

# Audit of manufactured products: Use of allergen advisory labels and identification of labeling ambiguities

Mariah M. Pieretti, MD,<sup>a</sup> Danna Chung, MD,<sup>a</sup> Robert Pacenza, BA,<sup>b</sup> Todd Slotkin, BS, MBA,<sup>b</sup> and Scott H. Sicherer, MD<sup>a</sup>  
New York, NY

**Background:** The Food Allergy Labeling and Consumer Protection Act became effective January 1, 2006, and mandates disclosure of the 8 major allergens in plain English and as a source of ingredients in the ingredient statement. It does not regulate advisory labels.

**Objective:** We sought to determine the frequency and language used in voluntary advisory labels among commercially available products and to identify labeling ambiguities affecting consumers with allergy.

**Methods:** Trained surveyors performed a supermarket survey of 20,241 unique manufactured food products (from an original assessment of 49,604 products) for use of advisory labels. A second detailed survey of 744 unique products evaluated additional labeling practices.

**Results:** Overall, 17% of 20,241 products surveyed contain advisory labels. Chocolate candy, cookies, and baking mixes were the 3 categories of 24 with the greatest frequency ( $\geq 40\%$ ). Categorically, advisory warnings included "may contain" (38%), "shared equipment" (33%), and "within plant" (29%). The subsurvey disclosed 25 different types of advisory terminology. Nonspecific terms, such as "natural flavors" and "spices," were found on 65% of products and were not linked to a specific ingredient for 83% of them. Additional ambiguities included unclear sources of soy (lecithin vs protein), nondisclosure of sources of gelatin and lecithin, and simultaneous disclosure of "contains" and "may contain" for the same allergen, among others.

**Conclusion:** Numerous products have advisory labeling and ambiguities that present challenges to consumers with food allergy. Additional allergen labeling regulation could improve safety and quality of life for individuals with food allergy.

(*J Allergy Clin Immunol* 2009;124:337-41.)

**Key words:** Food allergy, advisory labeling, quality of life, regulation, FALCPA

## Abbreviations used

FALCPA: Food Allergy Labeling and Consumer Protection Act  
RMX: Retail Merchandising Xpress  
UPC: Universal Product Code

Food allergies are an increasing problem in the United States and much of the developed world, affecting ~6 % of young children and 3.5% to 4% of adults.<sup>1</sup> The treatment of food allergies requires strict avoidance of offending food allergens. For manufactured food products, successful avoidance requires careful reading of product ingredient labels. Severe allergic reactions to undisclosed allergens in manufactured products were reported before current labeling laws.<sup>2,3</sup> Manufacturing and labeling errors regarding allergens sometimes lead to recalls.<sup>4,5</sup> Studies performed before current labeling laws showed that labeling ambiguities resulted in errors in safe product selection by consumers.<sup>6</sup> In response to these problems, the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 was developed by the Food and Drug Administration. The law became effective January 1, 2006,<sup>7</sup> with the goal of mandating manufacturer disclosure of the most common allergens (milk, egg, wheat, soy, peanut, tree nuts, fish, and crustacean shellfish) in plain English in the ingredient list or in a separate "contains" statement.

Despite the improvements in labeling under FALCPA, limitations of the law may impose continued challenges for consumers with food allergy. For example, advisory labels, such as "may contain," are not regulated. The Food and Drug Administration indicates that advisory labels must be truthful and not misleading, but there are no additional guidelines. Studies show that consumers with food allergy are becoming less avoidant of products with advisory labels and assume incorrectly that terms such as "shared equipment," "shared facility," or "may contain" indicate different levels of risk.<sup>8</sup>

In this study, we sought to address the scope of the burden of current labeling practices for the individual with food allergy. We performed a survey of 49,604 supermarket products, focusing on advisory labeling, and an additional detailed survey of 744 products to identify additional labeling ambiguities currently affecting consumers with allergy. The data presented here indicate a significant burden and safety risk for consumers with food allergy, disclose information of importance for allergists in educating their patients, and identify deficiencies that can be addressed by additional labeling regulations.

