

Top Ten Food Safety Problems in the United States Food Processing Industry

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SUMMARY

The preventive controls are less rigorous at some food processing facilities than at others, potentially increasing the risk of microbiological, chemical, and physical food safety hazards. We used a modified three-round Delphi technique to generate expert opinion on the ten food safety problems that are of top concern for the food processing industry today, and the preventive controls needed to address them. The expert panel members evaluated the frequency and severity of the food safety risk posed for five food processing industry sectors (baked, dairy, frozen, refrigerated, and shelf-stable goods, excluding meat and poultry products) and three plant sizes for each of the ten most important problems identified. The experts collectively ranked “deficient employee training” as the top problem facing food processors today, followed by “poor plant and equipment sanitation” and “contamination of raw materials.” Other problems included “poor plant design and construction,” “post-process contamination,” “difficult-to-clean equipment,” and “incorrect labeling and packaging.” The expert panel also made recommendations on the types of preventive controls needed to address these problems. Some of the main recommendations with broad applicability across all food sectors included ongoing and targeted training of employees, management, and suppliers; periodic audits of facility and raw material suppliers; improved recordkeeping; and validation/evaluation of activities such as employee training and cleaning procedures.

INTRODUCTION

Food safety is paramount to food processing. Although the food processing industry has made big strides in enhancing the safety of foods manufactured, the food safety literature indicates that there remains room for further improvements in microbiological, chemical, and physical safety at food processing plants. Published reports indicate that some food processing plants continue to struggle with such food safety challenges as poor hygienic practices (5), ineffective employee training (1), deficient cleaning and sanitation of equipment and utensils (3, 10), raw material contamination (8, 11), and ineffective allergen control (2, 4), among others. Further, evolution of new agents as well as new vehicles transmitting known pathogens, increased reliance on food imports, adoption of more sophisticated food production and processing technologies, and increased automation make prevention of food contamination a moving target for food processors (9).

The majority of these problems can be remedied with basic common sense preventive controls, such as targeted employee training, monitoring of cleaning and sanitation effectiveness via environmental sampling and testing, and implementation of raw material supplier qualification and monitoring programs. Others are more difficult to control, such as post-processing contamination with *Listeria monocytogenes*, a pathogen that is ubiquitous in the processing environment.

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TABLE 1. Risk scoring grid for general and allergen risks

Frequency	Severity	
	High	Low
High	4	2
Low	3	1

Preventive controls also vary in cost, and given limited budgets, food processors may benefit from adopting a risk-based approach to prioritizing their food safety initiatives based on a risk-payoff analysis. For example, problems that pose the highest risk to food safety but are least costly to fix can be addressed earlier than those with low risk but high costs. This study is designed to provide a global perspective on the state of food manufacturing in the United States, with the goal of aiding regulators and food processors in developing such an analysis.

The objectives of this study were twofold: (1) To identify the main problems that pose microbiological (i.e., pathogenic bacteria, viruses, and parasites), chemical (i.e., allergens, cleaners and solvents, and mycotoxins), and/or physical (i.e., foreign objects such as glass and metal) safety hazards to food at the processor level, and (2) to determine the preventive controls that food manufacturers should implement to address each of the problems identified.

MATERIALS AND METHODS

The study objectives required gathering current data that are not accurately known and that did not easily lend themselves to highly precise analytical techniques, such as a statistical industry survey, which would entail asking manufacturers to release potentially sensitive information. Thus, we used a modified Delphi technique to generate the necessary information from a panel of nationally recognized experts in food safety. The Delphi technique involves eliciting opinions of experts on a collective basis and is widely applied in the forecasting and policy arenas (6, 7). A successful application of the technique requires assembling a panel, preferably consisting of 15 or more individuals who are considered experts in the given field of investigation, although some Delphi studies have been conducted with a panel consisting of as few as four experts.

Study design

We assembled a 15-member panel comprising nationally recognized experts

in food safety, HACCP, food plant sanitation, quality systems, process optimization, GMP compliance, and food microbiology. On average, the panel members possessed over 30 years of food industry experience in various sectors, such as canned foods, fresh produce, meat and poultry products, and seafood. In identifying the experts, we relied on recommendations from FDA, various food industry personnel, and other experts in food safety.

The study utilized a three-round design. In Round 1, we provided each panel member with a list of food safety problems previously identified through a literature review and discussions with selected expert panel members. We then asked each panel member to: (1) indicate the major food sectors, including baked, dairy, frozen, refrigerated, and shelf-stable, to which the listed problem is mainly applicable, (2) add to the list of food safety problems if necessary, and (3) select the ten most important food safety problems facing food manufacturers today, based on their frequency and severity.

