MS. SATCHELL: The question is directed to Dr. Jacobson and Ms. Munoz-Furlong. Both Ms. Hildwine and Katic mentioned three or four options in their presentation for presenting plain English labeling in conjunction with the ingredient statement. Allowing the flexibilities of these options, do you see that as being a stumbling block or confusing for allergic consumers?

MS. MUNOZ-FURLONG: On this issue, I don't think that it will be. The fact is that they reading the label. They need to have a place or a statement that they can understand. If we're looking at what they like, and I'll cover some of that in the next panel, they would prefer that we have a statement of "contains milk and eggs" immediately after that ingredient statement because then it saves them time. They don't have to read that entire paragraph in very small print. They can zoom in on that and put the package back on the shelf if it's not safe for them or put it in their shopping cart.

DR. LEWIS: Thank you very much.

DR. JACOBSON: I think there should be a

standardized label so consumers don't have to hunt around and say, oh, is there an asterisk here or is it boldfaced. It should always be in the same place and as Ms. Munoz-Furlong suggested, something at the end where it would say allergy information, and then milk, soy, whatever, is the best option.

DR. LEWIS: Thank you to the panelists. We'll now move to the questions from the audience, and I have several here that I think will probably easily take up our remaining time.

This question is about placement and it's directed to either Ms. Katic and/or Ms. Hildwine. Does the Alliance Allergy Labeling Program address labeling ingredients above and below the package seam?

For example, a Trail Energy Bar sent our son to the hospital because we were unaware that almonds were listed under the foil seam.

MS. HILDWINE: Well, that's a very difficult situation, and a consumer shouldn't be in that situation. Certainly, there are situations with respect to the design of packaging that are a challenge for the food industry.

The food companies do try to make that information as clear as they possibly can given the

constraints of the package size. In fact, food companies know that FDA has regulations regarding the sufficient prominence of food label information and, you know, NFPA does encourage its members to follow those regulations all the time.

I think you'll see in some cases, though, particular types of food are in particular types of packages that make, you know, using all the label space to present the required information very much of a challenge and we are working with our members to try and improve those situations.

MS. KATIC: The only thing I would add is that the program that was developed by the Allergy Issues Alliance does emphasize the prominence within the ingredient panel declaration, and that's what we would continue to support.

DR. LEWIS: Our second question from our attendees seems to be addressed for anyone who would like to deal with the topic. I suspect it's more oriented towards industry.

The question is what about "contains milk, wheat and egg ingredients," the way General Mills and Kellogg's are labeling? Is this accepted to the food allergic consumer? Is there data to support the way the industry should go for consumer

clarity?

MS. HILDWINE: Well, I'll start with this one as well. Certainly, those statements such as "contains milk, wheat or egg ingredients," this is one of the options that, in fact, the Food Allergy Issues Alliance included in our Food Allergen Labeling Guidelines. It is the top ranked option, as a matter of fact, in our presentation of the various options for presentation. And you know we think that a lot of food companies are starting to move in that direction to include this type of information that specifically says at the end of the ingredient statement that the product contains these ingredients. It reinforces the information in the ingredient statement.

MS. MUNOZ-FURLONG: Well, from the consumer's perspective, General Mills and Kellogg's are one of the companies that everybody talks about. They like their labels. They're in simple English and "that contains," and then the allergens in simple language is perceived as a shortcut and a very handy way to teach someone else how to read that label.

DR. LEWIS: Anything else from our panelist on this topic? We have a question to

three of the panelists regarding Dr. Jacobson's presentation, and it has to do with his small board that he presented. Do you folks support CSPI's ingredient facts proposal? Can you discuss it? Why and why not?

MS. MUNOZ-FURLONG: I can tell you that the allergy information statement, we have conducted some focus groups and people do like allergy information. It could also be substituted with "contain" statement and that would be acceptable as well.

MS. HILDWINE: Just focusing on the allergy information portion of the format for the moment, certainly that does present one of the options outlined in the food allergen labeling guidelines. I think there are things, though, in the format overall that need to be taken into careful consideration.

A couple weeks ago when Dr. Jacobson announced this new format, there was a side by side comparison of a current ingredient list and the proposed new format, and I, you know, just a minute ago talked about the challenges of fitting required label information on small packages, and if you do that side by side comparison, you will see that the

proposed new format takes up a great deal of label space. So that's a real practical problem that certainly needs to be explored further.

DR. LEWIS: My remaining cards focus largely on the issue of voluntary versus mandatory labeling. In our remaining five minutes, I'll try to summarize some of those. They are quite overlapping.