## METHODS

To determine the frequency and language used in allergen advisory labels, a market analysis of commercially packaged supermarket products was

From <sup>a</sup>the Mount Sinai School of Medicine and <sup>b</sup>the Food Allergy Initiative.

Supported by the Food Allergy Initiative, New York.

Disclosure of potential conflict of interest: S. H. Sicherer serves as a paid consultant for the Food Allergy Initiative, has received research grants from the National Institute of Allergy and Infectious Diseases/the National Institutes of Health, and has served as a medical advisor for the Food Allergy and Anaphylaxis Network. T. Slotkin is Chairman of the Board of Directors of the Food Allergy Initiative. R. Pacenza is Executive Director of the Food Allergy Initiative. The rest of the authors have declared that they have no conflict of interest.

Received for publication January 16, 2009; revised April 17, 2009; accepted for publication May 26, 2009.

Available online July 14, 2009.

Reprint requests: Mariah M. Pieretti, MD, Department of Pediatrics, Division of Allergy and Immunology, Mount Sinai School of Medicine, One Gustave L. Levy Place, Box 1198, New York, NY 10029. E-mail: mariah.pieretti@mssm.edu.

0091-6749/\$36.00

© 2009 American Academy of Allergy, Asthma & Immunology

doi:10.1016/j.jaci.2009.05.032

conducted from July 17 to August 18, 2006. Retail Merchandising Xpress (RMX, Tampa, Fla) was contracted for data collection. Surveyors ( $n = 34$ ) in 25 states were trained by RMX supervisors via conference calls; project instructions and survey workbooks were sent by mail to each surveyor. Surveyors were instructed to audit 10 to 50 products from among 24 different standard industry food categories. They were instructed to choose products randomly by as many manufacturers as possible to obtain a wide representation. A total of 500 products per supermarket location were audited. Products were chosen from 99 different supermarkets, representing 45 parent chains. Standard food industry categories included baby food, baking mixes, flour/meal, fresh bread/rolls, frozen bread/dough, cold cereal, hot cereal, chocolate candy, non-chocolate candy, frozen dinners/entrees, ice cream/sherbet, seafood, frozen seafood, gravy/sauce mixes, pancake mixes, syrup/molasses, pasta, spaghetti/Italian sauce, salad dressings, salty snacks, cookies, shortening/oil, soup, and spices/seasonings.

A questionnaire was completed by the surveyor for each product after review of the label. In the questionnaire, surveyors were asked to identify products with advisory labels and to classify the language used in the advisory label into 1 of 3 broad categories: "may contain," "shared equipment," and "within plant." Data were subsequently entered by each surveyor into an Excel spreadsheet, and data sheets were sent to a supervisor at RMX for review.

To determine further details of advisory labels and to identify any additional allergen labeling ambiguities, a second, more detailed audit was conducted on a smaller cohort of products from June 4 to 15, 2007. Ten surveyors were assigned specific product categories and were instructed to choose products from 3 to 4 different retailers. Each surveyor collected data on approximately 100 unique supermarket products. Unique products were identified by distinct Universal Product Codes (UPCs); surveyors were instructed to avoid choosing the same product in a different size, even if the UPC code was different. Surveyors completed a structured questionnaire, and 4 digital photographs (product name, UPC, ingredients/nutrition facts, product contact information) were taken of each product.

## RESULTS

An initial database of 49,604 manufactured products was created. After an initial review for duplicate products identified by identical Stock Keeping Units, a total of 20,241 unique products remained for analysis. From this database, it was determined that overall, 17% (3442/20,241) of products surveyed contained advisory labels. The categories of foods with the highest use of advisory labeling were chocolate candy, 54%; cookies, 53%; baking mixes, 40%; and pancake mixes, 32% (Fig 1). The categories of foods with the lowest use of advisory labels (<10% or less) included the following: frozen bread/dough, 8.6%; soup, 8.5%; frozen entrees, 6.3%; gravy/sauce mix, 6.2%; syrup, 5.7%; salad dressing, 4.9%; shortening/oil, 4.7%; frozen seafood, 4.6%; pasta sauce, 4.1%; canned fish, 2.2%; baby food, 1.3%; and spices, 1.1%. The language of the advisory statements when grouped into 3 general categories was distributed as follows: "may contain," 38%; "shared equipment," 33%; and "within plant," 29%.

