

Recalls of foods containing undeclared allergens reported to the US Food and Drug Administration, fiscal year 1999

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Background: Food recalls can play a role in preventing or reducing the number of allergic reactions that may occur after a product containing an undeclared allergen has been introduced into commerce.

Objective: We sought to summarize the US Food and Drug Administration's records of recalls classified for fiscal year 1999 involving foods containing undeclared allergens.

Methods: Food and Drug Administration food recall records were reviewed for fiscal year 1999 to identify recalls that occurred because of the undeclared presence of one or more of the following allergens: milk, eggs, fish, wheat, crustacean shellfish, tree nuts, peanuts, and soy. Each record was reviewed to determine the recalled product, the undeclared allergen present, the reason for recall, and reported adverse events.

Results: Of 659 total food products classified for recall during fiscal year 1999, 236 (36%) products were recalled because they contained one or more undeclared allergens. Consumers were the party most often responsible for identifying that an undeclared allergen was present in a product (56% of recalled products). A total of 34 consumers reported allergic reactions after consumption of the recalled products. Three principal factors contributed to the presence of undeclared allergens in the recalled products: ingredient-statement omissions and errors (51% of all recalled products); manufacturing equipment cross-contact (40%); and errors by ingredient suppliers or manufacturing firm employees (5%).

Conclusion: The presence of undeclared allergens in food products represents one of the more common reasons for food-product recall in the United States. A number of well-recognized allergens may be introduced into foods as a result of several different factors. (*J Allergy Clin Immunol* 2002;109:1022-6.)

Key words: Food allergy, egg, peanut, dairy, recalls

In the United States the prevalence of food allergy has been estimated to be up to 6% in children younger than 3 years old and approximately 1.5% in adults.¹ The latter estimate was supported by a more recent study that reported that 1.1% of a random sample of the US popu-

lation surveyed by means of telephone stated they were allergic to peanuts or tree nuts. In this same study only 7% of those respondents who reported experiencing an allergic reaction typical of an IgE-mediated response indicated that they had a self-injectable epinephrine device available at the time of the interview.² Thus the presence of undeclared allergens in food represents a potentially significant health hazard.

In previous reports of fatal or near-fatal anaphylaxis caused by food allergy, the implicated food item was often reported to be a dish eaten at a restaurant, school, or other institutional setting, whereas in other instances the reactions occurred in private homes after the consumption of foods that contained undeclared allergens.^{3,4} From these reports, it was not always clear whether the implicated food item was prepared de novo at the site of serving or whether it was a commercially prepared product that had simply been served at the site where the food was eaten. However, to our knowledge, 2 reports describe severe allergic reactions after the consumption of foods produced by commercial manufacturers.^{5,6} Both reactions involved individuals with preexisting peanut allergy who experienced severe allergic reactions after eating foods containing undeclared peanut. In one report the implicated food was gingersnap cookies; no source for the peanut contamination was determined.⁵ In the other report a dried soup mix was implicated that was made with a flavoring ingredient containing peanut flour.⁶

Food recalls, if executed promptly and thoroughly, can play a role in preventing or reducing the number of severe allergic reactions that may occur after a product containing an undeclared allergen has been introduced into commerce. Recall is a firm's removal or correction of a marketed product that the Food and Drug Administration (FDA) considers to be in violation of the laws it administers.⁷ Although the FDA does not have the authority to mandate food recalls, the FDA routinely monitors recalls conducted by the food industry. In this article we define a recall action as the regulatory events surrounding a recall involving one or more products from a single firm. Therefore a recall action may involve one or more different products being recalled from a single firm. During the 1990s, the number of recall actions of FDA-regulated foods containing one or more of the 8 common allergens (milk, eggs, fish, wheat, crustacean shellfish, tree nuts, peanuts, and soy) increased significantly (1 recall action in fiscal year 1990 versus 68 in fiscal year 1999). This increase may have been due to an

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Abbreviations used

CFSAN: Center for Food Safety and Applied Nutrition
FDA: Food and Drug Administration

increased ability to detect allergens and not necessarily because of a true increase in the presence of undeclared allergens in the food industry.

