

Analysis of U.S. Food and Drug Administration Food Allergen Recalls after Implementation of the Food Allergen Labeling and Consumer Protection Act

STEVEN M. GENDEL* AND JIANMEI ZHU

*U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, HFS-200,
College Park, Maryland 20740, USA*

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ABSTRACT

To avoid potentially life-threatening reactions, food allergic consumers rely on information on food labels to help them avoid exposure to a food or ingredient that could trigger a reaction. To help consumers in the United States obtain the information that they need, the Food Allergen Labeling and Consumer Protection Act of 2004 defined a major food allergen as being one of eight foods or food groups and any ingredient that contains protein from one of these foods or food groups. A food that contains an undeclared major food allergen is misbranded under the U.S. Food, Drug, and Cosmetic Act and is subject to recall. Food allergen labeling problems are the most common cause of recalls for U.S. Food and Drug Administration (FDA)-regulated food products. To help understand why food allergen recalls continue to occur at a high rate, information on each food allergen recall that occurred in fiscal years 2007 through 2012 was obtained from the FDA recall database. This information was analyzed to identify the food, allergen, root cause, and mode of discovery for each food allergen recall. Bakery products were the most frequently recalled food type, and milk was the most frequently undeclared major food allergen. Use of the wrong package or label was the most frequent problem leading to food allergen recalls. These data are the first reported that indicate the importance of label and package controls as public health measures.

Food allergy is an important public health issue that affects up to 2% of adults and 8% of children (3, 6). Food allergy is an immune-mediated hypersensitivity that can result in severe, and potentially life-threatening, reactions (7). Food allergic individuals and their caregivers must avoid exposure to food triggers to prevent such reactions. One way that the food industry and public health agencies support these consumers is by working to ensure that the labels on packaged foods provide the information that they need to make appropriate food choices. These food labels need to be complete and accurate; that is, all food allergens that are intended to be present in a food should be declared on the label and no unintended allergens should be present through cross-contact (2, 4).

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) amended the Federal Food, Drug, and Cosmetic Act to define a major food allergen as one of eight foods or food groups (egg, milk, peanut, soy, fish, crustacean shellfish, tree nuts, and wheat) and to require that these major food allergens be declared when they, or protein-containing ingredients derived from them, are present in a food. Food products that fail to declare the presence of a major food allergen are misbranded and subject to a recall (10).

Manufacturers prevent food allergen mislabeling by using label controls and preventive controls (1, 8). Label controls are intended to ensure that manufacturers are aware of all the allergens present in the food ingredients that they use and foods that they produce, that these allergens are appropriately identified on the package label, and that the correct label is used for each food product. Preventive controls are intended to prevent cross-contact through the application of supplier controls, production sequencing, physical separation, cleaning and sanitation, and process design. Although there are a number of resources available to manufacturers to help them develop allergen control programs (for example, (1, 8)), it is difficult to measure the success of such efforts.

Shortly after FALCPA was passed, Taylor et al. (9) carried out a small survey of companies that volunteered information on allergen control practices. More recently, Gendel et al. (2) used information gathered during a U.S. Food and Drug Administration (FDA) inspection assignment in fiscal year (FY) 2010 to assess allergen control practices in a broader industry cross section. In both cases, the surveys showed that awareness of the need for allergen control was widespread in the food industry, as was the use of most of the recognized allergen control strategies. However, both surveys also found that small manufacturers lagged in implementing allergen controls as compared to the larger manufacturers. Although the results of both surveys

* Author for correspondence. Tel: 240-402-1056; Fax: 301-436-2973;
E-mail: steven.gendel@fda.hhs.gov.

can be used to inform ongoing risk reduction efforts, they have important limitations. Neither survey was designed to be a statistically representative sample of the food industry in the United States. Therefore, it is not possible to assess whether there are differences among manufacturers of different types of foods. More importantly, both represent time-limited “snapshots” of industry practice.

An alternative approach for evaluating the effectiveness of allergen control practices in the food industry is to analyze information on allergen-related food recalls (allergen recalls). Recall data can be used to assess trends over time and to identify problematic allergens and foods. In addition, recall data can be used in a root cause analysis to identify those problems that most often led to the need for a recall. This analysis supports a risk-based decision-making process in both government and industry that will help focus both regulatory and educational resources in ways that will have the greatest impact on protecting the health of food allergic consumers.