To detail further the use of advisory labels and to identify additional ambiguities and labeling practices, the data from the second survey, containing 1015 unique products, were reviewed. Two investigators (M.M.P., D.C.) subsequently reviewed each of the products by verifying the data entered against the photographs collected for each. A total of 271 products were eliminated because photographs were incomplete or of poor quality (blurry, bad glare) and therefore impossible to review, leaving 744 unique products for analysis. The remaining descriptions of allergen labeling refer to this sample.

Overall, 13% (98/744) of the products disclosed an advisory label. The most common allergens listed in the advisory labels

were tree nuts (61%) and peanuts (48%; Fig 2). There were 25 different types of advisory terminology (Table I). The most common terms were "may contain," 21%; "may contain traces of", 13%; and "manufactured in a facility that also processes," 13%. "Allergen-free" terminology, including "gluten-free" and "lactose-free," was found in 3% of products.

We identified 6 products with FALCPA violations involving the use of scientific terms: "whey" without the term "milk" for 3 products, and failure to disclose "wheat" while using the term "durum flour" for an additional 3 products. FALCPA mandates the disclosure of the type of tree nut, fish, or crustacean shellfish if these categories of food are listed as an ingredient. All of the products surveyed containing at least 1 of these allergens ( $n = 151$ ) were compliant with this regulation.

Although the following are clearly not FALCPA violations, several labeling ambiguities were identified that represent areas of potential confusion for the individual with food allergy (Table II). Sources of gelatin (eg, fish, bovine) were not disclosed for 27 of 28 products (96%). If the source of gelatin was pork or beef, these labels were FALCPA compliant. One product listed fish gelatin within the ingredients but did not disclose the type of fish. For lecithin, the source, which could be soy, egg, sunflower seeds, or rice,<sup>9</sup> was not disclosed for 5 of 200 (2.5%) products. One product listed "flour" but did not identify the source. The simultaneous disclosure of "contains" and "may contain" for the same allergen was found for 25 of the 744 products. As an example, 1 product listed within the ingredients "wheat flour" and "whey (milk product)" and also included an advisory statement that declared the product was "manufactured in a facility that processes dairy products and wheat."

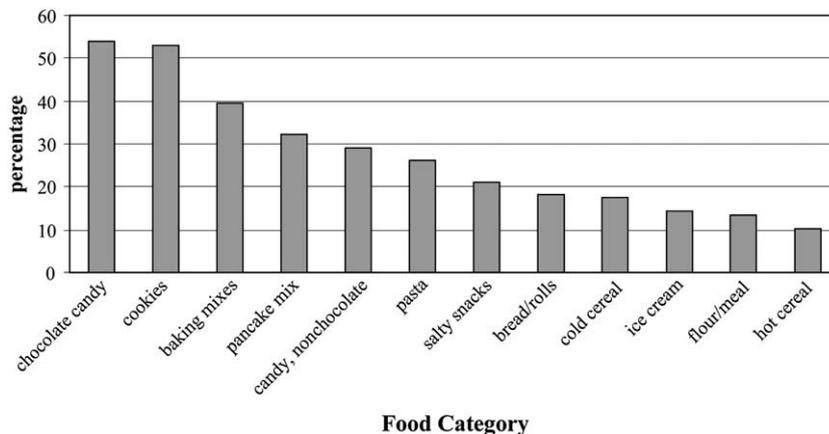
Because advisory labels are not regulated by FALCPA, the type of tree nut, shellfish, or fish does not need to be disclosed on the advisory label. We found that the type of tree nut (such as walnut) was not disclosed for 77% of 60 products with advisory labels for tree nuts. Only 1 product had an advisory label for fish, and the type (anchovies) was disclosed. Only 1 product listed an advisory label for shellfish, and the type was not disclosed.