There is a question for Ms. Hildwine. Is your reason for supporting voluntary labels instead of mandatory ones that it's too confusing for manufacturers and the FDA to agree on this, and therefore it would delay implementation? And if so, why not implement voluntary rules now and work on standard regulations for all companies?

MS. HILDWINE: Well, first of all, voluntary rules is an oxymoron. There is really no such thing. And certainly the work that the Food Allergy Issues Alliance has been doing is a voluntary approach and we announced this this spring, and food companies, some had already been following the precepts outlined in those guidelines. Other companies are starting to do that now.

We've been encouraging members to adopt

these presentation options and these guidelines. Our concern is is that some food companies may say, well, if FDA is going to develop regulations to require this to adopt a mandatory approach, well, I think maybe I'll just wait to see what the agency does now.

In plain fact, going the mandatory route will delay the adoption by the industry of those presentation options that have been outlined in the Food Allergen Labeling Guidelines. So we would, you know, not just to mention the overwhelming complexity of this--you may not realize it, but when FDA, well, when the law changed to require declaration of ingredients of standardized foods as part of the Nutrition Labeling and Education Act, FDA had to open up the regulations on every one of the standards of identity.

I believe there are about 72 regulations governing cheese, and this is only one category of standardized food. FDA would have to make amendments to an overwhelming number of regulations. It's not just a simple matter of requiring this in a particular section of regulations.

So it would be very complicated. It would

take quite a long time. There is no reason to wait. The voluntary program that's been established by the Food Allergen Labeling Guidelines is in implementation now. So we don't think that anybody should wait for rules and that it should continue to be on a voluntary basis.

DR. LEWIS: Thank you. Lisa.

MS. KATIC: Well, just building one comment on top of that, I think Regina pretty well laid out the complexity, which then leads to the next point, why we think voluntary versus mandatory is the way to go is that down the road the industry sees this program as evolving.

If there is research, enough research that is done on a particular ingredient that it does prove that it becomes an allergen or is a problem for the public, that would be incorporated into the program and can be done right away, whereas waiting for regulations to, you know, move through the process could take one to two years, where as the industry can act very quickly and institute or implement something pretty quickly.

DR. LEWIS: My remaining cards really do play on this, and you may have already made your points, but I will offer these questions to you.

To Regina Hildwine, because recalls are so high, on what basis do you think voluntary guidelines will be enough, and is it enforceable?

To Anne Munoz, Furlong, does FAAN support mandatory labeling and legislation in this area?

And then finally, if a number of NFPA and GMA members already are labeling voluntarily or plan to, why is the industry opposed to FDA regulations which would reach all industry members since those already doing this voluntarily will just be ahead?

Again, those are issues you've been addressing so I'll allow you to answer those or build on other comments you've already made if you wish.

MS. HILDWINE: Just with respect to the issue of recalls, these, as I've observed them over the past several years, are very much related to undeclared allergens, outright undeclared allergens. The issue of plain language labeling is not question.

Also, oftentimes the presence, the notation of a recall is an indication that enforcement type activity may have begun with respect to FDA. We believe that FDA has plenty of

authority to enforce regulations relative to undeclared, any undeclared ingredient including food allergens. That's all I have to say for that one.

DR. LEWIS: Anne, did you want to make a comment?

MS. MUNOZ-FURLONG: Yes. Regarding whether FAAN is for or against or whatever the term was for mandatory versus voluntary. FAAN's position is that we know we need label improvements immediately. We are going to support any and all initiatives that are going to get us there be they voluntary, regulatory, legislative, because ultimately they're going to benefit the consumer.

[Applause.]

DR. LEWIS: In the last few minutes, does anyone else on the panel have one more comment or question before we take a break? Thank you. We will take a 15 minute break, which means we'll be back here just a little before 9:40.

[Whereupon, a short break was taken.]

DR. LEWIS: All right. Let's get started. We do have a special presentation. I have been asked to remind the audience to please make note of the fact that there is no eating in the auditorium.

That's a very important issue here. Please do not consume vitals here in this particular auditorium.

Our second panel addresses advisory labeling, and before we actually get to the panel presentations, we have with us today Ms. Theresa Dziuk. She is with our Minnesota District at the Food and Drug Administration, and she will be presenting a summary of inspectional findings.

If you would please welcome, Ms. Dziuk. Thank you.

[Applause.]

MS. DZIUK: I'd like to thank the center for inviting me. I feel very fortunate to be here today. When this started, I was a compliance officer with the state of Minnesota. In 2000, I joined the FDA as a consumer safety officer. In October of 1998, the Food and Drug Administration formed a partnership with both the Minnesota and Wisconsin Departments of Agriculture.

