

Research Paper

Economic Factors Impacting Food Allergen Management: Perspectives from the Food Industry

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ABSTRACT

Food allergies affect up to 8% of children in the United States and may occasionally lead to severe life-threatening reactions. Because there is currently no cure for food allergies, strict avoidance of the allergen-containing foods is the only means of preventing an allergic reaction. Consumers rely on food manufacturers to reliably track and declare the presence of food allergens in products. Over the past 10 to 20 years, the food industry has increasingly adopted allergen control approaches in its processing facilities. However, the major industry costs related to food allergen management have not been fully described. The objective of this study was to characterize the factors that contribute to the economic impact of food allergen control practices on the food industry. A focus group ($n = 100$) was conducted with food industry professionals to identify key areas of cost for food allergen management. A survey based on the domains identified was then developed and disseminated to a convenience sample ($n = 50$) of quality control food industry specialists with knowledge of their company's food allergen management practices. Nearly all companies (92%) produced food products containing one or more of the top eight allergenic foods recognized by the U.S. Food and Drug Administration or sesame seeds. Cleaning procedures, employee training, and the potential for a recall due to allergen cross-contact were most frequently rated as the important factors in food allergen management. Recalls due to food allergen cross-contact, cleaning procedures, equipment and premises design, and employee training were ranked as the greatest allergen management expenses. Although 96% of companies had a food allergen control plan in place, nearly half (42%) had at least one food allergen-related recall within the past 5 years. The industry appears to endorse a willingness to unify precautionary allergen labeling to communicate a clear message more effectively to consumers.

Key words: Allergen; Cost; Economic; Food allergy; Industry; Precautionary allergen labeling

Food allergies affect nearly 8% of children in the United States and cost families and the health care system an estimated \$24.8 billion annually (8, 9). Food-induced anaphylaxis may manifest rapidly after the ingestion of an allergen and in some cases may be life-threatening. Thus, avoidance of patient-specific food allergens and the vigilant reading of food labels have been established as best practices to prevent inadvertent allergen exposures (2). Food-allergic consumers rely on food manufacturers to produce safe food products and to accurately label foods to communicate the presence of allergens. Food-allergic consumers spend approximately \$1.7 billion annually in the United States on special foods (8) that are free of their allergens and labeled as such.

The U.S. Food and Drug Administration (FDA) (20) has established good manufacturing practices that outline the requirements for the production of processed foods, including the tracing of the movement of raw materials

through the supply chain, handling of materials during processing, and appropriate labeling of final food products. These guidelines were updated through the passage of the Food Safety Modernization Act (FSMA) in 2011 (19), which identifies food allergen cross-contact as one of the key hazards that needs to be evaluated. When allergens have been identified as a hazard, the food manufacturing facilities are required under FSMA to establish elaborate preventive allergen control measures. In addition, the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 (18) mandates that the manufacturers of packaged foods must declare the presence of any of the top eight major food allergens (peanut, tree nuts, milk, egg, soy, wheat, fish, and crustacean shellfish) by source on the package label when these ingredients are intentionally added as intended ingredients. However, current guidelines do not establish specific requirements for allergen control during the manufacturing process. Although efforts are typically made to segregate foods containing major allergens during manufacturing, cross-contact (the unintentional introduction of allergen residues into a product that

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does not contain them as ingredients) may occur due to processing on shared equipment, mishandling during packaging, or the use of raw ingredients coming in unanalyzed from all parts of the world (14). Consequently, manufacturers routinely develop and implement independent allergen control plans to minimize the risk of product contact with food allergen contaminants and prevent recall events due to undeclared allergens. These plans typically specify practices for the safe handling and storage of raw materials, employee training, facility and equipment design, cleaning procedures, and production scheduling. In addition, companies may use precautionary allergen labeling (PAL) on packaging to label products for which there is a risk of cross-contact with food allergens during production. However, PAL usage remains voluntary and unregulated, and it currently presents consumers with considerable challenges due to its inconsistent use (10, 11, 15).