Nonspecific terms, such as "natural flavors," "flavors," and "spices," were frequently used and were frequently not linked to a specific ingredient. The term "natural flavors" was used in 44% of products (331/744 products) and was linked to either a major allergen or another ingredient only 11% of the time. The term "spice(s)" was listed in 23% of total products and was linked to an ingredient or an allergen in only 2 of 172 products (<1%). The term "flavors" was listed in 295 products and was linked to an allergen or an ingredient in only 57 of those products (19%). A further example of ambiguous labeling was found on 2 products that listed spices within the ingredients, and stipulated that the spices were "100% pure herbs and spices (no hidden ingredients)." Overall, nonspecific terms used without reference to an ingredient or allergen were included in 402 (54%) of the products.

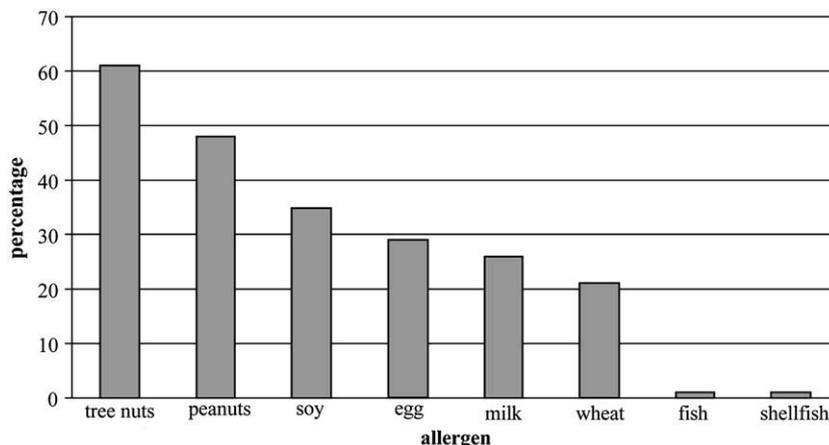
Finally, FALCPA regulations mandate that any product containing lecithin as soy must disclose soy on the ingredient label. Soy lecithin alone, as the only recognizable soy ingredient in a product, was responsible for 52% of the products being labeled as containing soy.

## DISCUSSION

Food allergies are a growing problem.<sup>10</sup> Currently, avoidance of the allergen is the only effective treatment. Allergen avoidance



**FIG 1.** The 12 categories (of 24) of convenience foods with the highest frequency of advisory labeling from a database of 20,241 supermarket products.



**FIG 2.** Thirteen percent of 744 products surveyed included a separate "may contain"-type advisory label. This figure displays the percentage of individual major allergens identified in these statements.

requires careful reading of product labels. FALCPA became effective in 2006, and manufacturers are now required to disclose the major allergens—milk, egg, soy, wheat, fish, crustacean shellfish, peanuts, and tree nuts—either within the ingredients or in a separate “contains” statement. FALCPA mandated disclosure of major allergens is an improvement for individuals with common food allergies. However, a study disclosed that parents of children with allergies to foods other than those regulated by FALCPA continue to restrict products, potentially unnecessarily, or call manufacturers for ingredient information.<sup>11</sup> In addition, products contain advisory labels that are voluntary and unregulated, which presents an additional challenge for individuals with food allergy. We conducted the current study to examine the use of advisory labels and to characterize additional current labeling ambiguities.

We found that 17% of products surveyed from the product database of 20,241 contained advisory labels and that certain categories of products, such as chocolate candy and cookies, were among the most common to use them. More than 50% of these products contained advisory labels. This observation is important because the high rate of use of advisory labels may explain why consumers with allergy are increasingly ignoring them.<sup>8,12</sup>

Consumers with allergy are typically told to avoid products with an advisory warning for the allergen they avoid, even though exact risks are unknown,<sup>9,13</sup> and the high rate of unregulated use evidently excludes many products.