This partnership was in response to reports of consumers who experienced adverse reactions following exposure to allergic substances in foods which were not declared on the food label. In addition, there was an increase in the number of allergen related recalls, and we had concerns over

manufacturing controls of undeclared allergen residues.

The goal of our partnership was to eliminate duplicate inspections and sample collections, to ensure uniform enforcement and to obtain current information on allergy awareness and provide feedback to industry.

While it is generally believed that nearly every food can cause an adverse reaction, eight foods are known to cause 90 percent. FDA recognizes these as peanuts, soybean, milk and milk products, eggs, wheat, tree nuts, fish and crustacea.

Although this partnership looked at the control of food allergens, we focused on industries that used peanuts and eggs. Ice cream, bakery and candy manufacturers were selected for coverage. 86 inspections were planned and 85 inspections were conducted. Establishments inspected were 45 bakeries, 13 ice cream manufacturers, and 18 candy manufacturers.

Inspections performed were routine GMP inspections. That's good manufacturing practice inspections. State inspectors and FDA investigators were trained in August of 1999. To

ensure uniform application of current good manufacturing practices, inspectors and investigators were standardized during initial joint inspections.

Inspections were conducted in September '99 through March 2000. This was a small study. Establishment selection was not intended to be scientifically significant, but to provide an overview of current industry practices. Selection was made randomly of small, medium and large establishments that were licensed and inspected by the state departments of agricultures, that conducted interstate commerce, and that were jointly scheduled on the agency's workplans.

One measurement of establishment size used by FDA is annual gross sales. What you'll see here on the left side, there are nine categories of annual gross sales. We broke those down into three groupings and considered them small, medium and large. I've broken out on the slides both Minnesota and Wisconsin. We inspected 85 total establishments. 17 were small, 51 medium, and 17 large.

During our inspections, our investigators utilized a specialized questionnaire to aid in

assessing industry practices. Example of the areas investigators observed during the inspections were the use of shared equipment, production practices such as handling of rework, labeling and product changeover, and any other mechanism that related to the control of allergens. Samples were obtained based on observation.

This following series of slides has a lot of information that I will not be covering. I'm going to be presenting totals, and it's important to recognize that there weren't differences between Minnesota and Wisconsin.

Each of these graphs is broken down on the left side by total, and then they're also broken down by commodity. There are bakeries, ice cream and chocolate. And again, I'm only going to be focusing on the total, and I present this other information so that you can see from your own interest.

The product label is the primary means to inform a consumer of potential product allergens. Our questionnaire contained a section on the use of allergenic ingredients. Ingredients used in the formulation of the product were compared to the corresponding finished product labeling.

45 of the 85 firms inspected, and that's the blue bar right here, felt that they had adequate procedures in place to verify label accuracy. Of the 45 firms that felt that they had adequate procedures to verify label accuracy, our investigators found that 15 percent had incorrect finished product labels.

Of the firms that didn't have procedures to verify their labels, 51 percent had incorrect finished product labels. Only one of the 85 firms inspected had a policy against the use of advisory labeling.

One bakery inspected reported that they had received a consumer complaint. The consumer stated that they had an allergic reaction after consuming a product that normally would not contain peanuts. The consumer called the bakery and said they were allergic to peanuts and had the reaction when they consumed this product. The bakery reported to inform the consumer that the labels states it may contain peanuts. The customer appeared to be satisfied and had no additional contact with the firm.

This is an example where advisory labeling may not always be effective. An advisory labeling

statement such as "may contain" are not a substitute for good manufacturing practices.

37 of the 85 firms inspected utilized rework. Procedures for handling rework varied by industry. Of the firms that utilized rework, 48 percent had product that tested positive for undeclared allergen residues. When using shared equipment, product changeover presents an unintentional opportunity for product that contains an allergen to contaminate a product that does not contain an allergen.

Equipment cleaning is critical to the control of allergens. While only three establishments inspected utilized analytical test methods to verify their cleaning and sanitization procedures, 41 of the 85 had standard operating procedures in place to control cross contact.

During our inspections, we observed that production was frequently not scheduled. Scheduling was conducted first in/first out where the first order received would be the first order manufactured, and allergen considerations were not addressed.

Scheduling was based on the color of production. For example, a sugar cookie would be

the first product manufactured, followed by various flavored chips, then peanut butter cookies and then finally ending the production run with gingersnaps.

Many firms did not have dedicated equipment for allergen and non-allergen product lines. Non-dedicated product lines were observed to be inadequately cleaned between production. Many times equipment was rinsed with only water or the equipment was cleaned at the end of the day. Only three of the 85 firms inspected utilized personnel that were trained and dedicated to allergen control.

