SECTION FOUR

COMMON FOOD SAFETY PROBLEMS IN THE U.S. FOOD PROCESSING INDUSTRY: A DELPHI STUDY

To improve understanding of the current state of food safety hazards at food processing facilities, ERG conducted an expert elicitation. The study had two primary objectives:

(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 and/or corrective actions that food manufacturers should implement to address each of the problems identified.

Such information helps identify those sectors where the processor-level problems are of high importance for public health. Further, the information on the effectiveness of preventive controls may help identify the most effective GMP requirements.

4.1 Methodology

The study objectives posited above require gathering current data not accurately known or available. Moreover, they do not easily lend themselves to more precise analytical techniques, such as an industry survey designed to yield statistically valid estimates of population parameters. The necessary information, however, can be gathered using the subjective judgments of experts on a collective basis (Linstone and Turoff, 2002). Thus, this study uses a modified three-round Delphi technique widely applied in the forecasting and policy arenas.

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. Thus, with guidance from the CFSAN Working Group, ERG 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 (see Table 4-1).[1] On average, each individual panel member

[1] Although our original expert panel had 17 members, we only received responses to all three Delphi rounds from 15 individuals.

possessed over 30 years of food industry experience in various sectors, such as canned foods, fresh produce, meat and poultry products, and seafood. Further, most of these individuals have served and/or are currently serving on numerous national committees related to food safety, HACCP, and GMPs.

4.2 Results

Like most Delphi studies, our study consisted of three Delphi rounds in which the collective responses of the panel were revealed to each individual prior to the commencement of the next round. The following sections summarize the findings from each of the Delphi rounds, highlighting key findings. As a modified fourth round, ERG and FDA also conducted two post-study discussions with select experts from the panel to review the findings of the study and obtain recommendations for the effort to modernize food GMPs. Section 4.2.4 summarizes the results from these discussions.

4.2.1 Round 1 Results

In the initial Delphi round, we provided our expert panel with a list of food safety problems previously identified through our literature review and through discussions with the FDA Food GMP Modernization Working Group and select expert panel members. We then asked each panel member (1) to indicate the food sectors to which the listed problem is mainly applicable and (2) to add to the food safety problem list if necessary. Only one individual expanded our list of food safety problems, adding "lack of chemical control programs" and "lack of allergen control programs." This lends support to the comprehensiveness of our original food safety problem list. Other main findings (see Table 4-2) based on the tabulation of responses to this question (Q1) include the following:

- Refrigerated and meat and poultry products are the two main sectors to which the majority of the food safety problems are applicable.
- While 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," "condensate on pipes and other equipment," and "stagnant water due to dead ends in plumbing," are more sector-specific. For example, biofilms are more of a concern for the refrigerated, frozen, and dairy sectors.
- The relative importance of a given food safety problem (measured by the number of votes received) varies by sector. The top-rated food safety problems by sector include (see Table 4-2, highlighted cells):

- "Incorrect labeling or packaging" and "poor plant and equipment sanitation" for baked goods;
- "Deficient employee training" and "biofilms" for dairy products;
- "Deficient employee training" and "poor plant and equipment sanitation" for frozen products;
- "Deficient employee training" and "condensate on pipes and other equipment" for refrigerated products;
- "Poor plant and equipment sanitation" for shelf-stable foods;
- "Poor plant and equipment sanitation" for meat and poultry products.

In this round, we also asked experts to select from the list provided (Q2) the ten most important food safety problems facing food manufacturers today based on the frequency and severity of the problems. Experts were directed not to include those problems that (1) are solely applicable to meat and poultry or (2) might be applicable to other food categories but whose importance is mainly driven by their frequency and severity in meat and poultry. Table 4-3 presents the ranking of food safety problems by number of votes. Interestingly, those problems identified as having broad applicability across all food sectors (i.e., "deficient employee training," "contamination of raw materials," "poor plant and equipment sanitation," and "poor plant design and construction") in the previous question ranked at the top of our top ten food safety problems list. The finding affirms, at least partially, the internal validity of our Delphi design.[2]