The objective of Round 2 was to determine whether each of the top ten problems identified in Round 1 posed a sufficiently different food safety risk for a particular food item (e.g., pies) within a major food category (e.g., baked goods) than for the major food category as a whole. Thus, we asked each panel member to indicate whether a separate risk score is more appropriate for a listed food item within a major food category for each of the ten food safety problems. To ensure consistency of responses in the identification of food items, a list of product categories (obtained from Information Resources, Inc. (IRI) InfoScan® Custom Store Tracking database) was included for each major food sector.

Round 3 involved assessing the risk posed by each of the top ten food safety problems identified by major food sector (baked, dairy, frozen, refrigerated, and shelf-stable) and facility size (small, medium, and large). Additionally, we asked each expert to determine the types of preventive controls necessary to address

each of the top ten problems identified. More specifically, experts were asked to assign a “general” as well as an “allergen” risk score from 1 to 4, Table 1, based on the problem’s frequency and severity by food sector and facility size. “General” risk score had to reflect the risk of the food safety problem with respect to all hazards (i.e., microbiological, physical, and chemical) except for allergens, and “Allergen” score had to reflect the risk of the food safety problem with respect to allergens only.

We also asked each expert to indicate the types of preventive controls that food processors need to implement to address each of the ten food safety problems by facility size and major food sector. Although large food processors might have the capital to invest in more sophisticated technologies, small processors are likely to face resource constraints that make such technologies infeasible. Therefore, the expert panel was instructed to take account of cost-effectiveness when making recommendations on the types of controls by size of food processor and main food sector (i.e., baked goods, dairy, frozen, refrigerated, and shelf-stable). Given the large number of food items identified for risk scoring in round 2, we asked experts to provide preventive control recommendations for only the main food sectors and to note any additional controls that might be needed for a subcategory.

Data analysis

We used STATA to perform descriptive univariate analysis as well as factor analysis on the data collected. We used STATA’s *factor*, *greigen*, *rotate*, and *score* functions for factor analysis, a data reduction technique that reduces the number of variables used in an analysis by creating new variables (called factors) that combine redundancy in the data. A factor analysis looks for correlations among the variables, and the first step is to determine the number of relevant factors. Although STATA’s algorithms used to solve factor analyses include methods of determining an appropriate number of factors, it is also possible to specify (fix) the number of factors in the analysis. For this study, we both allowed the algorithms to determine the number of factors and used judgment in determining the appropriate number of factors. The output from the factor analysis generates a table that relates each variable to each factor and assigns a numerical value between -1 and 1 to each relationship. The numerical values, referred to as factor loadings, reflect the strength of the relationship between the

TABLE 2. Ranking of food safety problems by number of votes across all food sectors

Food Safety Problem	Votes	
	Number	Percentage
Deficient employee training	15	(94%)
Contamination of raw materials	12	(75%)
Poor plant and equipment sanitation	12	(75%)
Poor plant design and construction	12	(75%)
No preventive maintenance	11	(69%)
Difficult-to-clean equipment	10	(63%)
Post-process contamination at manufacturing plant	10	(63%)
Contamination during processing	9	(56%)
Poor employee hygiene	9	(56%)
Incorrect labeling or packaging	7	(44%)
Contamination by reworked product	5	(31%)
Inadequate cooling	5	(31%)
Biofilms	4	(25%)
Lack of equipment knowledge	4	(25%)
Poor pest control	4	(25%)
Stagnant water due to dead ends in plumbing	4	(25%)
Condensate on pipes and other equipment	3	(19%)
Lack of crisis management protocol	3	(19%)
Lack of knowledge of welding standards	2	(13%)
Lack of product recovery protocol	2	(13%)
Lack of allergen control programs	1	(6%)
Lack of equipment parts reconciliation after repairs	1	(6%)
Use of unpotable water	1	(6%)

factors and the variables. Variables that are closely related to one another should all load highly on the same factor.

The method allowed us to generate an overall risk score that combines the information in all of the ten problems, as well as four factor risk scores by sector.

RESULTS

Descriptive analysis

Analysis of Round 1 data shows that “refrigerated products” is the one sector to which the majority of food safety problems are applicable. Additionally, although some problems, such as “deficient employee training,” “poor plant and equipment sanitation,” “contamination of raw materials,” and “poor plant design and

construction,” are applicable to all food sectors, other problems, such as “biofilms” and “condensate on pipes and other equipment,” are more sector-specific. The relative importance of a given food safety problem (measured by the number of votes received) varies from sector to sector. However, we find that those problems with broad applicability across all sectors (“deficient employee training,” “contamination of raw materials,” “poor plant and equipment sanitation,” and “poor plant design and construction”) also rank highest in the top-ten food safety problems list (Table 2).

