

Consumer attitudes and risks associated with packaged foods having advisory labeling regarding the presence of peanuts

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Background: Foods with advisory labeling (eg, “may contain”) are increasingly prevalent. Consumers with food allergies might ignore advisory labeling advice.

Objective: We sought to determine whether consumers with food allergy heeded advisory labels and whether products with advisory labels contained detectable peanut allergen.

Methods: Surveys (n = 625 in 2003 and n = 645 in 2006) were conducted at Food Allergy & Anaphylaxis Network patient conferences. Food products bearing advisory statements regarding peanuts were analyzed for the presence of peanut.

Results: Consumers were less likely to heed advisory labeling in 2006 (75%) compared with in 2003 (85%, $P < .01$); behavior varied significantly according to the form of the statement.

Peanut protein was detected in 10% (20/200) of total food products bearing advisory statements, although clinically significant levels of peanut (>1 mg of peanut or >0.25 mg of peanut protein) were detected in only 13 of 200 such products.

Conclusion: Consumers with food allergy are increasingly ignoring advisory labeling. Because food products with advisory labeling do contain detectable levels of peanuts, a risk exists to consumers choosing to eat such foods. The format of the labeling statement did not influence the likelihood of finding detectable peanut, except for products listing peanuts as a

minor ingredient, but did influence the choices of consumers with food allergy.

Clinical implications: Allergic patients are taking risks by increasingly disregarding advisory labeling. (J Allergy Clin Immunol 2007;120:171-6.)

Key words: Peanut, peanut allergy, labeling, advisory labeling, avoidance diets, quality of life, consumer behavior

Food allergy affects an estimated 6% to 8% of infants and young children and 3.5% to 4% of adults in the US population.¹⁻³ Peanut allergy is both comparatively common² and frequently severe.⁴⁻⁶ Specific avoidance diets are the primary approach for the prevention of allergic reactions among affected individuals.⁷ Thus consumers with food allergy become avid readers of the ingredient statements on packaged food products. The accuracy of these ingredient statements is pivotal to the success of specific avoidance diets. It is well known that consumers with food allergy occasionally experience allergic reactions from the ingestion of packaged food products containing hidden or undeclared residues of allergenic foods.^{6,8}

Hidden allergens can occur in foods for a variety of reasons, including formulation errors, packaging errors, the undeclared use of rework or leftovers, the presence of ingredients derived from the allergenic source, or the use of shared equipment or facilities.⁹ The presence of hidden allergens in foods can result in recalls of packaged foods from the marketplace.¹⁰ Recently, the Food Allergen Labeling and Consumer Protection Act (FALCPA) was enacted in the United States (<http://www.cfsan.fda.gov/~dms/algact.html>). A key feature of the FALCPA is the requirement to declare the source of ingredients derived from commonly allergenic foods (defined as milk, eggs, fish, crustacean shellfish, peanuts, soybeans, tree nuts, and wheat). Thus this cause of hidden allergens in packaged foods should disappear provided that compliance with the new law is good. Moreover, the undeclared use of rework from allergenic sources is a violation of US labeling regulations. However, the use of shared processing equipment and facilities in the food industry remains very common. In a recent report to Congress, the US Food and Drug Administration noted that the possibility of cross-contact between formulations containing commonly allergenic foods and formulations without such ingredients existed in about 25% of inspected facilities during the period of 2002 through 2004.¹¹ Among 59 food companies

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Abbreviations used

FAAN: Food Allergy & Anaphylaxis Network
FALCPA: Food Allergen Labeling and Consumer
Protection Act

participating in a survey, virtually all companies had some form of allergen control program,¹² but that survey involved mostly large food companies that are perhaps more likely to have developed such strategies.

Because of their fear of hidden allergens, consumers with food allergy have increasingly sought information regarding the use of shared equipment and facilities. In response, the food industry voluntarily began to include advisory labeling statements on packaged foods in addition to the ingredient statement. The prevalence of use of such statements has steadily increased in the United States. The advisory statements use numerous formats, although the 3 most popular (including slight variations on these statements) are as follows: (1) “may contain [allergen],” (2) “manufactured on shared equipment with [allergen],” and (3) “manufactured in the same facility with [allergen].” Because these advisory statements are voluntary, many different statements are used, and the criteria for use of such statements are likely to vary among different food companies. Among 59 food companies participating in a survey, the majority used some form of advisory labeling statements on packaged foods, although often on only a few of their food products.¹³ Primarily larger companies were included in this survey, and these companies likely have enhanced possibilities of dedicated equipment or adequate segregation of formulations.¹³