Food allergen-related recalls and preventive allergen controls are likely to be the sources of significant costs for the food manufacturing industry; however, estimates of the magnitude of these expenditures are lacking. The specific factors contributing to these food industry costs have not been well characterized. The current study sought to identify the major contributors to the costs associated with food allergen management in the food industry.

MATERIALS AND METHODS

Survey development and design. A preliminary focus group was conducted at the board meeting of the Food Allergy Research and Resource Program (FARRP), a food industry-funded research and industry outreach consortium at the University of Nebraska, to obtain information about the major categories of costs related to allergen control programs and to guide the development of the survey instrument. English-speaking FARRP members ($n = 100$) were recruited and informed consent was obtained verbally prior to their participation. The focus group was cofacilitated by two experienced food allergy researchers and was conducted in a secure room to maintain confidentiality. During the 2-h session, participants were asked to respond to nine questions pertaining to the allergen management costs incurred by the food industry and the feasibility of disseminating a survey to food industry representatives. Example questions included “What should be included when estimating food allergy costs from the industry perspective?” “What are the most important industry characteristics that impact costs?” and “Is it feasible to collect specific cost estimates using a phone interview or online survey?” The session was audio-recorded, and the participant responses were de-identified. The data were transcribed and stored on a secure data drive accessible only to the research team. Participants were not compensated for their time.

Based on the data obtained in the focus group, a survey was developed to characterize the major costs associated with food allergen management, consisting of 26 multiple-part, multiple-choice, and open-response questions with additional qualitative response choices built in (e.g., “please explain” or “fill in the blank”). Three active food industry professionals who had participated in the initial focus group subsequently completed a 1-h phone interview with a member of the research team to provide feedback on the survey design. The same methodologies for verbal consent, audio-recording, participant de-identification, and secure data storage were used. The participants were compensated with a \$20 electronic gift card for their participation.

Survey dissemination. The final survey was distributed via secure electronic Web link to food industry professionals representing a broad range of U.S. food manufacturing companies. The majority of respondents came from the 80 member companies of the FARRP consortium, but other participants were invited from a list of food industry professionals who had sought information from FARRP or had previously attended FARRP-sponsored workshops and conferences. The survey was distributed through the FARRP listserv over an 8-week period. Prior to the recipients completing the survey, a disclaimer explained the purpose of the study and the rights of the research participants. The survey required less than 30 min to complete. The study data were captured and managed using REDCap electronic data capture tools hosted at Northwestern University. All identifying information and survey responses were kept confidential using a secure server maintained by Northwestern University. The participants were compensated with a \$5 electronic gift card.

Statistical analyses. Frequencies were used to describe the survey responses. Chi-square and Fischer’s exact tests were used to calculate the associations between company income (dichotomized as greater than or less than \$500 million) and other variables (e.g., types of allergens manufactured, labeling practices, costs recorded, and recall practices). All analyses were performed using Stata/SE 14.0 (Stata Corp LP, College Station, TX).

RESULTS

A total of 51 individuals responded to the electronic survey. One individual was excluded due to not working in the food industry. This resulted in a final sample of 50 food industry professionals that was used for the analyses. Demographic data were not recorded for anonymity purposes. The majority of respondents (96%) reported working for companies based in the United States, 72% had ≥ 15 years of food industry experience, and 56% had job titles in regulatory compliance or quality control. Participants reported working for companies with annual net incomes that were roughly evenly divided between from $< \$10$ million to \$500 million (36%) and from $> \$500$ million to $> \$5$ billion (43%). However, 21% of respondents reported not having knowledge of their company’s annual net income. Ninety percent of respondents reported that their companies used suppliers outside the United States, and 88% reported having strict guidelines in place for supplier tracking and storage of raw materials. Respondents reported that the highest proportions of product distribution were to the United States (98%), Canada (74%), Mexico (58%), Asia (56%), and Europe (50%). Ninety-two percent of respondents reported that their company manufactured products containing one of the top eight food allergens or sesame, with peanut (92%), milk (82%), wheat (78%), soy (78%), egg (60%), tree nuts (50%), and sesame (50%) most frequently reported (Table 1). Ingredients (38%), bakery goods (30%), and snack foods (22%) were the most frequently manufactured products.