Examination of Round 2 responses shows that the number of food items selected across the food sectors for scoring in the subsequent round is lowest for shelf-stable foods. The refrigerated, fro-

zen, and dairy sectors have the highest number of food items selected. Overall, given the different areas of expertise of individual panel members, a large number of food items within each food sector were identified as meriting a separate risk score. The total number of categories for the panel members to score (for “general” as well as “allergen” risks) by facility size ranges from 70 to over 100 across the ten food safety problems, substantially increasing the respondent burden in the third round.

The risk score data in Round 3 shows that small and medium-sized facilities tend to have higher general and allergen risk scores than large facilities across all problems and food sectors. The food safety problems with the highest general risk scores include “deficient employee train-

TABLE 3. Overall risk scores and factor risk scores by sector, general risk category

Risk Factors	Baked Goods	Dairy	Food Sectors Frozen	Refrigerated	Shelf-Stable
Overall risk	-0.058	0.837	0.232	1.098	-0.513
Process-related contamination [a]	-0.376	0.665	0.128	0.518	-0.249
Equipment [b]	-0.084	0.254	0.259	0.848	-0.375
Quality control [c]	-0.037	0.670	-0.087	0.182	-0.102
Input-related contamination [d]	0.542	0.078	0.206	0.668	-0.333

[a] The process-related contamination risk factor loads highly on “contamination during processing,” “contamination of raw materials,” and “poor employee hygiene.” [b] The equipment risk factor loads highly on “poor plant design and construction,” “difficult-to-clean equipment,” and “poor plant and equipment sanitation.” [c] The quality control risk factor loads highly on “post-process contamination at plant,” “no preventative maintenance,” and “deficient employee training.” [d] The input-related contamination risk factor loads highly on “poor employee hygiene,” “difficult-to-clean equipment,” and “contamination of raw materials.”

ing,” “poor plant and equipment sanitation,” “difficult-to-clean equipment,” “poor employee hygiene,” and “contamination of raw materials.” The majority of these problems have also been identified as having broad applicability across sectors in the initial Delphi round. The problems with the highest allergen scores are “incorrect labeling or packaging,” followed by “deficient employee training” and “difficult-to-clean equipment.”

Factor analysis

Given the degree of overlap among various food safety problems, we expect that some underlying factors (i.e., root causes), which are smaller than the number of variables (i.e., number of food safety problems), are mainly responsible for the covariance among our variables. Therefore, we performed a factor analysis to determine the number of underlying dimensions in the risk score data collected. For the analysis, we separated the general risk scores from the allergen risk scores. Next, for each of the ten risk problems, we calculated an average risk score for each food item, taking the average of the experts’ scores. This reduced the data to fewer observations for both the general and allergen risk categories, with a total of ten variables (i.e., the average risk scores for each problem). We then performed a factor analysis on these two datasets (general and allergen risks) to determine how the information contained in the ten risk problems could be combined to provide summary information.

One-factor analysis allowed us to generate an overall risk score that com-

bined the information in all ten problems. Next, we performed a second set of factor analyses and determined that both general and allergen risks are best described by a four-factor model. That is, the ten variables can best be described by four underlying factors. This does not imply that each variable is assigned to a specific factor. Variables can (and will) be related to more than one factor. The four factors, differed slightly however, between the general and allergen categories. We named the four factors in the general category (1) process-related contamination risk, (2) equipment risk, (3) quality control risk, and (4) input-related risk. Similarly, the four factors in the allergen category were named (1) in-process contamination risk, (2) quality control risk, (3) other contamination risk, and (4) equipment risk. The names of factors were derived from those variables that contributed the most to the factor values and were subjective. For example, the “process-related contamination risk” factor got its name from the fact that the variables that contribute the most to it were “contamination during processing,” “contamination of raw materials,” and “poor employee hygiene.”

Tables 3 and 4 summarize the factor analysis results for general and allergen risk score data, respectively. One way to see the information in Tables 3 and 4 is as two sets of risk summaries. The four factors aggregate the information from the ten risk problems to four summary measures, whereas the overall risk factor summarizes the four risk factors, or the ten risk problems, into one measure for each

sector. The data on the ten risk problems generate a broad picture of the problems in each sector. The one- and four-factor models, however, account for correlations among the ten risk problem scores to generate summary measures.

As far as general food safety risks are concerned (Table 3), the study shows that the refrigerated products sector has the highest overall risk (1.098), followed by the dairy products sector (0.837). The shelf-stable and baked goods sectors, on the other hand, pose lower than average general food safety risks. Process-related contamination and quality control risks are highest in the dairy products sector, whereas equipment and input-related contamination risks are elevated in the refrigerated products sector. When allergen risks are considered (Table 4), refrigerated products have the highest overall risk (0.975) followed by baked goods (0.707). Further, the in-process contamination and equipment risks are the highest in the refrigerated products sector. Baked goods and frozen products sectors pose the highest risk with respect to quality control and other contamination, respectively.

