

A Survey of Food Allergen Control Practices in the U.S. Food Industry

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ABSTRACT

Despite awareness of the importance of food allergy as a public health issue, recalls and adverse reactions linked to undeclared allergens in foods continue to occur with high frequency. To reduce the overall incidence of such problems and to ensure that food-allergic consumers have the information they need to prevent adverse reactions, it is important to understand which allergen control practices are currently used by the food industry. Therefore, the U.S. Food and Drug Administration carried out directed inspections of registered food facilities in 2010 to obtain a broader understanding of industry allergen control practices in the United States. The results of these inspections show that allergen awareness and the use of allergen controls have increased greatly in the last decade, but that small facilities lag in implementing allergen controls.

Despite awareness of the importance of food allergy as a public health issue, recalls and adverse reactions linked to undeclared allergens in foods continue to occur with high frequency (14). In many cases, these events result from gaps in the design or execution of an allergen control plan (6). To reduce the overall incidence of such problems and to ensure that food-allergic consumers have the information they need to prevent adverse reactions, it is important to understand which allergen control practices are currently used by the food industry. This understanding will make it possible to prioritize regulatory and educational efforts to achieve the greatest affect on public health.

Because there is no cure for food allergy, allergic consumers must avoid foods containing ingredients that could provoke potentially life-threatening reactions (9, 15). The food industry and public health agencies such as the U.S. Food and Drug Administration (FDA) support these consumers by ensuring that the labels of packaged foods contain complete and accurate information about the presence of food allergens.

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 (peanut, milk, egg, soy, tree nuts, fish, crustacean shellfish, and wheat) or ingredients containing proteins from one of these. FALCPA also specified how the presence of a major food allergen should be declared on the label for foods sold in the United States. These requirements apply when the major food allergen is an ingredient, that is, it is present as an intended component

of the food. When a major food allergen is an ingredient in a food but is not declared on the label, that food is misbranded. Similar labeling requirements exist in many other countries (4). An undeclared major food allergen can also become an unintended component of a food through cross-contact. Cross-contact is the unintentional incorporation of a major food allergen in a food during processing. In either situation, allergic consumers do not have the information they need to avoid risk.

Manufacturers can prevent mislabeling and cross-contact through the use of an allergen control plan (1). An allergen control plan ensures that all major food allergens intended to be in a food are declared through label controls and that cross-contact is prevented through manufacturing controls. Labeling and manufacturing controls together ensure that the proper food is placed in the proper package.

A number of resources exist to help manufacturers develop and use allergen control plans (1, 3, 5, 12, 13). While these resources provide prescriptive guidance, there is little information on the actual allergen control practices used by the food industry. In 1998, the FDA, the Minnesota Department of Agriculture, and the Wisconsin Department of Agriculture, Trade, and Consumer Protection carried out 85 joint inspections of bakery, candy, and ice cream manufacturers in Minnesota and Wisconsin to assess allergen control practices. At that time, they found that a large fraction of the firms inspected did not use basic allergen controls such as label verification or rework controls (11). Since that time, awareness of the importance of allergen control has increased, and FALCPA was enacted.

To obtain a broader understanding of current industry allergen control practices, the FDA carried out inspections

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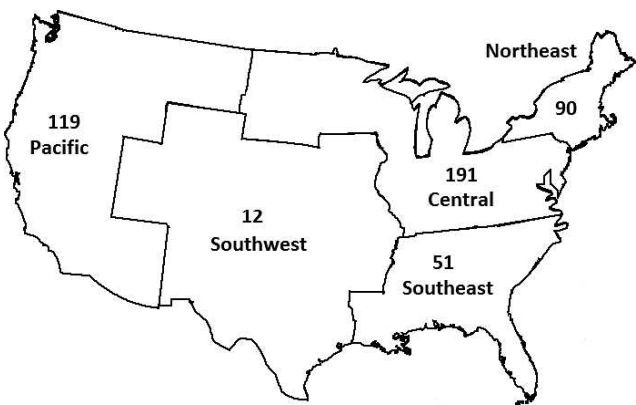


FIGURE 1. The number of inspected facilities that used major food allergens in each FDA region.

of registered food facilities in fiscal year 2010, specifically intended to gauge which and how frequently allergen control practices were being used by the food industry in the United States. These inspections were carried out on a broad cross-section of the food industry and indicate that allergen control practices have improved greatly in the last decade. However, the results also suggest that there are important gaps in allergen control practices, particularly among small facilities.