The type of advisory language used was relatively evenly distributed among 3 broad groups: “may contain” at 38%, “shared equipment” at 33%, and “within plant” at 29%. In the 744 product database, we found a great deal of variability in the type of language used. Among the 98 products that disclosed an advisory label, 25 unique phrases were used, which could confuse consumers by implying differential risks. A previous study showed that consumers wrongly assumed that the words used on the labels reflected the level of risk—for example, that the term “may contain” indicated a higher risk than “shared facility.”<sup>8</sup> It is important that allergists are informed about current labeling laws so they can educate patients properly.

We identified only 6 products among the 744 analyzed that were not in compliance with FALCPA. Three products listed whey without clearly identifying milk as the allergenic ingredient, and 3 products listed durum flour as an ingredient without listing wheat on the label. However, we do not know with certainty that these products were manufactured after FALCPA

**TABLE I.** Examples (out of 25) of the different types of language used in advisory labels

May contain
May contain traces of
Manufactured in a facility that also processes
Manufactured on shared equipment with products containing
Manufactured on a line that processes
Packaged in a facility that also packages products containing
Processed on equipment that makes products containing
Produced in a plant which manufactures products containing
Allergy information: produced in a facility that handles
Made on equipment that also processes
Allergen information: Good manufacturing practices used to segregate ingredients in a facility that also processes

**TABLE II.** Examples of labeling ambiguities and FALCPA limitations

Mollusks, such as squid, clams, mussels, and oysters, are excluded from regulatory labeling.
Nonspecific terms (such as spices, natural flavors and flavors) are frequently used and are frequently not linked to an allergen or to an ingredient.
Flour is listed as an ingredient, but the type of flour (eg, soy, wheat, rice) is not identified.
Product contains fish gelatin, yet the type of fish is not disclosed.
Products with advisory labels to tree nuts often do not disclose the type of tree nut the product may contain.
Soy lecithin is the only soy ingredient, yet product states "contains soy."
Soy oil is the only soy ingredient, yet the product lists a separate warning stating, "contains soy."
Lecithin is an ingredient, without the source disclosed.

regulations became effective; however this survey was conducted by selecting products 18 months after the legislation was passed, reducing this likelihood.

Though FALCPA has improved labeling for the consumer with food allergy, limitations and ambiguities persist, as summarized in Table II. Only crustacean shellfish are included in FALCPA legislation; therefore, mollusks, such as squid, clams, mussels, and oysters, are excluded from the same regulatory labeling. In the most likely scenario in which this could be problematic for the individual with mollusk allergy, the mollusks would be included, but not disclosed as a component of a flavor. In addition, nonspecific terms such as "spices," "natural flavors," and "flavors" were frequently used and, although legal, were frequently not linked to an ingredient. Because FALCPA regulates only the designated major allergens, other potential allergens (eg, sesame, mustard, poppy, garlic, and so forth) could be included in the ingredients but never specifically disclosed because they might be included in catch-all terms such as "spices" and "flavors." In fact, for spices, the ingredient was disclosed <1% of the time. We found that 402 of the 744 products had ambiguous terms ("spice," "natural flavor," "flavor") such that a person with a sesame or spice allergy would need to contact the manufacturer 54% of the time. These labels are likely compliant with FALCPA because we would not expect all such ingredients to be derived from commonly allergenic sources. However, for example, the individual with sesame allergy would be forced to continue to call the manufacturer each time a spice or flavor was listed without a source on the label.