At this time, a tolerance for undeclared allergen residues has not been defined. A standard method has not been approved by the AOAC. For the partnership, we utilized an ELISA test kit that was developed by the University of Nebraska and manufactured by the Neogen Corporation. This was used strictly as a screening tool.

Each sample was a composite of ten eight-ounce subs and a ten part per million test kit standard and a reagent blank were used as our controls. We determined a sample positive if it was reported positive at or above ten parts per million.

Samples were not obtained at every manufacturer inspected. Sample selection was based on manufacturing practices observed during the inspection. Our samples were used to confirm our observational findings. A sample was obtained if equipment was shared and a non-allergen containing product was produced after an allergen containing product without the equipment first being cleaned.

We identified areas where there was a potential for cross contact and then took a sample. Our goal was to assist industry in defining critical control points in their process.

We collected 118 partnership samples for analysis which was performed by the state laboratories. 73 samples were obtained for undeclared peanuts and 45 samples were obtained for undeclared eggs. 73 of the 85 firms used peanuts in their production. 18 of the 73 samples obtained were found positive for undeclared peanut residues. It's important to remember that we chose these samples based on our observational findings. So we expected to find residues in these samples, and these 18 samples is equivalent to 25 percent of the samples obtained.

When we look at the total picture

comparing our observations with the sample analysis, it was observed that 49 percent of the firms had a potential for cross-contact of allergens into non-allergen containing products. Of these firms, 50 percent had positive samples for undeclared allergens. Of the firms that utilized rework, 48 percent had samples that tested positive for undeclared allergens. Of the firms that didn't have procedures for label verification, 51 percent had incorrect finished product labels.

Allergen awareness was very high in some firms and extremely low in others. We held industry workshops to provide feedback on our partnership. Three workshops were held in May of 2000. We prepared an information pack with allergen education materials and for the firms that were unable to attend, we mailed this pack to them.

We conducted follow-up. All establishments that were inspected received a copy of their establishment inspection report. They also received a copy of their analytical results. We either met or sent a letter to the firms that had samples which tested positive for undeclared allergens and explained the significance of these findings. We conducted follow-up inspections at

these firms during August of 2000.

We conducted 21 follow-up inspections and collected 18 samples. We found that industry made every effort to address and modify their good manufacturing practices. The greatest change noted was in addressing cross-contact in the form of scheduling and sequencing. Firms dedicated equipment to non-allergen and allergen-containing products. They reconsidered their use of rework.

Many firms corrected their labels. Sanitation practices were improved and verification testing of equipment and finished product was implemented. Many firms trained their employees on the significance of allergen control.

Through this partnership, we felt that the FDA and states gained credibility with industry. We found that the industry was very open and willing to share their manufacturing practices. Adherence to good manufacturing practices are essential in the reduction of undeclared allergen, and advisory labeling is not a replacement for good manufacturing practices.

We are all in this together as consumers and labeling should be addressed as a food safety concern. Thank you.

[Applause.]

DR. LEWIS: We'll now begin Panel II which addresses the topic of advisory labeling. We have four presenters. First, Ms. Lisa Katic. Second, Regina Hildwine. Third, Anne Munoz-Furlong. And last, Dr. Michael Jacobson. Lisa.

MS. KATIC: Thank you.

MS. KATIC: GMA supports the use of supplemental statements such as "may contain peanuts" consistent with the criteria established in the Food Allergen Labeling Guidelines prepared by the Allergy Issues Alliance. These guidelines clearly state that consistent with the FDA policy on this issue, supplemental allergen statements should not and cannot be used in lieu of good manufacturing practices.

In addition, the guidelines restrict the instances in which a manufacturer can use these kinds of statements. Under the guidelines, supplemental statements only can be used when:

(1) The presence of a major food allergen is documented through visual examination or analytical testing of the processing line, equipment, ingredient or product or other means;

(2) The risk of a presence of a major food

allergen is unavoidable even when current good manufacturing practices are followed;

(3) A major food allergen is present in some but not all of the product; and

Last, the presence of a major food allergen is potentially hazard.

If some but not all of these four criteria are met, the guidelines do not allow the manufacturer to use a supplemental allergen statement. In such instances, the manufacturer must either consider an additional food allergen control measure and/or some other labeling strategy.

With regard to the placement of the supplemental allergen statement, the guidelines require the statement to appear at the end of or in immediate proximity to the ingredient statement. The guidelines require that the statement be as accurate and as conspicuous as possible. Examples of the type of supplemental statements that are being used include "may contain peanuts" and "processed on the same equipment as milk."

The guidelines provide the manufacturer with the flexibility to determine the type of supplemental statement that will best describe the

product.