MATERIALS AND METHODS

In fiscal year 2010, the FDA issued a field assignment that asked agency personnel to conduct an allergen inspection as a component of inspections conducted under the Domestic Food Safety Program. This assignment targeted, but was not exclusive to, facilities that produced foods likely to contain major food allergens (e.g., bakery, chocolate and candy products, pasta products) and facilities that might present cross-contact issues. Field investigators were provided with background information on labeling requirements for the major food allergens and on allergen control. Investigators were also provided with an inspection questionnaire to ensure a uniform inspectional approach and to facilitate collection and analysis of the results. These inspections were distributed geographically among the FDA districts in proportion to the number of registered food facilities in each district, among facilities of different sizes, and among facilities producing a variety of foods. In some cases, different inspected facilities were components of the same corporation. However, in all cases, the products produced or handled at these different facilities differed, and each site was considered to be an independent facility for this analysis.

The completed questionnaires were converted to individual electronic image files, and the responses were combined into a merged data set for analysis. Information describing each firm was obtained from the FDA Field Accomplishments and Compliance Tracking System (FACTS) database, which includes information submitted by the facilities as part of the facility registration process as well as information entered by FDA personnel. The facilities were classified by size according to annual sales volume as small (annual sales of <\$1,000,000), medium (\$1,000,000 to \$25,000,000), or large (>\$25,000,000), as reported by the facilities.

RESULTS

Characteristics of the inspected facilities. A total of 463 facilities that handled or used major food allergens were inspected by the FDA during fiscal year 2010 under the field

TABLE 1. Activities carried out by the facilities that used major food allergens

Activity ^a	No. of facilities ^b
Manufacturer	448
Packer/repacker	89
Warehouse	37
Importer/broker	29
Dealer/retail	8
Shipper	3

^a Activity descriptions taken from the Establishment Type designation for each facility in the FDA FACTS database.
^b Many of the facilities reported that they carry out multiple activities.

assignment. The geographic distribution of the inspected facilities is shown in Fig. 1. Among these facilities, there were 139 (30%) small, 210 (45%) medium, and 102 (22%) large. Sales volume information was not available for 12 (3%) of the facilities. The types of activities carried out by these facilities are described in Table 1, based on the establishment codes in the FDA FACTS database. The inspections focused on manufacturing facilities, because these are the locations under FDA jurisdiction where allergen control practices are most likely to affect the level of risk for allergic consumers. These facilities handled more than 35 different types of foods (by FDA product codes). Overall, these facilities constituted a broadly representative sample of the segment of the U.S. food industry that handled the major food allergens. There was no indication that allergen use and handling practices varied between the regions.

Use of the major food allergens. Table 2 shows the number of inspected facilities that used each of the major food allergens. These facilities frequently handled multiple allergens (Table 3), particularly milk, egg, wheat, and soy (Table 4). The use of multiple allergens in many facilities probably reflects the large number of ingredients derived from these major food allergens, the large number of uses for these ingredients, and the widespread use of wheat as a basic component of many foods.

TABLE 2. Number of facilities that used each of the major food allergens

Major food allergen	No. (%) of facilities ^a
Milk	352 (76)
Wheat	341 (74)
Soy	288 (62)
Egg	282 (61)
Tree nuts	235 (51)
Peanut	186 (40)
Fish	95 (20)
Crustacean shellfish	62 (13)

^a Percentages based on all facilities that use major food allergens. A single facility might use multiple major food allergens.

TABLE 3. *The number of facilities that used multiple major food allergens*

No. of major food allergens used by a facility	No. (%) of facilities ^a
1	47 (10)
2	60 (13)
3	80 (17)
4	79 (17)
5	89 (19)
6	88 (19)
7	15 (3)
8	5 (3)

^a Percentages based on all facilities that used major food allergens.

Allergen control practices. Although allergen control is an integrated process, specific allergen control practices were assessed during receiving and storage of ingredients, equipment use and cleaning, production, and labeling, as appropriate for each inspected facility.

The most common allergen control practices used by these facilities during receiving and storage of ingredients and raw materials were segregation and identification of stored allergen-containing material. The identification of allergen-containing ingredients can be particularly difficult for materials stored in bulk tanks. Overall, about 70% of the facilities segregated allergen-containing ingredients when they were received, although the proportion was significantly higher in large than in small facilities (Table 5). The proportion of facilities that identified allergen-containing ingredients in bulk tanks was lower (less than 40%), particularly among the small facilities (less than 25%). The structure of the questionnaire did not make it possible to determine whether the difference reflects less frequent use of bulk tanks for storing ingredient in smaller facilities.

Carryover of allergen-containing material on shared equipment is an important potential source of cross-contact in food processing environments. Carryover can be prevented by using dedicated equipment; however, this is

TABLE 4. *The most frequent combinations of major food allergens used by individual facilities that used more than one major food allergens*

Combinations	No. (%) of facilities ^a
Pairs	
Milk and wheat	286 (62)
Milk and soy	250 (54)
Wheat and egg	249 (54)
Milk and egg	248 (54)
Wheat and soy	247 (53)
Triplets	
Milk, wheat, and egg	221 (47)
Milk, wheat, and soy	218 (47)
Wheat, soy, and egg	187 (40)
Milk, wheat, and tree nuts	164 (35)
Wheat, soy, and tree nuts	143 (31)

^a Percentages based on all facilities that used major food allergens. The numbers and percentages are not cumulative.