Therefore, we analyzed information from the FDA Recall Enterprise System (RES) database on allergen recalls for FDA-regulated food products that occurred in FY 2007 through FY 2012 to identify the foods and allergens involved in each recall as well as the root cause for the problem that created the need for the recall. These data highlight the importance of label and package controls as public health measures.

MATERIALS AND METHODS

Information on all recalls for FDA-regulated products is contained in the FDA RES database (12). RES includes a description of the product or products involved in each recall, the firm(s) conducting the recall, the nature of the problem that led to the need for a recall, and additional information obtained by the agency recall coordinators and field inspectors. Each recall is assigned an event ID and a recall number and is associated with one of the FDA product centers. In addition, the FDA Center for Food Safety and Applied Nutrition (CFSAN) maintains a database of all recalls for food products. This database contains additional information on the Health Hazard Evaluations used to classify recalls.

The RES database was searched for all recalls associated with CFSAN using the keywords “unlabeled” and “allergen” that occurred during FY 2007 through FY 2012. This time period was used because FY 2007 was the first full fiscal year in which the FALCPA labeling requirements were in effect. The recalls that were identified were further filtered to remove those that involved recalls for unlabeled sulfites, mislabeling of nutrition information, or mislabeling involving standards of identity. A similar search of the CFSAN recall database was used to ensure that all relevant recalls were identified. In some cases, a single problem can lead to multiple food products being recalled or to multiple recall events. In these cases, the duplicate or subsequent events were removed from the results. For example, a single manufacturer might fail to declare the presence of an ingredient in multiple food products. This would lead to multiple product recalls. Although a large number of products might be involved, this was considered to be a single event for this analysis. In another example, cross-contact occurring at an ingredient supplier facility might result in multiple products being recalled from

TABLE 1. *Food categories*

Category	Description
Bakery	Bread, pastry, cookies, cakes
Beverage	Drinks and drink mixes
Breakfast cereal	Boxed cereals, granola, instant cereals
Candy	Chocolates, confections, sweets
Composite	Sandwiches, wraps, egg rolls, samosas, and similar products
Dairy	Milk-based products, spreads, dips
Dressing	Sauces, salad dressings, pasta sauces, gravies
Imitation milk	Soy milk, almond milk, rice milk, other milk alternatives
Meals	Frozen dinners, packaged multicomponent meals
Other	Miscellaneous
Pasta	Pasta, macaroni, noodle products
Produce	Vegetables, fresh herbs, raw agricultural commodities
Salad	Deli salads, bagged salads, fruit salads
Seafood	Fish and fish-based products
Snack	Snack foods, pretzels, chips, novelty, trail mix, granola bars
Soup	Canned, refrigerated, dry, ramen, and packaged soups and soup mixes
Supplement	Vitamins, dietary supplements, and related products

several manufacturers. This was also considered to be a single event for this analysis.

The RES database entry for each recall was examined to identify the food product category, the allergen or allergens involved, the root cause or problem that created the need for the recall, the event that led to the identification of the need for a recall, and the recall classification. A class 1 recall is defined as a situation in which there is a reasonable probability that the use of or exposure to a product will cause serious adverse health consequences or death, a class 2 recall is a situation in which use of or exposure to a product may cause temporary or medically reversible adverse health consequences or in which the probability of serious adverse health consequences is remote, and a class 3 recall is a situation in which use of or exposure to a product is not likely to cause adverse health consequences (Code of Federal Regulations Title 21, Section 7.3). Recalls that involve only undeclared wheat are considered class 2 by the agency medical officers; recalls involving the other major food allergens are generally considered class 1 unless there is a mitigating circumstance (15).

The food products involved in each recall were classified using the product categories that are used to classify reports in the Reportable Food Registry (RFR) (Table 1) (11). The RFR categories were used because they correspond more closely to the way that foods are described and marketed than do the FDA product codes, which are used to inform regulatory activities. Only those RFR product categories that were involved in a food allergen recall during the years examined are listed in Table 1.

The root cause for each recall was determined and classified using the scheme shown in Table 2. These descriptions are based on the narrative terms used by the FDA recall coordinators and inspectors in creating the entries in RES. The narrative descriptions in RES were also used to identify the event or occurrence that led to the recognition of the need for a recall in each case (Table 3).