4.2.2 Round 2 Results

The objective of the second Delphi round (Q3) was to determine whether each of the top ten problems identified in the previous round 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 the risk for the major food category as a whole.[3] Thus, we asked the expert panel members 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 and also make it possible to use related data, such as unit

[2] Note that the initial question asks the respondent to evaluate the food safety problem according to one dimension, "applicability," within each food sector. The second question, however, asks the respondent to consider the food safety problem with regards to two dimensions, "frequency" and "severity."

sales, we included a list of IRI product categories for each food sector from which experts were asked to select.[4] An all-capture subcategory titled "All other" was also included within each food sector to ensure comprehensiveness.

Table 4-4 provides the list of food items (by food sector and food safety problem) that the panel members indicated as requiring separate risk scores. Overall, the number of food subsectors selected across the food sectors was lowest for shelf-stable foods. The refrigerated, frozen, and dairy sectors, however, had the highest number of subsectors selected for scoring in the next round. Overall, given the different areas of expertise of individual panel members, the number of food items (i.e., subsectors) within each food sector identified as meriting a separate risk score was extensive. The total number of categories for the panel members to score for "general" as well as "allergen" risks by facility size ranged from 70 to over 100 across the ten food safety problems. This substantially increased the respondent burden in the subsequent round.

4.2.3 Round 3 Results

The primary objectives of the third Delphi round were (1) to assess the risk posed by each of the top ten food safety problems by food sector and facility size and (2) to determine the types of preventive controls and/or corrective actions necessary to address each of these problems by food sector and facility size. Therefore, we asked our expert panel members to assign a "general" as well as an "allergen" risk score from 1 to 4 based on the problem's frequency and severity by food sector and facility size (Q4). We further instructed our panel that:

- The "general" risk score assigned should reflect the risk of the food safety problem with respect to all hazards (i.e., microbiological, physical, and chemical) *except* for allergens
- The "allergen" score should reflect the risk of the food safety problem with respect to allergens *only*.

[3] The need for this round was determined during the study pilot, in which some experts indicated that certain subsectors within each main food sector (baked goods, dairy, frozen, etc.) merit different risk scores.

[4] "IRI" refers to the InfoScan® Custom Store Tracking database provided by Information Resources, Inc. (IRI). The database consists of scanner data collected weekly from more than 32,000 supermarket, drug, and mass merchandiser outlets across the United States and is current as of January 2, 2000—the version available to FDA under its contract with IRI at the time this study was conducted. The database provides detailed information on average unit prices, sales volumes, and other measures at the product, brand, and Universal Product Code (UPC) levels.

To ensure consistency of responses, we requested that risk scores be assigned according to the scheme outlined in Table 4-5 below. Thus, each individual expert first had to assess whether the problem occurred at a high or low frequency in the specified food sector (i.e., how widespread the problem is) and then to evaluate whether the probability that food could be rendered unsafe due to the problem was high or low (i.e., assess the severity of potential consequences of the problem) given the typical practices of a manufacturer that experiences the problem. We also directed the panel members to skip those categories to which they thought the food safety problem did not apply or that were not relevant to "general" or "allergen" hazards.[5]

Table 4-5: Risk Scoring Grid

	Severity	
Frequency	**High**	**Low**
High	4	2
Low	3	1

Because of the number of food sectors that individuals had to score, data generated from this question were voluminous (over 77,000 observations). A cursory analysis of the risk score data leads to the following observations:

- Overall, the general and allergen risk scores for small and medium-sized facilities are higher than those of large ones across all problems and food sectors.
- Problems that have received the highest general risk scores (2.75 or higher) include "deficient employee training," "poor plant and equipment sanitation," "difficult-to-clean equipment," "poor employee hygiene," and "contamination of raw materials." The majority of these problems also have been identified as having broad applicability across sectors in the initial round.
- The problems that have received the highest allergen scores are "incorrect labeling or packaging," followed by "deficient employee training," and "difficult-to-clean equipment."