Nine key factors associated with food allergen management and safety were derived from the preliminary focus group with industry professionals; these are listed in Table 2. Raw material traceability was identified as a major preprocessing factor, with emphasis given to the fact that raw materials are imported from a range of suppliers from all

TABLE 1. Respondent and company characteristics

Characteristic	% (n)
Respondent characteristics	
Food industry experience ≥ 15 yr	72 (34)
Job title in regulatory compliance or quality control	56 (28)
Company characteristics	
U.S.-based company	96 (48)
Annual net income	
$\leq \$10$ million to $\$500$ million	36
$> \$500$ million to $\geq \$5$ billion	43
Current allergen management policy	96 (48)
Suppliers from outside United States	90 (44)
Strict guidelines for supplier tracking and raw material storage	88 (44)
Location of product distribution	
United States	98 (49)
Asia	56 (28)
Australia	48 (24)
Canada	74 (37)
Central America	40 (20)
Europe	50 (25)
Mexico	58 (29)
South America	42 (21)
United Kingdom	42 (21)
Other	20 (10)
Processing of food allergens	92 (46)
Peanut	92 (46)
Milk	82 (41)
Soy	78 (39)
Wheat	78 (39)
Egg	60 (30)
Sesame	50 (25)
Tree nuts	50 (25)
Crustacean shellfish	30 (15)
Fin fish	28 (14)
Other	8 (4)

around the world. Factors directly related to the manufacturing process included the design of processing equipment and facilities, employee training, process scheduling, cleaning and other change-over procedures, and product testing and holding. Postprocessing factors included potential recalls due to food allergen cross-contact, insurance, and legal expenses and lawsuits.

The survey respondents were asked to rank the importance of each of these factors and also to estimate the actual costs to their company using a forced choice response (Table 2). All the respondents indicated that employee training and cleaning and change-over procedures were important to consider, and nearly all considered the potential for recall due to food allergen cross-contact (94%) and process scheduling (92%) to be important. However, respondents were less confident in their estimates of the costs associated with each factor, with 50% selecting "Not sure" or "These data are not tracked" for eight of the nine cost factors. Recalls due to food allergen cross-contact (39%), cleaning and change-over procedures (21%), equipment and premises design (16%), and training of employees (16%) were ranked as allergen management practices with the highest costs.

The respondents were further asked about the costs and processes associated with food allergen-related recalls (Table 3). Of the respondents, 42% reported at least one recall in the past 5 years; 41% reported that the final estimate of product recall losses took less than 6 months to prepare, but 36% reported that they did not have knowledge of the length of time required. Product retrieval and disposal (48%), transportation (42%), and customer reimbursement (38%) were the most frequently reported costs associated with product recall. Insurance (68%) and customer and supplier indemnification contracts (44%) were most frequently used to manage the legal risks associated with allergen-related product recalls. Of the respondents, 35% reported that their companies engaged outside service providers to be involved in product recalls, with scientific experts (26%) being most frequently retained.

To examine the associations with company annual net income, the companies were dichotomized based on earnings into small companies ($\leq \$500$ million annually; 36%) and large companies ($> \$500$ million annually; 43%). Fisher's exact tests were conducted for the processing of one or more of the top eight allergens or sesame, cost factor importance, and costs associated with product recall. Large companies were significantly more likely to be involved in soy processing than small companies (96 and 64%, respectively; $P < 0.05$), and large companies were significantly more likely than small companies to incur business interruption costs due to recall events (43 and 12%, respectively; $P < 0.05$). There were no significant

TABLE 2. Key allergen management factors

Factor	% (n) endorsing factor as important	Annual cost estimate per company ^a
Employee training	100 (50)	$< \$1\text{M}$
Cleaning and change-over procedures	100 (50)	$\$1\text{M}$ to $\$2.5\text{M}$
Potential for recall due to food allergen cross-contact	94 (47)	$< \$9\text{M}$
Production scheduling	92 (46)	$< \$1\text{M}$
Raw material traceability	88 (44)	$< \$1\text{M}$
Equipment and premises design	88 (44)	$\$1\text{M}$ to $\$2.5\text{M}$
Testing and holding of product	64 (32)	$< \$1\text{M}$
Legal expenses and lawsuits	54 (27)	$< \$1\text{M}$
Insurance for food allergen management	42 (21)	$\$1\text{M}$ to $\$2.5\text{M}$

^a M, million.