We identified a number of additional ambiguities. One pasta product listed "unbleached, enriched flour," yet the type of flour

(eg, soy, wheat, rice) was not identified. Another product disclosed that it contained fish gelatin, yet the type of fish was not disclosed. Although this is technically a violation of FALCPA, it is unlikely to be clinically significant for the individual with fish allergy.<sup>14</sup> The majority (77%) of products with advisory labels to tree nuts did not disclose the type of tree nut. Some patients with tree nut allergy are able to tolerate specific tree nuts and may choose to eat particular ones. However, if the product does not specify the type of tree nut in the advisory label, the consumer is unable to use the product.

We also found that soy labeling under FALCPA may lead to confusion for consumers. FALCPA mandates that products containing lecithin derived from soy disclose soy on the ingredient label. We found that 52% of products labeled as soy-containing appeared to contain only soy lecithin. Although not extensively studied, soy lecithin contains only trace amounts of soy protein, and an allergist might allow specific patients with soy allergy to consume soy lecithin, because the residual soy protein might be well below a patient's threshold.<sup>11</sup> However, the simultaneous labeling of the product as "contains soy" may confuse the individual with soy allergy; the consumer might not know whether "contains soy" referred only to the lecithin or whether soy was a component of the product in another form as well. If the manufacturer made this distinction more clear, the individual with food allergy could more easily distinguish products likely to be tolerated (ie, containing soy lecithin as the only form of soy). On the other hand, FALCPA does not mandate disclosure of soy when it is derived from highly refined oils because these oils typically do not contain significant soy protein to induce a food-allergic reaction in patients with soy allergy.<sup>15</sup> We found 21 products in which only soy oil was listed within the ingredients, yet the product listed a separate warning stating, "contains soy." For these products, which might very well be FALCPA compliant, the consumer with soy allergy might assume soy protein was an ingredient when it might not have been.

We found that 70% of commercial products in this survey contained at least 1 of the FALCPA-designated major allergens (data not shown). Although FALCPA does mandate disclosure of the major allergens, the means of disclosure may vary. Therefore, allergens are listed within the ingredients as a separate "contains" statement in boldface or within parentheses. Taking into account the frequency of multiple ingredients in a product and small print, it remains possible for the consumer to miss finding the allergen of concern. The use of standardized declarations of allergens could be helpful to many consumers. This could be especially true for those who are allergic to multiple allergens or any consumer who has difficulty with English or reading small print. Furthermore, individuals with food allergy have reported as a serious concern that food labels do not always alert individuals when new ingredients are added to a food<sup>16</sup>; it also may be reasonable for manufacturers to highlight changes to the ingredient label in a standardized way.

In summary, our study finds that although general compliance with FALCPA legislation appears to be high, discrepancies and ambiguities were identified that pose potential risks and challenges for the consumer with food allergy. The unregulated use of advisory labels is a source of frustration for the consumer with food allergy because there has been a perceived increase in this type of labeling. Regulations regarding when and how to use advisory labels, and limiting the terminology used, could improve consumer safety and allow meaningful risk assessment.

Presumably, when feasible, efforts to separate lines, clean equipment, run allergens after allergen-free products, and use of allergen assays, among other approaches, could be incorporated to reduce the need for advisory labels. In addition, determining no observed adverse effect levels for individual allergens could potentially reduce the need for advisory labels if residual allergen was low by assays. Although this strategy would be beneficial, more studies need to be done to determine no observed adverse effect levels for individual allergens.<sup>17</sup>

Several labeling ambiguities were identified in our study, such as the frequent use of nonspecific terms like “spices” and “flavors.” Although it is not likely feasible to declare all proprietary ingredients encompassed by these terms, additional study is needed to determine whether potent allergens such as sesame and others should be disclosed when they are an intentional ingredient of flavors or spices. Further regulations regarding soy, such as specifying “this product contains soy as lecithin only” or not including “contains soy” if soy oil is the only soy ingredient, could expand the products available to the individual with soy allergy. Our data support the notion that the unregulated use of allergen advisory labeling presents the consumer with food allergy with frequent but unclear warnings. Although FALCPA has clarified labeling for the top allergens, rectifiable ambiguities persist.