[5] This, in effect, results in censored score data, which might be analyzed using applicable econometric methods, such as Tobit.

- The general risk scores assigned to the refrigerated food categories tend to be higher than those of other food categories across all problems. The next highest general risk scores are assigned to frozen and dairy food categories.

Given the degree of overlap among various food safety problems, we expect that some underlying factors, which are smaller than the number of variables, are mainly responsible for the covariance among our variables. Therefore, we performed an exploratory factor analysis to determine how many underlying dimensions there are for the risk score data collected. In a nutshell, factor analysis enables one to detect structure in the relationships between variables as a means of exploring the data for possible data reduction. The method also enables one to test specific hypotheses regarding the number of underlying dimensions and whether certain variables belong to a given dimension while others belong to another (Kim and Mueller, 1978). A more detailed discussion of factor analysis can be found in Appendix D.

In performing the factor analysis, ERG 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 subsector, taking the average over the experts' scores. This reduced the data to 396 observations (subsectors) for both the general and allergen risk categories, with a total of ten variables (i.e., the average risk scores for each problem). ERG 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.

The factor analysis technique allows us to generate an overall risk score that combines the information in all of the ten problems. The mean values by sector for overall risk are presented in Tables 4-6 and 4-7. The mean for all sectors (and subsectors) is centered at zero. Thus, stratifying the average by sector provides an indication of the relative risk of these sectors. A value that exceeds zero indicates that overall risk in the relevant sector is greater than average risk.

The overall risk score reflects the results from using a one-factor analysis model. That is, we calculated the relationship between all of the variables and one underlying factor that we call "overall risk." Factor analysis can also separate the variables into more than one factor. ERG performed a set of preliminary 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.[6] The four factors,

[6] This does not imply that each variable is assigned to specific factor. Variables can (and will) be related to more than one factor.

however, differ slightly between the general and allergen categories. We named the four factors in the general category as:

- Process-related contamination risk,
- Equipment risk,
- Quality control risk, and
- Input-related risk.

The four factors in the allergen category were named:

- In-process contamination risk,
- Quality control risk,
- Other contamination risk, and
- Equipment risk.

The names of factors are derived from those variables that contribute the most to the factor values.[7] For example, the "process-related contamination risk" factor gets its name from the fact that the variables that contribute the most to it are "contamination during processing," "contamination of raw materials," and "poor employee hygiene." The average scores by sector are presented in Tables 4-6 and 4-7 for each of the four factors. Once again, values that exceed zero indicate above-average risk.

For comparison's sake, we have also generated the average scores (in standardized form) for each of the ten risk problems presented to the experts by sector. These are presented in Tables 4-8 and 4-9. We present these as standardized values (i.e., mean centered and zero with a standard deviation of one) to be comparable to the values presented in Tables 4-6 and 4-7.[8] Once again, values that exceed zero indicate above-average risk.

One way to see the information in Tables 4-6 to 4-9 is as three sets of summaries of risk. The least aggregated form is that of the standardized average scores presented in Tables 4-8 and 4-9 for the ten

[7] The name of a factor is subjective.

[8] Factor analysis uses and generates standardized values.

risk problems. The four factors presented in Tables 4-6 and 4-7 aggregate the information from the ten risk problems to four summary measures. Finally, 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.

After the assignment of risk scores, we asked our expert panel to consider the types of preventive controls and/or corrective actions that food processors need to address each of the ten food safety problems by facility size (Q5).[9] While large food processors might have the capital to invest in more sophisticated technologies, small processors are likely to face resource constraints, making such technologies infeasible. Therefore, we instructed our experts to take account of cost-effectiveness when making recommendations on the types of controls/actions by size of food processor and main food sector (i.e., baked goods, dairy, frozen, refrigerated, and shelf-stable).[10]

Although the experts interviewed for the pilot indicated the need for size-specific preventive controls, a review of responses indicates that the majority did not, in fact, differentiate by facility size in their preventive control recommendations. Some even explicitly noted that facility size should not be a factor. Additionally, for some problems, experts did not feel that it was important to differentiate by food sector, hence applying the same set of preventive controls to all major food sectors for the problem in question. A minority of experts assigned different preventive controls to a minority of food subsectors.