TABLE 2. *Problems that caused food allergen recalls*

Cause	Description
Computer error	A labeling error resulted from use of the wrong computer file, misuse of a computerized labeling system, or by improper alteration of a computer file.
Cross-contact	A manufacturer did not clean between products containing different allergens, or between products with and without allergens, or the cleaning was ineffective.
In process	An unfinished product was added to the process stream for another product that was not intended to have the same allergen(s).
Ingredient mislabeled	An ingredient used to manufacture a product did not declare the presence of an allergen, leading to omission of that allergen on the finished product label.
Knowledge	The manufacturer was not aware of the allergen labeling requirements or the product was labeled in accordance with the allergen labeling regulations in another country.
No carry-through	The product label did not declare the presence of an allergen that was declared (or known to be in) an ingredient used to manufacture that product.
No declaration	The ingredient declaration was missing.
Not updated	The product label was not updated to reflect a formulation change.
Omission	One or more allergens were not declared, no other cause noted.
Other	All other causes.
Rework	A finished product was added to the process stream for another product that was not intended to contain the same allergen(s).
Terminology	The ingredient declaration on a product did not use the correct terminology to identify a major food allergen (e.g., butter is declared but not milk).
Unknown	The root cause was not described in RES.
Wrong ingredient	An allergen-containing ingredient was used in a product where it was not intended.
Wrong label	An incorrect label was used on the product package.
Wrong package	The product was placed in the wrong package, or the wrong packaging film was used.

RESULTS

A total of 732 allergen recalls were identified in the FDA RES database for FY 2007 through FY 2012. Except for FY 2009, there was a clear trend of increasing numbers of allergen recalls over time (Fig. 1). Approximately 98.5% of all allergen recalls were either class 1 or class 2, with a decrease in the proportion of class 1 recalls from 82% in FY 2007 to 52% in FY 2012.

The distribution of allergen recalls among the categories of foods is shown in Table 4. Five of the 17 food categories (bakery, snacks, candy, dressing, and dairy) accounted for over 70% of the allergen recalls, with bakery accounting for almost one-third of the recalls. Some recalls involved multiple products; however, because the foods involved were described using the RFR categories and because we analyzed the primary event or occurrence that created the need for a recall, each recall could be allocated to a single food category. Within the dairy food category,

60% of the recalls were associated with ice cream or frozen dessert products.

The distribution of recalls among the major food allergens is shown in Table 5. When a recall involved multiple allergens, that recall was counted for each of the allergens. Therefore, the total number of recalls listed in Table 5 is higher than in Table 4. Most (80%) of the recalls involved a single major food allergen, 13% involved two allergens, and the rest (7%) involved three or more allergens. Recalls involving milk were the most frequent, followed by wheat, soy, and egg. The proportion of recalls involving each of the major food allergens did not change over time. Table 6 shows the most frequent combinations of foods and allergens. Bakery products with undeclared milk are the most problematic combination, accounting for 15% of all recalls and 36% of the recalls involving milk.

The ability to prevent recalls depends on understanding why they occur; that is, in identifying the problem that leads to the need for a recall. Table 7 shows the root causes for

TABLE 3. *The event or occurrence that led to recognition of the need for an allergen recall^a*

Event/occurrence	Description
Complaint	Discovered through a complaint by a consumer, distributor, or retailer, but not associated with an allergic reaction
FDA	Discovered by an FDA inspector
Firm	Discovered by the manufacturer or producer ^b
Other government	Discovered by a USDA inspector, a state or local government inspector, or a government entity in another country
Reaction	Discovered because an allergic consumer had a reaction
Unknown	Not described in RESz

^a USDA, U.S. Department of Agriculture.

^b The manufacturing firm discovered the problem through a mechanism such as an internal audit, production record check, or product inspection after the product had been distributed or had left the location where it was manufactured.

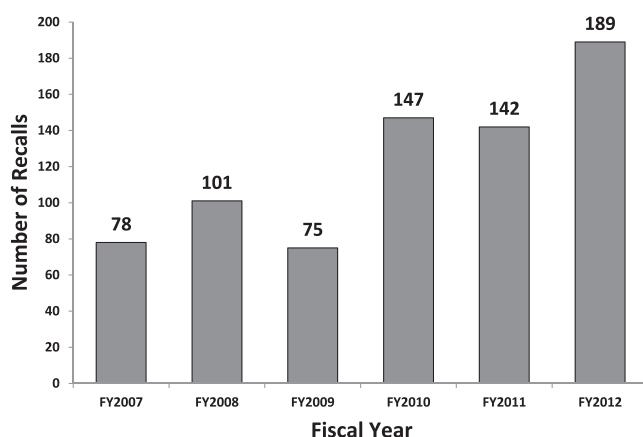


FIGURE 1. The number of food allergen recalls in FY 2007 through FY 2012.