**Clinical implications: Supermarket product labeling deficiencies and ambiguities are prevalent. Allergists must continue to educate their patients about these problems, which could be addressed by strict enforcement of current labeling laws as well as additional regulation.**

#### REFERENCES

1. Sicherer SH, Sampson HA. Food allergy. *J Allergy Clin Immunol* 2006;117:S470-5.
2. McKenna C, Klontz KC. Systemic allergic reaction following ingestion of undeclared peanut flour in a peanut-sensitive woman. *Ann Allergy Asthma Immunol* 1997;79:234-6.
3. Gern JE, Yang E, Evrard HM, Sampson HA. Allergic reactions to milk-contaminated “nondairy” products. *N Engl J Med* 1991;324:976-9.
4. Altschul AS, Scherrer DL, Munoz-Furlong A, Sicherer SH. Manufacturing and labeling issues for commercial products: relevance to food allergy. *J Allergy Clin Immunol* 2001;108:468.
5. Vierk K, Falci K, Wolyniak C, Klontz KC. Recalls of foods containing undeclared allergens reported to the US Food and Drug Administration, fiscal year 1999. *J Allergy Clin Immunol* 2002;109:1022-6.
6. Joshi P, Mofidi S, Sicherer SH. Interpretation of commercial food ingredient labels by parents of food-allergic children. *J Allergy Clin Immunol* 2002;109:1019-21.
7. Center for Food Safety and Applied Nutrition. Food Allergen Labeling and Consumer Protection Act 2004. Publication no. 108-282. Report to the Committee on Health, Education, Labor, and Pensions, United States Senate and the Committee on Energy and Commerce, United States House of Representatives, 2006. <http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/ucm106187.htm>. Accessed June 18, 2009.
8. Hefle SL, Furlong TJ, Niemann L, Lemon-Mule H, Sicherer S, Taylor SL. Consumer attitudes and risks associated with packaged foods having advisory labeling regarding the presence of peanuts. *J Allergy Clin Immunol* 2007;120:171-6.
9. Taylor SL, Hefle SL. Food allergen labeling in the USA and Europe. *Curr Opin Allergy Clin Immunol* 2006;6:186-90.
10. Branum AM, Lukacs SL. Food allergy among U.S. children: trends in prevalence and hospitalizations. CDC NCHS data brief no. 10, October 2008. <http://www.cdc.gov/nchs/data/databriefs/db10.htm>. Accessed June 18, 2009.
11. Simons E, Weiss CC, Furlong TJ, Sicherer SH. Impact of ingredient labeling practices of food allergic consumers. *Ann Allergy Asthma Immunol* 2005;95:426-8.
12. Ahn SS, Furlong TJ, Weiss C, Sicherer SH. Consumer attitudes and response to new food allergen labeling. *J Allergy Clin Immunol* 2008;121:S182.
13. Mills ENC, Valovirta E, Madsen C, Taylor SL, Vieths S, Anklam E, et al. Information provision for allergic consumers: where are we going with food allergen labeling? *Allergy* 2004;59:1262-8.
14. Hansen TK, Pulsen LK, Stah Skov P, Hefle SL, Hlywka JJ, Taylor SL, et al. A randomized, double-blinded, placebo-controlled oral challenge study to evaluate the allergenicity of commercial, food-grade fish gelatin. *Food Chem Toxicol* 2004;42:2037-44.
15. Bush RK, Taylor SL, Nordlee JA, Busse WW. Soybean oil is not allergenic to soybean-sensitive individuals. *J Allergy Clin Immunol* 1985;76:242-5.
16. Vierk KA, Koehler KM, Fein SB, Street DA. Prevalence of self-reported food allergy in American adults and use of food labels. *J Allergy Clin Immunol* 2007;119:1504-10.
17. Crevel RW, Ballmer-Weber BK, Holzhauser T, Hourihane JO, Knulst AC, Mackie AR, et al. Thresholds for food allergens and their value to different stakeholders. *Allergy* 2008;63:597-609.