TABLE 5. *Receiving and storage practices of facilities that used major food allergens*

Facility size ^a	No. (%) of facilities ^b	
	Segregate allergen-containing ingredients	Identify allergen-containing ingredients in bulk tanks
Small	82 (59)	35 (25)
Medium	145 (69)	77 (37)
Large	82 (80)	57 (56)
Unknown	9 (75)	4 (33)
All	319 (69)	173 (37)

^a Facility size determined as described in “Materials and Methods.”

^b Percentages based on the number of facilities in each size class that used major food allergens.

often not feasible. In fact, the inspection results indicated that over 70% of inspected facilities of all sizes used shared equipment (Table 6). When shared equipment is used, cleaning procedures that remove food residues can be used to control cross-contact. The recognized importance of cleaning for allergen control is reflected in the data, showing that about 90% of the inspected facilities that used shared equipment cleaned the equipment between allergen-containing and non-allergen-containing products. However, while written procedures and records were used by all of the large facilities, they were not as widely used by small and medium facilities. In particular, 40% of small facilities using shared equipment had written cleaning procedures, while only 28% kept written records of the results.

The allergen controls that can be used on a processing line while a product is in production can encompass a variety of activities such as dust control, control of product movement patterns, or product sequencing. The specific controls that are appropriate for any particular processing environment depend on the nature of allergen-containing products in a facility (for example, liquid or dry products), other products produced in the same facility, facility design, and the volume of product produced. Table 7 shows that approximately 70% of the inspected facilities that used food allergens utilized some form of allergen control to protect products from cross-contact during production. However, less than half of all inspected facilities used product sequencing to prevent cross-contact through product carryover. A significantly higher proportion of large facilities used sequencing as an allergen control. It was not possible to determine if the lower use of product sequencing among the small facilities (32%) reflected the production of a smaller number of products in a facility. It could also be the case that multiple products produced in small facilities contain the same food allergens.

Tracking and monitoring of rework is also important for allergen control. The observed use of rework among the facilities inspected under this assignment was unexpectedly low, although it was significantly more common among large facilities than among medium and small facilities (Table 8). It was not possible to determine whether the use of rework was more common among facilities that produced and handled specific types of products. Among those inspected facilities that were observed to use rework, almost

TABLE 6. *Equipment practices of facilities that used major food allergens*

Facility size ^a	No. (%) of facilities				
	Use shared equipment ^b	Have written allergen cleaning procedure ^c	Equipment is checked after cleaning ^c	Clean between allergen and non-allergen products ^c	Written record of check ^d
Small	99 (71)	40 (40)	90 (91)	91 (92)	25 (28)
Medium	167 (79)	121 (72)	163 (98)	149 (89)	119 (73)
Large	81 (80)	81 (100)	81 (100)	78 (96)	81 (100)
Unknown	12 (100)	8 (67)	11 (92)	9 (75)	7 (64)
All	359 (77)	254 (71)	351 (98)	327 (91)	236 (67)

^a Facility size determined as described in “Materials and Methods.”
^b Percentages based on the number of facilities in each size class that used major food allergens.
^c Percentages based on facilities in each size class that use shared equipment.
^d Percentages based on the number of facilities in each size class that check cleaning.

all of them added rework only to products containing the same allergens. However, only about half of the facilities of all sizes maintained and reconciled a rework inventory.

Labeling controls. Because the major food allergens and ingredients derived from them are desirable and nutritious components of many foods, the most important food allergen risk management strategy is to ensure that product labels provide complete and accurate information to allergic consumers. Proper labeling begins at the product development stage. Overall, about 90% of the inspected facilities that used major food allergens stated that they identified the major food allergens in their products during product development (Table 9). Despite this, only 80% of the inspected facilities that used major food allergens declared all of the allergens on product labels. Small facilities were more likely not to declare one or more of the major food allergens than were large facilities. Less than half of all inspected facilities used an advisory label (such as a “may contain” statement).

About three quarters of the inspected facilities checked their labels for accuracy when they were received from outside sources. On the other hand, less than 20% of the facilities used documented procedures to confirm that labels were applied to the correct products during production. It was not possible to assess whether any general or quality assurance label controls (such as color coding of label art work) that were in use at a facility were also intended to serve as allergen labeling controls.