TABLE 3. *Food allergen recall characteristics*

Characteristic	% (n)
No. of recalls in past 5 yr	
0	58 (29)
1	20 (10)
2	4 (2)
3	10 (5)
>3	8 (4)
Time to prepare final recall estimate	
<6 mo	41 (16)
6 mo to 1 yr	20 (8)
>2 yr	3 (1)
Not sure	36 (14)
Captured recall costs	
Product retrieval/disposal	48 (24)
Transportation	42 (21)
Customer reimbursement	38 (19)
Business interruption	32 (16)
Internal time and expense	30 (15)
Warehousing	28 (14)
Investigational costs	28 (14)
External professional fees	20 (10)
Cleaning/sanitation of facilities	20 (10)
Managing legal risk	
Insurance	68 (34)
Customer and supplier indemnification contracts	44 (22)
etain risk	26 (13)
Not sure	22 (11)
Other	2 (1)
Use of outside service providers	
Scientific experts	26 (13)
Regulatory lawyers	24 (12)
Analytical service experts	18 (9)
Insurance lawyers	14 (7)
Public relations	12 (6)
Operational experts	8 (4)
Defense lawyers	6 (3)
Forensic accountants	2 (1)

differences between small and large companies for cost factor importance.

To assess industry practices and attitudes toward PAL, respondents were asked about their company's PAL usage. Current PAL usage was reported by 34% of the respondents, with "may contain" (30%) being the labeling used most frequently, followed by "manufactured in" (16%), "manufactured on" (10%), and "other" (4%) (Table 4). These results indicate that manufacturers use multiple allergen labels on their products. However, 78% of the respondents reported that having only a single option for PAL (e.g., "may contain") would improve their industry. Respondents were also asked about the impact of regulations on PAL; 36% reported that their industry's PAL-related costs increased after the passing of FALCPA. However, the majority of respondents who reported cost increases were unable to provide estimates of those costs. Only three respondents provided a discrete cost estimate (an increase between 10 and 30%), and only one respondent reported a

TABLE 4. *Use of PAL*

	% (n)
Currently using PAL on products	34 (17)
May contain	30 (15)
Manufactured in	16 (8)
Manufactured on	10 (5)
Other	4 (2)
One PAL would benefit food industry	78 (38)
FALCPA increased PAL costs	36 (18)
FSMA projected to increase PAL costs	57 (28)

dollar amount increase (between \$2 million and \$5 million). Moreover, 57% anticipated that the costs associated with PAL would increase after the implementation of FSMA.

DISCUSSION

The current study sought to describe the factors that affect the economic costs to the food industry from food allergen control practices on a per-company basis. Nearly all the food industry professionals surveyed reported that their companies manufactured products containing at least one of the top eight allergens or sesame, and nearly all had an allergen control plan in place. Previous studies and food industry surveys (5, 16) have similarly shown that the use of the major allergenic foods is widespread and that virtually all food companies have an allergen control plan, but they have also documented that the components of the allergen control plans and the validation of their effectiveness are variable. It is worth noting that in our study a substantially higher proportion of companies (92%) reported processing peanut than has been found previously (5, 16), although the rates of processing of other top allergens were similar to previous reports. One possible explanation is that, because peanut is a highly publicized allergenic food, the employees of companies that process peanut were more likely to respond to a survey on food allergen management. Collectively, these results indicate that allergen control plans are needed by most food processing facilities because of the widespread processing of major allergens. These results also suggest that allergen control probably represents an economic burden for the majority of food manufacturers.