In light of the increased number of recall actions the FDA processed in the past decade and recognizing the potentially serious ramifications of allergic reactions in persons with food hypersensitivities, we examined all food recalls classified by the FDA in fiscal year 1999 to determine what foods were recalled because of the presence of undeclared allergens. In this report we also describe the available information on the nature of allergic reactions that reportedly occurred after the consumption of some of these products and outline the relative roles that various groups (government, industry, and consumers) played in identifying products that were found to have undeclared allergens.

METHODS

The Center for Food Safety and Applied Nutrition (CFSAN) within the FDA has the responsibility for ensuring that foods marketed for interstate commerce in the United States other than meats, poultry, and eggs (at the farm level) are safe and properly labeled. Food products that violate the laws administered by the FDA, including those pertaining to labeling, are subject to voluntary recall. The relative degree of health hazard attributed to each recalled product by the FDA is reflected in an assigned recall classification number (ie, I, II, or III). A class I recall is defined as a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. Class II recalls involve situations in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or in cases in which the probability of serious adverse health consequences is remote. Finally, class III recalls entail situations in which use of or exposure to a violative product is not likely to cause adverse health consequences.⁷ For each recall action, the FDA works with the recalling firm to develop a recall strategy and to monitor the recall process. Among other things, this strategy determines whether public warnings should be issued, the level in the distribution chain to which recalls are extended, and the extent to which checks are performed by the firm, the FDA, or both to ensure that consignees have received notification about the recall and have taken appropriate actions. Recalls classified as I or II were reviewed for this study. Class III recalls were excluded because these recalled products are not likely to have caused adverse health consequences.

For every recall or recall action, the FDA maintains a record, with information pertaining to each recalled product. Details captured in the recall record include the reason for the recall, the strategy used by the manufacturer or distributor to remove the product from distribution, and the actions the FDA took in processing the recall. Additionally, each recall record contains information pertaining to adverse events, if any, that were reported by consumers to either the firm or the FDA after consumption of the product.

For this study, we reviewed all FDA recall records for recalls classified in fiscal year 1999 (October 1, 1998, through September 30, 1999) to identify those recalls that took place because of the

presence of undeclared allergens in food products. We limited our search to recalled products that contained one or more of the following 8 most common food allergens in the United States: milk, eggs, fish, wheat, crustacean shellfish, tree nuts, peanuts, and soy. Each record was reviewed to determine the following information: the nature of the product recalled; the allergen or allergens present; the reason for the presence of the allergen in the product; the country of origin of the product; a description of adverse events, if any, reported by consumers who ate the product; the party responsible for first detecting the presence of the undeclared allergen or allergens; and the recall classification (I or II). With respect to consumer-reported adverse events, we obtained details pertaining to clinical illnesses from the recall record, which captures reports of illnesses reported to the manufacturing firm, or from an FDA form entitled "Consumer Complaint/Injury Report," a standard form that FDA investigators use to record reports of illnesses or injuries linked to FDA-regulated products.

RESULTS

During fiscal year 1999, a total of 280 recall actions were classified as I or II by the FDA's CFSAN involving 659 different food products. Of these, a total of 68 (24%) recall actions involving 236 different food products were conducted because of the presence of one or more of the 8 common allergens.

Undeclared egg allergens accounted for the greatest number of recall actions (38%) and recalled products (38%, Table I). No food products were recalled because they contained only fish or shellfish; however, 6 products, included in the combination category of Table I, were recalled because they contained both undeclared fish and another allergen, such as wheat, egg, or both. Over 80% of the allergen-related recalled foods fell into 5 leading product categories that are summarized in Table II. Candies were the category of products most often recalled for containing an undeclared allergen.