the food allergen recalls that were identified during the period studied and the distribution of recall classifications for each root cause. In 206 (approximately 28%) of the recalls the root cause was either not given (unknown) or was simply described as being due to failure to declare one or more major food allergens (omission) with no further elaboration. Of the remaining recalls, use of the wrong package and use of the wrong label together caused the most recalls (26%), followed by terminology problems, lack of carry-through of an allergen declaration from an ingredient, and cross-contact. These five problems caused about 66% of the recalls for which a root cause was identified. Only one recall was caused by deliberate addition of an allergen with intent to cause harm.

The only root cause that led to more class 2 than class 1 recalls was use of improper terminology. In many of these recalls caused by terminology problems, the major food allergen was identified in the ingredient list but not in a manner consistent with FALCPA. For example, in some cases a product declared that butter was an ingredient but did not indicate “milk,” or a product declared that tree nuts

TABLE 4. Distribution of food allergen recalls among the food categories

Food	No. (%) of recalls	Recall class (1/2/3)
Bakery	231 (31.5)	144/86/1
Beverages	23 (3.1)	14/8/1
Breakfast cereal	10 (1.4)	5/5/0
Candy	73 (10.0)	46/26/1
Composite	46 (6.3)	31/14/1
Dairy	58 (7.9)	38/19/1
Dressing	59 (8.0)	42/17/0
Imitation milk	5 (0.7)	5/0/0
Meals	14 (1.9)	12/2/0
Other	25 (3.4)	16/9/0
Pasta	13 (1.8)	5/8/0
Produce	10 (1.4)	3/6/1
Salad	5 (0.7)	3/1/1
Seafood	32 (4.4)	22/10/0
Snack	89 (12.1)	55/32/2
Soup	21 (2.8)	12/8/1
Supplement	18 (2.5)	10/7/1
Total	732 (100)	463/258/11

TABLE 5. Distribution of allergen recalls among the major food allergens

Allergen	Recalls ^a
Milk	296
Wheat	171
Soy	153
Tree nuts	119
Egg	108
Peanut	69
Fish	28
Crustacean shellfish	11
Unspecified	8

^a A single recall might involve multiple allergens. In those cases, each recall was counted multiple times, depending on the number of allergens involved.

were present but did not identify the specific type of tree nut. In these cases, the agency medical officers thought that the information in the ingredient declaration reduced the risk for allergic consumers to a level appropriate for a class 2 recall. Bakery products accounted for about half of all recalls caused by terminology problems (48%).

In addition to understanding the root cause of the problem leading to a recall, it is also important to understand how the need for a recall was first discovered (Table 8). In approximately 44% of the recalls in which the information was available, the need for a recall was discovered during an inspection or audit by a government regulatory authority. Approximately 12% of the recalls were initiated after a report of a consumer reaction, and 27% were initiated after a complaint without a reported reaction.

DISCUSSION

The ability to manage risk for food allergic consumers depends, among other things, on understanding how risk arises in the food production system. This requires identifying the most significant food-hazard pairs and the nature of the problems that create risk. A detailed analysis of recalls for FDA-regulated food products during FY 2007 to FY 2012 was used to fill both of these information needs.

The number of food recalls related to allergen problems is a large and growing problem (14). The 732 recalls analyzed here were only the primary recalls and did not include recalls for additional products from the same manufacturer or products from other manufacturers that incorporated a recalled ingredient. Nevertheless, it is clear from these results that the number of allergen recalls per year continues to increase. Because the complete food recall database was not analyzed, it is not possible to determine how the rate of allergen recalls compares to the overall rate of food recalls. The fact that 63% of these recalls were class 1 indicates that the products involved in these recalls pose a substantial risk for food allergic consumers.