Supplemental allergen statements are an integral component of the Alliance's labeling document. Although the food industry is diligent in its efforts to prevent major food allergens from inadvertently ending up in food products, the nature of the food supply and our manufacturing processes in some instances make it impossible to avoid.

Farmers generally grow numerous crops and use the same equipment to harvest, store and transport corn, soybeans, wheat, peanuts and other crops. This can lead, for example, to the presence of soy in corn or wheat in peanuts.

Inadvertent contact can also occur in the manufacturing facility where the same processing equipment is used to manufacture a wide variety of products. In an attempt to prevent the inadvertent presence of allergens in products, many in the food industry have adopted a three-tiered approach to minimize this inadvertent contact with allergens.

This approach involves dedication when possible, separation, and as a last resort labeling. First, when possible, the industry will use a dedicated system. This may be possible for

some large volume products where continual production on the same or multiple lines is needed to meet consumer demand. It is not financially possible, however, to have a dedicated system for each product that is manufactured by a company.

When a dedicated system is not a possibility, the company will use separation as a means to minimize inadvertent contact. This can be accomplished by physical barriers, the use of dedicated containers for raw materials that contain allergens, and other means to prevent the inadvertent contact of a major allergen with non-allergenic ingredients.

Companies will also schedule production so that when possible, a non-allergen containing product will be manufactured on a line before a product that contains an allergen.

Companies will also thoroughly clean a line that has been used to manufacture a product containing a major food allergen before manufacturing a product that does not contain that allergen.

Cleaning, however, will not always succeed in removing the allergens from all services of the equipment. It has been proven time and time again

that water is the most efficient method for removing allergenic proteins from processing equipment. There are numerous foods and food systems, however, where water cannot be used as part of the cleaning process due to the nature of the food or due to microbiological safety concerns.

Chocolate and peanut butter manufacturing systems are examples of processes where water cannot be used to clean the machinery because these foods do not readily dissolve in water and the use of water can lead to microbiological concerns due to the puddling of water somewhere in the system.

Water also cannot be used in the cleaning of certain packaging and electrical equipment such as baking ovens and cooling tunnels for obvious reasons. Water and electricity don't match.

In instances when water cannot be used for cleaning, the food industry frequently will use a dry process for cleaning, such as flushing the line with a safe, non-allergenic dry ingredient or food that removes the food from the system.

The use of these dry ingredients is recognized as an appropriate good manufacturing practice and in many instances is dictated by the microbiological concerns that are present by wet

cleaning.

The use of dry ingredients to clean a system, however, is not always successful in completely and 100 percent removal of the allergens. Systems that rely on this type of cleaning frequently cannot be cleaned to remove all residues of a major allergen.

In those instances when neither dedication nor separation can prevent the inadvertent contact with the major allergen, the industry will resort to labeling, labeling consistent with the four criteria established in the Alliance's labeling program that I stated earlier.

These criteria are designed to ensure that supplemental allergen statements are used only in limited situations and not as a substitute for good GMPs.

Supplemental allergen statements are designed to alert the food allergic consumer that the product in question may have an allergen that they need to avoid. We recognize that a certain percentage of a given product bearing this supplemental allergen statement may be free of the named allergen and safe for consumption for the food allergic consumer. However, the allergen may

be present in some of the foods manufactured on that line. Thus, necessitating the use of a supplemental statement that alerts the food allergic consumer to the possible presence of this allergen.

As stated in many comments earlier, we believe that the allergen labeling issues can be best addressed through the voluntary program and that additional regulations are unnecessary. Although the existing regulations do not mandate the use of common English names or establish criteria for the use of supplemental allergen statements, the industry through the Alliance has reached agreement on these labeling issues and is now in the implementation phase.

We believe that continued educational efforts will be one of the most effective means to address this issue. GMA has educated its member companies about the importance of the allergen issue, and as stated this morning, the senior management from each of our member companies has agreed to adopt the labeling program.

We recognize, however, that we also have to reach the small and medium sized companies that may not be members of GMA or of the other alliances

that are part of the Allergy Issues Alliance. The Allergy Issues Alliance is in the process of developing educational programs for these other smaller companies. Moreover, FDA has the existing statutory and regulatory tools to take enforcement action against those companies that market products with undeclared allergens.

The unacceptably high level of recalls due to the presence of undeclared allergens is perhaps the strongest evidence supporting the agency's ability under its existing regulatory framework to address this issue.

We also encourage FDA to develop and maintain a strong enforcement presence for food allergens. One of the best ways to effect change and to encourage all companies regardless of size to make certain that their products are properly labeled and that their foods are manufactured in accordance with good GMPs is through continued inspections and when necessary enforcement actions.