Consumers with food allergy, as observed by the Food Allergy & Anaphylaxis Network (FAAN) in the surveys discussed here, have grown increasingly frustrated by the proliferation of advisory labeling statements on packaged foods. The FAAN has conducted several surveys of individuals attending their annual patient conferences regarding advisory labeling in an attempt to determine whether consumers with food allergy are heeding or ignoring the advice. The results of these surveys are presented here. We also conducted a survey of retail packaged foods having advisory labeling statements for peanuts to determine the prevalence of detectable peanut residues to assess the potential risks associated with ignoring advisory labeling statements. The purpose of this study was to survey FAAN members to determine the percentage that might choose to ignore advisory labels on food products and to assess the risks that consumers with peanut allergy might face if they choose to eat food products bearing advisory labels indicating the possible presence of peanuts.

METHODS

Patients

An anonymous market analysis survey was conducted during FAAN patient conferences in Baltimore, Chicago, and New York in

2003 and 2006. Parents of children with food allergy and consumers with food allergy were presented with 8 common forms of advisory labels and requested to indicate how often they would purchase food labeled with each form, choosing “never,” “sometimes,” or “always.”

Statistical analysis

Data were analyzed by using the χ^2 test to determine the changes in patterns of exclusion between the years and among the 3 main formats of “may contain,” “shared equipment,” and “in a facility.” A *P* value of less than .05 was considered significant.

Packaged food samples

A total of 200 different packaged foods were purchased at retail outlets in Lincoln, Nebraska. The samples included 179 products with allergy advisory labels and 21 products with peanuts listed as a minor ingredient at or near the end of the ingredient statement. Products included nutrition/meal bars, cereals/cereal bars, confectionery products, snack foods, frozen desserts, instant/quick meals, baking ingredients, and bakery products. Two different lot numbers from each product were obtained (400 total samples).

Peanut analysis

The products were analyzed for residual peanut protein by using the Neogen Veratox Quantitative Peanut Allergen Test (Neogen Corp, Lansing, Mich).¹⁴ The lower limit of detection is 2.5 ppm (microgram per gram of food) peanut, which is equivalent to approximately 0.8 ppm peanut protein.

Food samples were prepared for analysis according to instructions provided with the kit.

RESULTS

Consumer behavior

A total of 645 surveys were completed in 2006, and 625 were completed in 2003; 96% of surveys were completed by a parent of a child with food allergy. In the 2006 survey consumers were asked whether they noted new advisory labels on products in the preceding year, and 84% indicated they had. Considering the overall response to advisory labeling, 85% would “never” purchase a product with an advisory warning in 2003, which decreased to 75% in 2006 (*P* < .01). Each of the 8 advisory statements is shown in Fig 1, with an indication of the percentage of respondents who would never purchase a product with each label format in each year. For each of the 8 statement formats, the percentage of respondents who excluded products bearing such label statements was significantly less in 2006 compared with that in 2003 (*P* < .05).

There were no significant differences in exclusion rates between label formats that were thematically similar (eg, “may contain allergen” vs “may contain traces of allergen”; “manufactured on shared equipment...” vs “manufactured on the same equipment...” and “...on the same line...”; or “manufactured in a facility that also processes...” vs “...that also uses...”). Considering the data for 2006, there were significant differences (*P* < .002) in the rate at which thematically different labels were heeded in 2006 (ie, “may contain...” = 86%, “...shared equipment...” = 79%, and “...facility that also...”