These results show that this risk is not evenly distributed among the different types of foods. Bakery products accounted for 31% of the recalls, snacks 12.5%, and candy 10%. These results also show that among the major food allergens milk, wheat, and soy are most problematic. This is consistent with the results reported by

TABLE 6. *The number of recalls involving each of the most frequent food-allergen combinations FY 2007 through FY 2012*

	Bakery	Snack	Candy	Dressing	Dairy
Peanut	10	19	18	0	9
Egg	44	4	6	8	11
Milk	107	41	22	21	13
Soy	36	25	14	21	12
Wheat	58	11	7	17	10
Tree nuts	44	17	20	3	18

Malyukova et al. (5) based on an analysis of the FDA Health Hazard Evaluation database. The combined number of recalls that involved either peanuts or tree nuts was lower than the number that involved milk. This may be related to the fact that milk and milk-derived ingredients are used in many forms. It is also consistent with the results in Gendel et al. (2) showing that milk, wheat, and soy are widely used in the food industry. An analysis of FDA allergen recalls in FY 1999, before FALCPA, also showed that egg and milk were the allergens most commonly involved in recalls and that candy and bakery products were the most commonly recalled foods (15). One effect of the FALCPA designation of the major food allergens can be seen in the fact that in FY 1999 only three recalls involved wheat. It is not possible to compare the total number of allergen recalls in FY 1999 to the numbers in FYs 2007 to 2012 because the earlier analysis considered all allergen recalls, whereas this analysis only considered the primary recalls as described in "Materials and Methods." The small number of recalls involving fish and crustacean shellfish may reflect the fact that the FDA seafood hazard analysis and critical control point program includes consideration of allergens as potential hazards (13).

These results also show that a relatively small number of root causes are responsible for a large proportion of allergen recalls. Although 16 root causes were identified, 2 of these

TABLE 7. *The number of allergen recalls and the distribution of recall classifications for each root cause FY 2007 to FY 2012*

Root cause ^a	No.	Recall class (1/2/3)
Computer error	21	15/4/2
Cross-contact	52	41/11/0
In process	19	15/4/0
Ingredient mislabeled	26	16/10/0
Knowledge	28	14/14/0
No carry-through	70	39/31/0
No declaration	12	1/10/1
Not updated	22	12/9/1
Omission	191	128/63/0
Other	14	12/2/0
Rework	9	9/0/0
Terminology	85	20/63/2
Unknown	15	15/0/0
Wrong ingredient	31	26/4/1
Wrong label	50	37/10/3
Wrong package	87	63/23/1

^a The root cause designations are described in detail in Table 2.

TABLE 8. *Mechanisms of discovery of the need for a food allergen recall*

Discovery	No. of recalls
Reaction	80
Complaint	170
FDA	201
Other government	79
Firm	105
Unknown	97

(omission and unknown) described situations in which the actual cause was not addressed in the RES database entry for the recall, and 1 category (other) included recalls with unique causes. Of the remaining 13 root causes, 8 were failures of label control (computer error, knowledge, no carry-through, no declaration, not updated, terminology, wrong label, wrong package), 4 were failures in good manufacturing practice controls (cross-contact, in process, rework, wrong ingredient), and 1 was a supplier control problem (ingredient mislabeled) (see Table 2).

The large number of recalls caused by failures in label control (67% of the recalls with a known root cause) shows that the control of nonfood items is as important for protecting the health of allergic consumers as are the controls on foods and food contact surfaces that have been the focus of the existing good manufacturing practices. Within the label controls, failure to provide the necessary information on the label (knowledge, no carry-through, no declaration, not updated, terminology) was more common (58% of the recalls caused by failures in label control) than was use of the wrong package or label.

The large number of recalls caused by failures in label controls is consistent with the fact that 44% of the recalls followed the discovery of a problem during an inspection by a government authority. These recalls did not include those in which a reaction or consumer complaint led to a facility inspection. These inspections generally include a label review to assess all aspects of product labeling. Therefore, the problems identified by the government inspectors could have been identified and corrected by the manufacturer, possibly avoiding the need for a product recall. There is no indication that the number of allergen labeling problems being identified during these label reviews is decreasing over time.

Overall, these data show that allergen recalls continue to occur at a high rate despite the increased awareness that followed the implementation of FALCPA. While a transient increase in recalls might have been expected in the years immediately following the January 2006 implementation of FALCPA, these data show an ongoing increase instead. These data could also be seen as indicating a bimodal trend, a transient increase in recalls following the implementation of FALCPA and an ongoing increase following the implementation of the Reportable Food Registry in September 2009. Because reportable foods meet the definition of a class I recall (6) and the proportion of class I food allergen recalls fell during this period, it is possible

that the need to submit reports to the RFR helped increase awareness of food allergens as a safety issue.

The data also provide information that can be used to focus outreach and education efforts on the most critical sectors of the food industry and to address the most common problems. These data are the first reported that indicate the importance of label and package controls as public health measures.

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