Of the products recalled that contained undeclared food allergens, 128 (54%) were designated as class I recalls, and 108 (46%) were designated as class II recalls (Table III). Undeclared egg was the allergen that accounted for the greatest number of class I allergen-related recalls (66 recalled products; 52% of all class I recalls). All of the 24 class II undeclared egg product recalls listed in Table III involved foods that contained mayonnaise made from eggs as an ingredient in which the ingredient statement declared "mayonnaise" but not "eggs."

Foods containing undeclared peanuts constituted the second leading cause of class I recalls associated with undeclared allergens during the study period (34 recalled products; 27% of all class I recalls). In fact, with the exception of one product, a product whose package listed "nut meats" without listing "peanuts" specifically, foods that contained undeclared peanuts were classified as class I recalls.

Products containing undeclared dairy protein constituted the majority (68%) of class II recalls associated with undeclared allergens (Table III). Of the 11 recalls of products containing undeclared tree nuts, 7 were class I and 4 were class II. The 7 class I tree nut recalls involved products containing undeclared walnuts (3 products), unde-

TABLE I. Number of recall actions and number of products recalled (class I and II) for undeclared allergens, FDA, fiscal year 1999

Allergen	No. of recall actions (%)	No. of recalled products (%)
Egg	26 (38)	90 (38)
Peanuts	16 (24)	35 (15)
Dairy	11 (16)	74 (31)
Tree nuts	7 (10)	11 (5)
Wheat	2 (3)	3 (1)
Combination*	6 (9)	23 (10)
Total	68 (100)	236 (100)

*Combination refers to multiple undeclared allergens.

TABLE II. Categories of food products recalled for undeclared allergens (class I and II), FDA, fiscal year 1999

Food category	No. of products recalled	(% of total)
Candy (includes chocolate)	87	(37)
Bakery items	34	(15)
Deli foods	28	(12)
Seafood	21	(9)
Snacks	20	(8)
Egg rolls	16	(7)
Sandwiches	13	(5)
Other	17	(7)
Total	236	(100)

TABLE III. Recall classification (class I and II only) of food products recalled because of undeclared allergens by allergen, FDA, fiscal year 1999

Allergen	Recall classification (n)		
	I	II	Total
Egg	66	24	90
Dairy	1	73	74
Peanuts	34	1	35
Tree nuts	7	4	11
Wheat	0	3	3
Combination	20	3	23
Total	128	108	236

clared hazelnuts (2 products), and undeclared pecans and pine nuts (1 product each). The 4 class II tree nut recalls involved 2 products containing undeclared almonds (a raspberry-flavored candy and a cheesecake) and 2 products containing undeclared pecans. One of the class II pecan recalls involved a turtle cheesecake product that had pecans visible on the top of the cake, although no mention of pecans was made in the ingredient statement. The other class II pecan recall involved a praline pecan cheesecake that had pecans visible on it and no mention of pecans in the ingredient statement; however, the title of the product included the word "pecan" in it.

The United States was the site of manufacture for nearly all (93%) products recalled during the study period because of undeclared allergens. Consumers were the party most often responsible for identifying that an aller-

gen was present in a product (50% of recall actions; 56% of recalled products). Other groups that played an important role in identifying the presence of undeclared allergens included the FDA (31% of recall actions; 22% of products recalled), state regulatory agencies (10% of recall actions; 16% of products recalled), and manufacturers (6% of recall actions; 4% of products recalled). The Canadian Food Inspection Agency was responsible for discovering the presence of an undeclared allergen in 6 recalled products (3% of recall actions).

In 18 (26%) of the 68 allergen-related recall actions that took place during fiscal year 1999, one or more consumers reported experiencing an allergic reaction after eating a product containing an undeclared allergen. Four of the 34 consumers who reported allergic reactions were treated in emergency departments; however, none died or were hospitalized. Ten consumers (29% of those with allergic reactions) became ill after eating a product that had undeclared peanuts in it, and an additional 10 experienced reactions after ingesting products with undeclared tree nuts. Undeclared dairy protein caused allergic reactions in 8 consumers, and undeclared egg-containing products produced reactions in 5 consumers. One consumer reported becoming ill after eating a product that had wheat in it. Bakery products and candies accounted for almost three fourths of the types of foods that were consumed by persons who experienced allergic reactions during fiscal year 1999.