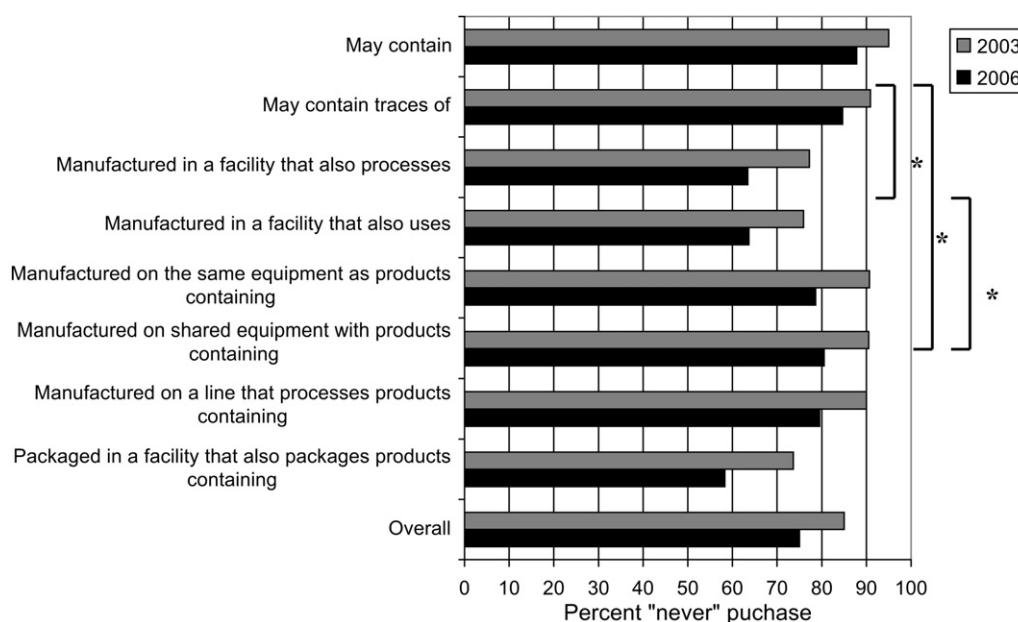


FIG 1. Percentage of respondents who reported avoidance of each advisory statement format in 2006 compared with 2003.

= 64%). The only exception was the statement “packaged in a facility that also packages products that contain allergen” that was heeded only 58% of the time, which was not significantly different from “facility that also uses/processes,” which was heeded 63.5% of the time. However, this nonsignificant difference indicates that some consumers distinguish between “packaged” and “facility that uses/processes,” suggesting a distinction between packaging and manufacturing.

Allergen content of products

Peanut was detected in at least one lot in 10% (20/200) of all products tested (Table I). Of the 179 packages with allergy advisory statements, 13 products had detectable levels of peanut in one or both lots, including 2 of 51 products with a “may contain” statement, 3 of 57 products with a “shared equipment” statement, 7 of 68 products with a “shared facility” statement, and 1 of 3 products with a unique allergy advisory statement. Detectable residues of peanut were found in the nutrition/meal bar (4/28 samples), confectionery/candy (7/36), and cereal/cereal bar (2/26) categories. No detectable peanut was found in any of the products with allergy advisory labeling from the baking ingredients (0/15), bakery products/mixes (0/32), snack foods (0/25), frozen desserts (0/9), or instant/quick meal (0/8) categories. Of the 21 packages listing peanuts as a minor ingredient, 7 products had detectable levels of peanut in one or both lots. Detectable residues of peanut were found in the nutrition/meal bar (2/2 samples), confectionery/candy (1/1), snack foods (1/4), and cereal/cereal bar (3/11) categories. No detectable peanut was found in any of the products with peanuts as a minor ingredient in the bakery product/mixes category. No products with peanuts listed as a minor ingredient were found in the retail

markets in the bakery ingredient, frozen dessert, and instant/quick meals categories.

The levels of residual peanut found in 13 products with allergy advisory labeling and detectable peanut residues ranged from 3 to 4000 ppm (Table I). Nine of the 13 products had detectable peanut residues ranging from 3 to 81 ppm in only one of the 2 lots tested. Residual peanut levels were also inconsistent in 3 of the remaining 4 products, with levels of 27 and 249 ppm found in 2 lots of a nutrition bar product, 221 and 4000 ppm in 2 lots of a different nutrition bar product, and 50 and 206 ppm in 2 lots of a confectionery product. In products with a “may contain” statement and detectable residual peanut, the levels of peanut residue were 53 and 81 ppm. In products with a “shared equipment” statement and detectable residual peanut, the levels of peanut residue were less than 5 ppm in each of the 3 products tested. In products with a “shared facility” statement and detectable residual peanut, the levels of peanut residue ranged from 3 to 4000 ppm, with only one product having less than 5 ppm in one of 2 lots.

The levels of residual peanut found in 7 products with peanuts listed as a minor ingredient and detectable peanut residues ranged from 4 to 3260 ppm (Table I). Four of the 7 products had detectable peanut residues ranging from 4 to 21 ppm in only one of the 2 lots tested. In the 3 remaining products, levels of residual peanut were relatively consistent between lots but ranged from 12 and 63 ppm for a snack food product to 2230 and 3260 ppm for a confectionery product.