We believe that a strong FDA presence and the knowledge that there is a "cop on the beat," if you will, would be a much more effective use of agency resources rather than additional regulations.

In conclusion, GMA supports the use of supplemental allergen statements in those limited instances when the four criteria in the Alliance's labeling program are satisfied. Consistent with FDA's guidance on this issue and the terms of the Alliance's labeling program, supplemental allergen labeling cannot and should not be used as a substitute for GMPs. Thank you.

[Applause.]

MS. HILDWINE: Thank you very much. Episodes of inadvertent cross-contact between foods that contain major allergens and foods that are not intended to contain those allergens coupled with the resultant problem of undeclared allergens in the product where they are not intended indicate that both production controls and labeling approaches must be discussed for these foods.

FDA's questions focus on the issue of supplementary or advisory labeling, the so-called "may contain" statements. But NFPA believes that this discussion may include a mention of manufacturing practices. NFPA believes that this is the correct approach since we advocate the limited and carefully controlled use of supplementary of advisory food allergen labeling.

Food processors that prepare foods that may be exposed to inadvertent contact with major food allergens acknowledge that labeling is not a substitute for good manufacturing practices. GMPs and their resultant controls must be considered first before labeling approaches are considered. Processors should review the plant environment including storage conditions and production line architecture; should review the products, controls and practices of their supplier; should examine their own production operations, including separation, sanitation and scheduling practices; and then should create optimum conditions for food allergen control including employee training as far as they are able.

When this process is completed, if the risk that the food allergens may be present, that risk still exists, then supplementary allergen labeling must be considered. Supplementary or advisory labeling should not be an easy shortcut to bypass activities that are food processors' responsibilities, but rather should be viewed as an approach of last resort when the risk of presence of a food allergen cannot be avoided with absolute certainty.

Supplementary or advisory labels should be relatively rare, not increasingly more common. Nevertheless, given the difficulties of achieving absolute certainty that there is no risk of presence of major food allergens in a variety of operational situations, supplementary or advisory labeling is necessary and should be permitted.

The food industry has taken numerous steps over the past several years to change manufacturing processes to reduce the potential for cross-contact with major food allergens. At NFPA, we have a Food Allergens Committee that has been working, meeting for several years, to discuss these practices. As a result of these discussions, last year NFPA issued a "Code of Practice for Controlling Food Allergens," and this year we have started an elaboration of the Code of Practice, a how to implement the code of practice for the use of our members, which, by the way, cover the broad gamut of food processing, various sectors in the food processing industry.

The food industry recognizes that under existing GMP regulations, reasonable precautions must be taken to prevent cross-contact with major allergenic proteins. In instances, when

cross-contact cannot be avoided even when complying with GMPs, food and ingredient manufacturers then use labeling that informs the food allergic consumer of the possible presence of allergens in the food.

However, only supplementary label statements that are used in careful controlled circumstances would provide a food allergic consumer with enough information to make a clear decision about whether or not a food is appropriate for them to eat.

The Food Allergen Labeling Guidelines of the Food Allergy Issues Alliance outlined four conditions that spell out the carefully controlled circumstances to govern responsible consideration of supplemental food allergen statements. Lisa went through these and I'm going to do it again because we believe these are very important.

The guidelines present a reasonable yet rigorous approach to the criteria for determining whether supplemental labeling statements should be used. These type of food allergen statements should be used judiciously only when all four of the following criteria are met:

First, the presence of a major food

allergen is documented through visual examination or analytic testing of the processing line, equipment, ingredient or product, or through other means.

Thus, the first step is to affirm that the major food allergen is in the environment. This affirmation can be accomplished through examination of the physical plant, processing procedure, analytical testing where available, or through documentation.

Second, the risk of presence of a major food allergen is not unavoidable even when current good manufacturing practices are followed. This criterion signifies that all the feasible operational issues that can be addressed have been addressed with respect to control of the major food allergens, yet even under those conditions, there is not a complete certainty that one can avoid the risk that the allergen could be present.

Third, the major food allergen is present in some but not all of the product in question. Clearly, if this criterion is not met, "may contain" type label statements could not apply. If the allergen is present in all of the product, there is nothing may about it. The product does

contain the allergen.

The occasional or sporadic presence of an allergen may provide additional information that allows the food processor to diagnose a situation with a supplier, the plant environment, a piece of equipment or a processing procedure. This information would then trigger a review back to the second criterion.

If one can identify a feature that would enable the processor to control further the risk of presence of an allergen, then steps should be taken to exert additional controls.