Of the 34 persons who reported experiencing allergic reactions, information on age was available for 10. The mean age of these individuals was 6.7 years, and 7 of the ten reported eating products containing undeclared peanuts before becoming ill. Twenty-four (71%) of the 34 persons described their illness as a "mild allergic reaction"; no specific symptoms were recorded for any of these individuals in either the recall record or in a Consumer Complaint Injury/Illness form. The remaining 10 (29%) consumers reported a variety of symptoms consistent with allergic reactions, such as hives, itching, swelling, coughing, vomiting, and difficulty breathing or swallowing. Information regarding treatment (self-treatment, treatment by a health care professional, or both) was available for 5 of the 34 individuals. Four consumers reported taking diphenhydramine alone, and 1 individual was administered epinephrine and diphenhydramine.

We identified 3 principal factors that contributed to the presence of undeclared food allergens in the recalled products for fiscal year 1999. Ingredient-statement omissions and errors (defined as ingredient statements or labels that contained an incorrect list of ingredients) were the most common, accounting for 51% of all recalled products (60% of all recall actions). Examples of such omissions and errors included situations in which the presence of the allergen was simply omitted from the ingredient list or those in which an ingredient statement translated from another language failed to list the allergen.

The second most common problem accounting for recalled products was manufacturing equipment cross-contact from one run to the next (40% of all products

recalled; 18% of recall actions). An example of such a recalled product that occurred during the period reviewed involved yogurt-covered raisins that unintentionally came into contact with yogurt-covered peanuts as a result of a failure to adequately clean the manufacturing equipment used to produce the 2 different products. Overall, candies were the type of product most often involved in a recall in which the problem was manufacturing equipment cross-contact between runs; chocolates, in particular, were often involved as a result of containing traces of peanuts, tree nuts, or milk.

Errors by ingredient suppliers or manufacturing firm employees accounted for a small number of products recalled (5% of products recalled; 18% of recall actions). Examples here included instances in which packaging for a nonallergen-containing product was used to package a product containing allergens and one instance in which a supplier provided the wrong ingredients for a product and failed to alert the manufacturer of the presence of an allergen. Although ingredient-statement omissions and errors accounted for the greatest number of product recalls, both ingredient-statement omissions and errors and supplier-employee errors had the same number of allergic reactions reported by consumers. Finally, unknown reasons for the presence of undeclared allergen accounted for 4% of the products recalled and 4% of recall actions.

DISCUSSION

The purpose of the present work was to summarize the US FDA's records of recall actions and recalled products for fiscal year 1999 involving foods that contained undeclared allergens. We found that there were 3 principal factors that accounted for the vast majority (96%) of recall actions involving undeclared allergens: ingredient-statement omissions and errors; cross-contact from manufacturing equipment; and errors committed by suppliers or employees of manufacturing firms. Our findings also suggest that a number of well-recognized allergens make their way into a wide spectrum of foods and that the presence of undeclared allergens introduced as a result of the 3 factors mentioned above accounts for a significant number of food-product recalls in the United States.

For the time period reviewed, the factor that accounted for the greatest number of recalls was ingredient-statement omissions and errors (51% of all products recalled; 60% of recall actions). In these instances products were formulated to contain at least one of the 8 most common allergens considered here but failed to declare the ingredient or ingredients on the label. The second leading contributor was manufacturing equipment cross-contact, a factor that accounted for 40% of recalled products (18% of recall actions). In these instances food products that were not intended to contain at least one of the 8 most common allergens ended up incorporating these allergens as an ingredient because of cross-contact from manufacturing equipment. The third factor that contributed to product recalls was one we designated supplier-employee errors (5% of products recalled; 18% of recall actions). In

these instances no direct errors were committed with respect to the ingredient statement *per se*; instead, other errors on the part of suppliers or employees in the production area allowed an unintended allergen to be incorporated into food products. In the remaining 4% of recall actions (4% recalled products), no reason could be ascertained to explain the presence of undeclared allergens.