The amount of detectable peanut residues in these products on a per-serving basis are also presented in Table I. Based on the recommended serving size for each product, the estimated doses ranged from 0.1 to 180 mg of

TABLE I. Concentration and serving-size doses of peanut in packaged foods bearing allergy advisory statements for peanut or indicating the presence of peanut as a minor ingredient

Product category	"May contain" labeling			"Shared equipment" labeling			"Shared facility" labeling		
	No.*	Conc†	Dose‡	No.	Conc	Dose	No.	Conc	Dose
Baking ingredients	3 (0)	—	—	4 (0)	—	—	8 (0)	—	—
Baked goods/mixes	11 (0)	—	—	11 (0)	—	—	9 (0)	—	—
Candy/confectionary	11 (1)	53 ppm,	2.7 mg,	13 (2)	3 ppm,	0.1 mg,	12 (4)	3 ppm,	0.1 mg,
		BLD	<0.12 mg		BLD	<0.08 mg		BLD	<0.08 mg
		—	—		4 ppm,	0.2 mg,		50 ppm,	2 mg, 8.2 mg
		—	—		BLD	<0.12 mg		206 ppm	
Cereals/cereal bars	10 (0)	—	—	6 (1)	—	—	9 (0)	26 ppm,	1 mg,
		—	—		—	—		BLD	<0.10 mg
		—	—		—	—		37 ppm,	1.5 mg,
		—	—		—	—		BLD	<0.10 mg
Frozen desserts	1 (0)	—	—	5 (0)	—	—	3 (0)	—	—
Instant/quick meals	—	—	—	—	—	—	7 (0)	—	—
Nutrition/meal bars	10 (1)	81 ppm,	3 mg,	9 (0)	—	—	9 (3)	249 ppm,	15.3 mg,
		BLD	<0.10 mg		—	—		27 ppm	1.7 mg
		—	—		—	—		221 ppm,	10 mg,
		—	—		—	—		4000 ppm	180 mg
Snack foods	5 (0)	—	—	9 (0)	—	—	11 (0)	14 ppm,	0.7 mg,
		—	—		—	—		BLD	<0.12 mg
Total	51 (2)	—	—	57 (3)	—	—	68 (7)	—	—

BLD, Below the lower limit of quantitation: 2.5 ppm.

*Number of samples tested (number of samples with detectable peanut in one or more lots).

†Concentration in parts per million (micrograms per gram).

‡Dose in milligrams per suggested serving.

peanut (0.025–45 mg of peanut protein) for all products with detectable peanut. Of course, a consumer might eat more or less than the recommended serving size on any particular eating occasion, and therefore the dose levels presented in Table I are estimates.

DISCUSSION

These consumer survey results clearly indicate that an increasing number of consumers with food allergy or their caregivers are ignoring allergy advisory labeling and ingesting packaged food products bearing such statements. Because these surveys were conducted at FAAN patient conferences presumably attended by a self-selected group of very concerned individuals, an argument might be made that this group of consumers would be more vigilant about their avoidance diets than a more representative cross-section of all patients with food allergy. Further studies of the behavior of a broader group of consumers with peanut allergy are needed to address this possibility. Perhaps allergic consumers are apparently heeding these warnings less because they are noting a proliferation of such warnings, have noted no reactions to products that were previously not labeled, and possibly

presume that warnings are presented for legal rather than practical concerns. In addition, without specific guidance about risk, consumers differentially heed advisory labels according to the implied risk based on the format of the statement. Our data show that "may contain" statements are apparently more effective deterrents than "shared facility" statements, and "shared equipment" statements are intermediate in effectiveness.

In the analytic survey of products bearing allergy advisory statements indicating the possible presence of peanuts, 7% (13/179) of all products had detectable peanut residues in one or both lots tested. Detectable peanut residues were found in some product categories but not in others. However, this was not an exhaustive survey of all products in the marketplace with allergy advisory statements, and therefore it should not be presumed that certain product categories never contain detectable peanut residues. Furthermore, only 2 distinct lots of each product were tested. Certainly, it is possible that detectable levels of residual peanut might be found on occasion if more lots were tested. For example, a company might put allergy advisory labeling on a product because they occasionally manufacture a peanut-containing formulation on shared equipment ahead of a formulation that does not intentionally contain peanut. However, if this occurs sporadically,