TABLE 7. *Allergen control during production by facilities that used major food allergens*

Facility size ^a	No. (%) of facilities ^b	
	Protect from cross-contact	Use product sequencing
Small	93 (67)	45 (32)
Medium	144 (69)	101 (48)
Large	78 (78)	65 (64)
Unknown	8 (67)	5 (42)
All	323 (70)	216 (47)

^a Facility size determined as described in “Materials and Methods.”
^b Percentages based on the number of facilities in each size class that used major food allergens.

DISCUSSION

These data are an extensive assessment to date of allergen control practices among food industry facilities that use or handle major food allergens in the United States. Because these data were obtained as part of a regulatory inspection program, they do not represent a random sample of the entire food industry. In addition, only those allergen control practices observed by agency inspectors at the time that they visited each facility could be noted. Other important practices, such as regular training, could not be assessed. However, because of the large number of facilities inspected, these data provide a qualitative assessment of industry practices. More importantly, the data allow a comparison of practices among facilities of different sizes.

The data show the extensive use of several of the major food allergens in the food industry, particularly milk, egg, wheat, and soy. This reflects both the importance of these allergens as fundamental components of many foods and the wide variety of ingredients that are derived from them. This is consistent with data from the FDA Reportable Food Registry (14) and food recall database, which indicate that unlabeled milk, egg, and wheat are the leading causes of allergen-related recalls of FDA-regulated products (6).

In addition, it is clear that allergen awareness and the use of allergen controls have greatly increased since 1998. However, it appears that there might remain important gaps

TABLE 8. *Rework practices by facilities that used major food allergens*

Facility size ^a	No. (%) of facilities		
	Use rework ^b	If so, it is added back to product with same allergen(s) ^c	If so, the rework inventory is reconciled ^c
Small	27 (19)	27 (100)	15 (56)
Medium	59 (28)	52 (88)	26 (44)
Large	45 (44)	44 (98)	25 (56)
Unknown	6 (50)	6 (100)	3 (50)
All	137 (30)	129 (95)	69 (50)

^a Facility size determined as described in “Materials and Methods.”
^b Percentages based on the number of facilities in each size class that used major food allergens.
^c Percentages based on number of facilities in each size class that used rework.

TABLE 9. Allergen labeling controls used by facilities that used major food allergens

Facility size ^a	No. (%) of facilities ^b				
	Allergens identified in product development	Labels declare all allergens	Use advisory label(s)	Labels checked when received	Check label–product match when used
Small	112 (80)	102 (73)	52 (37)	97 (70)	16 (11)
Medium	184 (88)	184 (88)	97 (46)	155 (74)	32 (15)
Large	99 (97)	88 (87)	48 (47)	86 (85)	25 (25)
Unknown	9 (75)	11 (92)	7 (58)	10 (83)	6 (50)
All	404 (87)	385 (83)	204 (44)	348 (75)	79 (17)

^a Facility size determined as described in “Materials and Methods.”
^b Percentages based on the number of facilities in each size class that used major food allergens.

in allergen control practices. For example, approximately 20% of the facilities did not declare all of the major food allergens used, and approximately 30% of the facilities did not protect products from cross-contact during production. Facilities might have used other effective allergen practices, but these were not observed by the agency inspectors or were not documented by the facilities.

In 2006, Taylor et al. (10) reported the results of a survey of allergen control practices by 59 food companies. The data in that survey were obtained via self-reporting by voluntary participants rather than by observation in regulated facilities. Many of the results of that survey are consistent with the results reported here, particularly that small facilities were less likely to use all of the allergen control practices that were assessed.

It is not possible to assess the public health impact of the gaps in allergen control practices that were observed. This is primarily because there is no active surveillance system for tracking allergic reactions caused by undeclared or mislabeled allergens in the United States. Several studies have used hospital records or other medical databases to estimate the frequency of food-allergic reactions (2, 7, 8). There has been no systematic effort to determine what proportion of reactions result in hospital or emergency department visits, or to assess the relative importance of the different routes of exposure (such as mislabeled packaged foods and mishandling in food service).

The data show that small facilities differ significantly in all aspects of allergen control compared with large facilities. While many of the small firms used some of the allergen control practices that were assessed, a relatively large proportion did not use all of the controls. For example, small firms were much less likely than large firms to segregate allergen-containing ingredients during receiving and storage. On the other hand, some controls, such as checking that labels and products match during processing, might not be as important for small firms that produce a limited range of products. It was not possible to determine whether the observed differences reflect less familiarity with allergen control practices or the need for fewer controls or less complex systems in small facilities.

Overall, these data show that allergen awareness is widespread in the food industry, and that most firms have allergen control programs. The results also indicate that there are potentially significant gaps that can be addressed through guidance and education programs. They also suggest that the most significant impact from these activities can be obtained by focusing on the allergen control practices of small food facilities.

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