Analysis of expert panel responses to the second part of Round 3 reveals that there is a range of preventive controls that could effectively address most of the food safety problems faced by the food processing industry today. Although the list of preventive controls recommended to address each food safety problem is extensive, some of the recurring themes across all sectors and food safety problems include:

TABLE 4. Overall risk scores and factor risk scores by sector, allergen risk category

Risk Factors	Baked Goods	Dairy	Food Sectors Frozen	Refrigerated	Shelf-Stable
Overall risk	0.707	0.107	0.453	0.975	-0.527
In-process contamination [a]	0.197	-0.102	0.250	0.551	-0.261
Quality control [b]	0.434	0.391	0.228	0.364	-0.269
Other contamination [c]	-0.007	0.017	0.301	0.272	-0.184
Equipment [d]	0.470	-0.005	0.222	0.756	-0.351

[a] The in-process risk factor loads very highly on “contamination during processing,” and moderately high on “incorrect labeling or packaging.” [b] The quality control risk factor loads highly on “no preventative maintenance,” “deficient employee training,” and “post-process contamination at plant.” [c] The other contamination risk factor loads highly on “contamination or raw materials” and “poor employee hygiene.” [d] The equipment risk factor loads highly on “poor plant design and construction,” “poor plant and equipment sanitation,” and “difficult-to-clean equipment.”

- *Training* - Ongoing and targeted training on issues such as allergen control, cleaning and sanitation procedures, incoming ingredient receipt protocol, and monitoring; training of employees, management, and suppliers,
- *Audits* - Periodic audits and inspections of facility and raw material suppliers, either in-house or by third-party firms,
- *Documentation* - Documentation of training activities, raw material handling policies and activities, cleaning and sanitation, receiving records, and use of sign-off logs, and
- *Validation/evaluation* - Evaluation of training effectiveness and establishment of accountability; validation of cleaning through testing (e.g., swabs, organoleptic evaluations, and bioluminescence tests).

Other commonly noted problem-specific preventive controls were:

- Supplier audits and supplier certification programs for “raw material contamination” problems,
- Plant design reconfiguration and use of outside consultants for plant design, better sanitation, and improved flow and access to equipment for “poor plant design and construction” problems,
- Sanitation standard operating procedures (SSOPs) and environmental sampling and other monitoring for “difficult-to-clean equipment” problems,
- Use of preventive maintenance programs and documentation for deficiencies in preventive maintenance and assignment of accountability for “contamination during processing” problems,
- Environmental sampling, proper implementation of SSOPs, institution of HACCP, and product and process flow controls for “post-process contamination problems,” and
- Label review and verification for “incorrect labeling or packaging” problems.

DISCUSSION

The study provides a global perspective on safety problems in the food manufacturing industry as well as information on the relative importance of these problems across various food sectors and firm sizes. Our findings indicate that the following are the top ten problems faced by food manufacturers today, in order of decreasing importance:

- Deficient employee training
- Contamination of raw materials
- Poor plant and equipment sanitation
- Poor plant design and construction
- No preventive maintenance,
- Difficult to clean equipment
- Post-process contamination at manufacturing plant
- Contamination during processing
- Poor employee hygiene
- Incorrect labeling and packaging.

Not surprisingly, these are also the most frequently mentioned problems in the food safety literature.

Although refrigerated and dairy foods have the highest general risk of food safety problems compared to other food categories, baked and refrigerated foods pose the highest risk in terms of allergen hazards. Additionally, the study shows that the extent of these problems at small and medium-sized manufacturers likely varies from that at larger processors, with smaller facilities generating higher general and allergen risk scores than large facilities across all food safety problems and sectors.

The expert panel agrees that the majority of food safety problems identified could be addressed with better training of employees; regular third-party or in-house audits of food facility operations; improved recordkeeping, especially documentation of training activities, HACCP, and SSOPs; and validation/evaluation of activities such as cleaning and training effectiveness. Although the risk scores vary by food sector and facility size, the study shows that the preventive controls for addressing the food safety problems do not.

The study findings may have implications for food policy in general. As regulators are increasingly embracing a more risk-based approach to setting priorities and allocating resources for food safety, the results of this study can help focus their efforts. For example, results from the study indicate that training is a key component of preventing foodborne hazards in food processing plants. One area that

policymakers may therefore want to explore further is the role of government in improving employee training.

Our findings may also aid food processors in prioritizing their in-plant food safety initiatives. The study helps clarify which food safety problems are most likely to occur in food processing plants, taking into account sector-specific challenges. This ranking can help food processors understand what processes in their plant pose the greatest risk in terms of food contamination. Furthermore, the study provides information on the most effective preventive controls available to increase the safety of the food that they produce. Given the limited budgets of food processors, these data might help them to determine where they should focus their spending to ensure that the foods that they produce are safe.

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