This third criterion highlights that the review of allergen control procedures is not static, but dynamic. Review of the criteria for supplemental labeling should be undertaken whenever there is a change to one of the operating variables such as ingredients, suppliers, equipment or processing techniques.

The fourth criterion is that the presence of the major food allergen is potentially hazardous. At the present time, scientists do not agree that there is a condition under which the presence of the major food allergen is not potentially hazardous, so this particular criterion

at the present time would always apply.

Now, if some, but not all of these criteria are met, food and ingredient manufacturers should consider food allergen control or food allergen labeling strategies other than supplemental allergen statements. Meeting all four criteria will ensure that supplementary or advisory label statements are considered only after due diligence.

Meeting all the criteria also ensures that labeling statements are not used capriciously or as a theoretical precaution. For food processors, adhering to these criteria undoubtedly will have associated costs for reviews, self-inspections, audits, documentation of procedures, post-sanitation testing, personnel training and sometimes new equipment or facilities.

However, failure to be vigilant with GMPs or such widespread use of supplemental labeling that food allergic consumers no longer believe the statements, these can have consequences that are not only costly but are tragic.

If supplemental allergen labeling is used responsibly, the likelihood is that food allergic consumers will believe the statements and will

statement should be to prompt food allergic consumers to draw the conclusion that they should not consume the product.

In order to provide for different production circumstances, there should be flexibility to the presentation of supplementary or advisory food allergen statements. If such statements are to be accurate, then the one-size-fits-all approach is not feasible.

For this reason, FDA should permit but should not mandate such labeling in proximity to the ingredient declaration and food processors should adhere to the necessary food allergen controls and evaluation criteria regarding the use of these statements. Thank you.

[Applause.]

MS. MUNOZ-FURLONG: I have some slides. Okay. What I'm going to talk about I will continue to refer to as "may contain" labeling, but I really am intending for it to be all of the precautionary allergen statements.

May I have the next slide? Now my objectives here are to provide you with information about what the industry is currently doing and how that is impacting on the consumer and the consumer

last week, and the product that their child has been eating for years and years has been safe. This week, they can no longer purchase that product because it says main contain on it.

The only difference is that the "may contain" has been added to the ingredient declaration. There are no other ingredients that have changed. This is causing a lot of frustration and a lot of confusion to the allergic consumer.

Can we go back on that slide one more time? We can't go back. Okay. All right. Well, I'm going to make my point anyway. The point is that because of the proliferation of "may contain" statements, the integrity of all of the precautionary labels are being questioned by consumers.

A perfect example came to our office several days ago. One of our members was on an airplane and was given a bag of raisins. She looked at the ingredient label simply because our members are trained to read ingredients for everything. On a bag of raisins, it said may contain peanuts. You have to wonder what's going on.

Now, as a result of the proliferation of

some of these statements, some of the physicians are telling their patients to ignore these statements because they're on everything and they don't believe that they're really there for anybody but the company's safety.

As a result, some patients are making the decision on their own to ignore these statements. This to me is playing Russian roulette. The other concern I have about this is that we are talking about children and it concerns me greatly that parents and others are making decisions because they're so confused about what's going on out there.

Next slide, please. Now, as I mentioned earlier, when we asked for the write-in to our survey, what were the three major concerns from our membership, "may contain" was at the top of the list. Some of the comments that we got, and we got hundreds of comments in our book about some of these issues, were that "may contain" is perceived to be a defensive legal tactic or a way of avoiding good manufacturing practices.

Again, this is because the consumers have been left to their own to try and decipher some of these labels.

Now when we go on and look at some of the data from our study, when we asked them how the perceive these statements, if it says contains whatever the allergen is, 96 percent of the membership reported that they do not purchase that product.

When they see "may contain," 92 percent do not purchase that product. When they see "processed on shared equipment," 87 percent of the people do not purchase the product. And manufactured in a plant that also produces nuts or peanuts or whatever the allergen is, 66 percent never purchase the product.

The point I want to make here is that if a company is putting these types of statements, manufactured in a plant or processed on shared equipment, because of a risk to the consumer, because they intend that the consumer not purchase that product, we can see from this information that they're missing the mark, and there is a huge group of people that are at potential risk because they don't understand what you're trying to tell them with these labels.

Now when we drilled down a little deeper and we asked about the "may contain," how do they

interpret this, "may contain" to this group is a gray area. They live in a black and white world. If you're allergic, you avoid the food. "May contain," they ask is it in there or isn't it in there, how can we tell?

When we asked about may contain any and all of the following, and then there is usually a long list of allergens, they want to know when is it in there? How can we tell? Is there a code on the package? How does this happen that a manufacturer does not know what is in the product that I'm about to eat? And then don't they clean? They're concerned that these statements are being used in lieu of good manufacturing practices.