Other unique labeling			Total		Minor ingredient labeling		Grand total
No.	Conc	Dose	No.	No.	Conc	Dose	
—	—	—	15 (0)	—	—	—	15 (0)
1 (0)	—	—	32 (0)	3 (0)	—	—	35 (0)
—	—	—	36 (7)	1 (1)	2230 ppm, 3260 ppm	109 mg, 160 mg	37 (8)
—	—	—	—	—	—	—	—
—	—	—	—	—	—	—	—
—	—	—	—	—	—	—	—
1 (1)	107 ppm, 99 ppm	3 mg, 2.8 mg	27 (2)	11 (3)	106 ppm, 83 ppm	2.9 mg, 2.3 mg	38 (5)
—	—	—	—	—	5 ppm, BLD	0.2 mg, <0.10 mg	—
—	—	—	—	—	12 ppm, BLD	1.4 mg, <0.30 mg	—
—	—	—	9 (0)	—	—	—	9 (0)
1 (0)	—	—	8 (0)	—	—	—	8 (0)
—	—	—	28 (4)	2 (2)	4 ppm, BLD	0.3 mg, <0.19 mg	30 (6)
—	—	—	—	—	21 ppm, BLD	1.6 mg, <0.19 mg	—
—	—	—	—	—	—	—	—
—	—	—	24 (0)	4 (1)	63 ppm, 12 ppm	1.9 mg, 0.4 mg	28 (1)
3 (1)	—	—	179 (13)	21 (7)	—	—	200 (20)

the examination of 2 lots might be insufficient to detect peanut residues. However, the use of allergy advisory labeling is voluntary, and therefore different companies likely have different criteria for using such labeling. General provisions in the Food, Drug, and Cosmetics Act prohibit the use of labeling terms that are not truthful and might be misleading. The use of allergy advisory labeling might be truthful, even in situations in which the likelihood of detectable peanut residues is quite small and perhaps nonexistent. Our results show that the vast majority of packaged food products with allergy advisory labeling statements contain no detectable peanut residues.

Although consumers with food allergy are more likely to buy products with “shared facility” statements compared with “may contain” statements, our survey indicated that only 2 of 51 products with “may contain” statements had detectable peanut residues in one or both lots versus 7 of 68 products with “shared facility” statements. The attempts by consumers with food allergy to attach comparative risk assessment values to allergy advisory statements are therefore potentially faulty. Instead, all of these statements, regardless of form, should be construed to mean that some level of risk exists because detectable peanut was found in some products with any of the allergy advisory statements.

Food products with peanuts declared as a minor ingredient were also examined. We know that some food companies use this labeling strategy as opposed to allergy advisory labeling in an attempt to dissuade consumers with food allergy from eating these products. Our results indicate that 33% (7/21) of these products contained detectable peanut residues. However, it is noteworthy that the majority of these products (67%) contained no detectable peanut, even though the presence of peanut was declared on the label. Again, this was not an exhaustive survey of all products in the marketplace bearing such labeling, and the examination of only 2 lots of each product is insufficient to reach the conclusion that specific products would never contain detectable peanut residues.

What is the risk to individuals with peanut allergy of consuming packaged food products with allergy advisory statements for peanuts or having peanuts as a minor ingredient? Because 2 lots of each product were examined and inconsistent results were obtained for detection of peanut residues in both lots for some products, our survey indicates that the likelihood of selecting a product with detectable peanut residues is 4.7% (17/358) for products bearing allergy advisory statements and 23.8% (10/42) for products with ingredient statements showing peanut as a minor ingredient. However, would the level of peanut

residues in these products elicit a reaction in individuals with peanut allergy? Consensus does not exist with respect to the minimal amount or threshold dose of peanut that is likely to elicit an allergic reaction in the most sensitive individual. However, low-dose clinical challenge trials in individuals with peanut allergy have documented that the most sensitive individuals challenged thus far react with mild objective symptoms at a level of 1 mg of peanut or about 0.25 mg of peanut protein,¹⁵ and the range of minimal eliciting doses among individuals with peanut allergy goes from 1 mg up to 6 to 8 g of peanut.¹⁵⁻¹⁸ Some of the products examined in our survey had levels of 5 ppm peanut or less (6/20 products with detectable peanut). If a serving size of the products is assumed to be 100 g, then 5 ppm peanut is equivalent to 0.5 mg per 100 g. Thus some of the products with detectable levels of residual peanut would likely be tolerated by many, and perhaps all, consumers with peanut allergy. Seven of the 20 products with detectable peanut from Table I contained less than 1 mg of peanut per recommended serving size, the observed threshold dose from oral challenge trials.¹⁵ However, the ingestion of 100 g of a product containing 250 ppm or 4000 ppm peanut would provide 25 mg or 400 mg, respectively. These amounts would certainly be sufficient to elicit allergic reactions in some individuals with peanut allergy.

Because 7% of food products bearing allergy advisory labeling for peanuts contain detectable levels of peanut in amounts that in some cases could elicit allergic reactions, individuals with peanut allergy would be wise to avoid ingestion of such products. The risk is even higher for food products listing peanut as a minor ingredient. Physicians should advise their patients with peanut allergy to avoid packaged food products with peanut listed as a minor ingredient or bearing an allergy advisory statement for peanuts.

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