The results of this survey indicate that many respondents, despite being management professionals employed by food manufacturing companies, did not know the costs associated with the implementation of allergen controls. Because the cost factors in our survey spanned multiple levels in a food processing operation, it is possible that no single company employee would be likely to know the costs associated with all the steps of allergen control. For instance, whereas regulatory officials may have knowledge of the recall costs, quality supervisors are more likely to know the costs associated with equipment and facility design. Apparently, the various costs of allergen control are not collected centrally in food processing companies or are not widely shared within management if they are collected. In addition, larger one-time costs, such as those associated with recall or capital improvements of facilities and equipment, may be tracked more carefully than recurring costs, such as

longer times spent cleaning the equipment. Thus, the survey was able to track the qualitative perceptions of comparative costs among respondents rather than the specific cost magnitude. Finally, because respondents represented companies of a range of sizes, it is worth noting that the costs associated with allergen management were higher for larger than for smaller companies.

Employee training, cleaning and change-over procedures, and potential recalls due to food allergen cross-contamination were considered to be the most important components of the allergen management plans (Table 2). However, these components are not necessarily the most costly elements of food allergen management. Recalls are episodic and often expensive events that fall outside the normal corporate budgeting process and that may also lead to consumer dissatisfaction and even consumer illnesses. Hence, most food companies assign a very high importance to the elimination or limitation of product recalls. Employee training is obviously important because employees must be knowledgeable of the allergen control plan and their role in its successful implementation. Because most employee training is conducted on-site and episodically, training may not be costly. With the implementation of FSMA, the importance of employee training will increase because effective allergen training will become more pivotal to passing FDA inspections. Cleaning for allergens occurs regularly because the food processing industry shares equipment and facilities with great frequency. The incrementally increased costs associated with the extra time and effort needed for allergen cleaning compared with less thorough cleaning are not likely to be well documented in the food industry. However, as noted in Table 2, respondents indicated that allergen cleaning procedures were important and costly elements of the allergen control plans.

In contrast, insurance and equipment and premises design were identified as costly but less important components of allergen control plans. When allergen control requires the modification or replacement of equipment or facilities, those costs are often quite high. However, in some food processing companies the costs associated with equipment and premises design will have already been borne, thus lessening the ongoing importance of this factor. Thus, the lower importance ranking may simply indicate that the equipment and facilities in some food processing facilities are already suitable for effective allergen control. Insurance typically is intended to cover the nonbudget costs associated with product recalls. Because recalls are expensive, insurance coverage is a high cost. Insurance would certainly be considered to be important and unavoidable by the highest levels of food industry management, but its importance was not as well recognized by our respondents.

Many of the costs associated with allergen control are shared with other aspects of the overall food safety plan (pathogen control, chemicals control, etc.) for each manufacturing facility. Cleaning practices, employee training, and insurance for allergens are likely to be shared with and overlap with the costs for these other food safety hazards. The survey did not attempt to compare the costs for allergen control with the costs for pathogen control, chemicals control, or other food safety aspects.

Food allergen-related recalls were considered to be among the most important and costly factors related to allergen control. Nearly half the respondents reported that their company had issued at least one allergen-related product recall in the past 5 years, indicating that recalls are not uncommon and probably represent a substantial economic burden on the food industry. Although the majority of respondents did not have enough knowledge to estimate their company's costs for allergen-related recalls, potential annual recall costs were most frequently estimated to be $\leq$ \$9 million, although some estimates reached as high as $\geq$ \$100 million. This is similar to the findings of two surveys of large food manufacturers conducted in 2009 and 2011, which found that the average cost of a product recall for any reason was \$10 million (6) and was $<$ \$9 million in 48% of cases (7). Recall costs are going to be highly variable based on a number of factors and especially on the amount of product that must be recalled and the geographic scope of the recall. In addition to the direct costs, food recalls may also indirectly affect the manufacturer's profits owing to legal liability costs, damage to brand reputation, and loss of future sales. For instance, large well-capitalized companies commonly prepare for legal liability by paying high insurance deductibles as part of a strategy to assume the risk of product recall, but the cumulative estimates of these costs have yet to be established in the literature (7). It is notable that recalls occurred despite nearly all respondents reporting that their companies had an allergen control plan in place, suggesting that there is room for improvement in allergen management.