Next slide, please. And when we ask them about manufactured in a plant that also processes--most commonly we see this with nuts or peanuts, they questions that came back to us and that are coming back to the industry, are how far is the allergen and non-allergen containing equipment from each other, and when you give me that information, can you tell me what the risk will be to me?

Obviously, none of us can answer this question. Therefore, this kind of labeling raises

more questions to the consumer than it really answers and it causes again additional frustration. Another problem that we're seeing with this type of labeling is when we have multiple product packages, the outside of the product packaged does not match what's inside so we may have a may contains something on individual packages on the inside, but not on the outside.

Next slide, please. Now when we asked them about contains, and I mentioned this at the earlier panel, this to them is very black and white. It contains it. I'm allergic. I can't have it.

If they see the allergens bolded or highlighted or in a contains statement immediately after the ingredient declaration so that it's still within that visual range that they scan on that package, this again is a shortcut and is perceived to be a favor that a company is doing to them because it's helping them read that label very quickly and it saves time with each product that has to be read.

So, in summary, the food allergic consumers need to know what is in the product. This is a health and safety issue for this

population. The companies have a responsibility to provide accurate, reliable, consistent information about that information, and I think we all agree that we all need a standard guideline for when these precautionary statements will be used so that we can educate the consumer about what they are supposed to do when they see these statements.

We also would like all companies to use these statements judiciously. Now, the guidelines that we worked with on the industry certainly address this issue, and I applaud the companies that worked on this with us and are already doing this. However, I am concerned as I hear more and more smaller companies saying we're not going to do this until it's regulated and we will wait and see what FDA does.

So there is a lot of work that needs to be done in this issue. I'd also like to make a point that this is an international issue. We are hearing the same thing from our colleagues in other countries.

If we could have the lights, I want to read very quickly in my remaining two minutes an e-mail that is very typical of what we get in our office from our members. This is from a woman who

says my son has tree nut allergies. Recently it seems that many manufacturers are placing warning statements on their packages such as "may contain nuts," "may contain traces of peanut or other nut particles due to manufacturing," or a candy corn product that the list includes "may contain peanuts, walnuts, almonds, pecans, cashews and other ingredients."

I realize that the foods might be manufactured on the same machinery as foods that do contain nuts, but it is increasingly difficult to know the true ingredients. I'm afraid it will become likened to the boy who cried wolf and we will all start doubting the ingredients. And with that, I'd like to conclude. Thank you.

[Applause.]

DR. LEWIS: Just a quick reminder to the audience, you can write your questions on the cards and we will have someone collect them from you.

DR. JACOBSON: Contamination of food with undeclared allergens is what makes life so fearful for people with severe allergies. They live in terror that a food contains an allergen not listed on the label.

Unfortunately, such contamination occurs

fairly frequently as we heard a few minutes ago from the FDA consumer safety officer who did the study in Minnesota and Wisconsin.

That study found that in a selected sample of 85 ice cream cooking and candy manufacturers, 21 marketed products containing undeclared peanut or egg ingredients, and those are the only two allergens studied. If they had looked at others, there may have been other problems.

Similarly, the Oregon Department of Agriculture tested 62 chocolate candies that were not supposed to contain peanuts, but 23 percent of those did contain significant levels of peanuts, and University of Nebraska researchers found peanut allergens in four out of 19 packaged foods that neither listed peanuts as an ingredient nor warned consumers that the products might contain peanuts.

In some of those cases, the products may simply have been mislabeled. Others may have been unintentionally contaminated. Though actual problems from cross-contamination are very difficult to identify, at least three reports in the medical literature have found cross-contamination having caused allergic reactions.

In two different cases, toddlers suffered anaphylaxis due to milk protein in sorbets. Peanut antigen in gingersnap cookies was the cause of a 34 year old man's reaction.

"May contain" language is sometimes appropriate to inform consumers of the presence of possible allergens. But excessive use of such statements deprives sensitive consumers of choice and may cover up sloppy manufacturing practices.

We strongly support the FDA's position that quote "such labeling should not be the norm and that manufacturers should strive to eliminate the presence of allergenic materials that are not intentionally added to a specific food product."

That policy was first enunciated in Commissioner Kessler's 1996 letter to food trade associations stating that quote: "Precautionary labeling should not be used in lieu of strict adherence to good manufacturing practice to effectively reduce and eliminate the likelihood of cross-contamination, label mix-up or employee error." Five years ago.

Unfortunately, we have heard that some industry lawyers are advising manufacturers not to test for allergens because of product liability