In classifying the degree of health hazard posed by foods that contain allergens not listed on the ingredient statement, the FDA's CFSAN considers several factors, including whether any allergic reactions have been reported after the consumption of the food, the severity of the reactions, and whether any particular segments of the population are more likely to consume the product. Recognizing that the 8 most common allergens have the potential to cause IgE-mediated anaphylaxis, the FDA also relies on the peer-reviewed medical literature to determine whether the ingestion of specific food allergens has been reported to cause fatal outcomes. Specifically, products that contain undeclared allergens for which there are reports of fatal reactions in the literature have been, as a rule, classified as class I recalls. Compared with class II and class III recalls, class I recalls are normally conducted with a concomitant public warning (ie, a press release issued by the manufacturing firm or distributor, the FDA, or both), whereas for class II recalls public warnings may or may not be issued. In addition, for class I recalls, the depth of recall is often greater than for class II or III recalls; that is, the recall strategy used by the manufacturer, distributor, or both for class I recalls will specify a working plan by which the involved product is recalled not just from the wholesale and retail level but from the consumer as well.

In light of the approach described above, products containing undeclared eggs, peanuts, and certain tree nuts (eg, walnuts, pine nuts, pecans, and hazelnuts) were consistently classified as class I recalls during fiscal year 1999 given the fact that fatalities associated with the consumption of these allergens have been reported in the peer-reviewed medical literature.^{4,8} Exceptions to this rule occurred when there were certain mitigating circumstances, such as when a food-product label contained a partial listing of the allergen. In contrast, to the best of our knowledge, at the time the recalls were classified during the time period considered in this report, we were unaware of any published reports of fatal anaphylaxis caused by milk and certain other tree nuts; consequently, recalls of products containing milk or almonds, for example, were classified as class II recalls. The recent report of a fatal case of milk-associated anaphylaxis in a 12-year-old boy in the United Kingdom may prompt the FDA to reevaluate the future recall classification of products containing undeclared milk protein.^{8,9} Similarly, the FDA is giving consideration to the prospect of reclassifying all undeclared tree nut, crustacea, fish, and soy product recalls.^{3,8,10}

Our results also underscore the role consumers play in identifying the presence of undeclared allergens in food products (accounting for half of all recall actions). This finding highlights the need for improved control methods

or procedures to prevent the introduction of foods with undeclared allergens into the market. In our view a comprehensive approach would be one that systematically reduces employee and ingredient-statement errors and precludes the unintended inclusion of allergens. Although at times this might appear to be an elusive goal, constant vigilance on food-processing lines is required. The principal benefit of such vigilance would be that it would significantly reduce the risk that persons with food allergies face when purchasing and consuming food products sold in interstate commerce. We believe that reducing the presence of undeclared allergens will require input from multiple parties. Regulatory efforts by the FDA are needed to ensure that food-product labels are complete and accurate, and increased industry efforts are needed to reduce food-labeling errors and cross-contact during food production. Finally, we believe that food processors should take all possible allergen-control measures to prevent the introduction of undeclared allergenic ingredients in food by continually improving good manufacturing practices.

Over the next year, the FDA will increase its inspections of food-processing firms. During these inspections, the FDA inspectors will share their knowledge about how to reduce the presence of undeclared allergens and will observe and record good manufacturing practices currently used on the food-processing lines in firms. In addition, the FDA will continue its outreach efforts both with con-

sumers and with the food industry. FDA efforts to develop ELISA test kit detection of food allergen proteins in various food matrices will increase, and FDA plans to cooperate with the food industry in this endeavor. Finally, the FDA encourages the development and undertaking of clinical studies designed to demonstrate whether threshold levels of allergenic proteins may exist safely in food.

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