Only one-third of respondents indicated that their company currently uses PAL on their products. This finding is reasonably consistent with the results obtained from the respondents from large companies in a mid-2005 survey (15) of food manufacturers conducted in the year prior to the implementation of FALCPA. Clearly in the mid-2005 time frame of that survey, the food industry was already preparing for FALCPA implementation. That earlier survey further indicated that the use of PAL was greater among small companies than large ones. Thus, the results of the current survey may indicate that the preponderance of respondents were from larger companies that have the manufacturing size and flexibility to avoid the need for PAL on some products. Interestingly, the vast majority of respondents reported that having a single version of PAL (e.g., "may contain") would improve the industry. Currently, the use of PAL is voluntary, and there is no industry-wide standard for the circumstances and form in which the labeling is applied. Various phrases may be used, including "may contain," "may contain traces of," "produced in a factory which handles," or "packaged in an environment where (allergen) may be present" (17). In addition, manufacturers vary in the conditions under which they use PAL; these range from whenever an allergen is in the facility to only those circumstances when they feel that their cleaning procedures may have been insufficient to prevent cross-contact. This lack of standardization and regulation of PAL conveys inconsistent messages to consumers, which may lead to confusion and distrust of labeling and products (4, 12). As a consequence, on the one hand, food-allergic

consumers may unnecessarily restrict their food purchases and consumption, in turn negatively impacting their quality of life by limiting their social interactions and increasing their caregiver burden (22). On the other hand, variable PAL phrasing may be associated with increased consumer risk taking owing to the mistaken belief that the different phrases imply distinct levels of potential cross-contact (11, 15, 21). For example, a global survey of consumer perceptions of food allergen thresholds found that consumers were less likely to purchase food labeled “may contain” (16%) than food labeled “may contain traces of” (25%), and “manufactured in a facility that also processes” (41%) (11). In addition, the ubiquity of PAL may produce “warning fatigue,” in which consumers become desensitized to and ignore PAL indications, thus increasing their risk-taking behavior (3, 10). For instance, consumers who frequently encounter PAL may assess that there is a low risk of allergen exposure or discredit the PAL when the specific allergen is not listed as an ingredient or when other product qualities, such as discounted cost, encourage a reappraisal in favor of the purchase (1, 12). Given the current lack of consumer confidence in PAL, the food industry and the regulatory authorities have been given the task of reforming PAL to be more risk-based (10, 15, 17). Our results support the recommendation of the recent National Academy of Medicine study (13) that PAL phrasing should be consolidated and standardized to improve the effectiveness of PAL.

To our knowledge, the present study is the first to use a refined survey instrument to examine the perceptions of experienced food industry professionals in the United States of the economic cost factors associated with food allergen management. The data were gathered from companies with a range of incomes that were likely to be involved in the manufacture of one or more of the top eight food allergens or sesame. However, a limitation of the study is that the overall number of survey respondents was low given the high number of industry professionals who were contacted via listserv during the survey dissemination. The nonresponders may have had reservations regarding anonymity or lacked the time or knowledge to complete the survey in its entirety. The respondents did confirm by some of their answers that many industry professionals do not know the economic costs associated with their company’s allergen management efforts. Moreover, many respondents represented companies with markedly high annual net incomes, suggesting that the results of the present study may not be applicable to smaller companies. Indeed, FARRP member companies are likely to be larger and more diverse than the industry average and may also have more resources to devote to allergen control. For example, studies (15, 16) have shown that company size can directly impact the need for, methods used in, and costs of implementing PAL.

In addition, the cost estimates provided did not take into account the differences in company size, number of production facilities, products manufactured, or allergens handled. Processing facilities with increased complexity, with respect to the number of allergens handled, face greater challenges in allergen control, especially if these companies are smaller and have less flexibility in equipment use. An

insufficient number of responses were obtained to determine whether allergen complexity affected the costs of allergen control. Larger companies with more or larger processing facilities may be able to more easily control allergens by segregating their use to specific facilities or processing lines. Such approaches are not available to smaller companies.

Finally, despite being able to identify and endorse the importance of the cost factors related to allergen management, the majority of industry professionals in the current study were unable to estimate the costs based on forced choice responses. In future studies, these shortcomings should be addressed by surveying individuals with a greater knowledge of their company’s food allergen management costs. However, it is possible that this economic information is not carefully monitored within companies.

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