Table 4-10 provides the complete set of preventive control recommendations for the top four food safety problems with broad applicability across all food sectors, mainly "deficient employee training," "contamination of raw materials," "poor plant and equipment sanitation," and "poor plant design and construction." Some of the recurring themes from the table are:

- 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,

[9] Although the terminology "corrective actions" was included in input received during the study pilot, none of the recommendations fell into this category.

[10] Given the large number of food subsectors identified for risk scoring in round 2, we only asked experts to provide preventive control recommendations for the main food sectors and note any additional controls that might be needed for a subcategory, if any.

- Evaluation of training effectiveness and establishment of accountability,
- Validation of cleaning through testing (e.g., swabs, organoleptic evaluations, and bioluminescence tests),
- Periodic audits and inspections of facility and raw material suppliers either in-house or by third-party firms, and
- Documentation of training activities, raw material handling policies and activities, cleaning and sanitation, receiving records, and use of sign-off logs.

Tables 4-11 through 4-12 present the preventive control recommendations for the remaining six food safety problems, "contamination during processing," "poor employee hygiene," "difficult-to-clean equipment," "post-process contamination at manufacturing plant," "incorrect labeling and packaging," and "no preventive maintenance." Interestingly, for majority of these problems, some experts indicated implementing GMPs and/or HACCP. The finding indicates that there are two dimensions to some of the processor-level problems, such as "contamination during processing," "poor employee hygiene," and "difficult-to-clean equipment." Food safety hazards may arise due to the lack of GMPs (i.e., plain noncompliance), through ineffective application of GMPs (i.e., deficient employee training programs), or through a combination of both.

Some experts also indicated a need for clearly defined GMP expectations for such problems as "incorrect labeling and packaging," "poor plant design and construction," and "no preventive maintenance." Ambiguities in the definitions in the food GMPs may lead to ill-defined expectations at the processor level. The same issue was also brought up during our discussions with select experts during the study pilot, as well as post-study discussions.

Across the ten food safety problems, the most frequently mentioned preventive controls include training (in-house or by outside consultants) and third-party or in-house audits of GMPs, HACCP, SSOPs, and quality programs, and implementation of HACCP and SSOPs (see Table 4-13). 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,

- 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.

As noted previously, institution of certain types of records, such as training activities, raw material handling policies and activities, cleaning and sanitation, and receiving records, is one of the recurring themes in the preventive control recommendations of experts. Table 4-14 presents the frequency of the various types of records recommended as preventive controls. As the table shows, the most frequently mentioned record types include cleaning and sanitation related records (87 percent) and equipment maintenance records (73 percent), followed by supplier audit records (67 percent) and personnel records (60 percent). Other types of records indicated by some experts as preventive controls include raw material/ingredient records, labeling and packaging records, warehousing/inventory/storage records, and corrective action documentation.

4.2.4 Post-Study Discussions with Select Experts

To review the findings of the Delphi study and discuss suggestions for improvements with respect to food GMPs, ERG and FDA conducted two post-study meetings with four experts from the panel. The meetings were held on May 5th and May 26th, 2004, at FDA's Center for Food Safety and Applied Nutrition in College Park, Maryland.

Charlie Cook and Cameron Hackney were the food safety experts invited to the May 5th meeting. Cook is an independent consultant who has served in the food industry for 55 years. Throughout these years in the food industry, he has directed product and process development, quality management, regulatory compliance, food safety, and product crisis activities. Hackney is Dean of the Davis College of Agriculture, Forestry, and Consumer Sciences at West Virginia University and has extensive experience in food microbiology, dairy processing, and food toxicology.

C. Dee Clingman and Donn Ward were the food safety experts invited to the May 26th meeting. Clingman is President of CDC Global Quality and Safety and was the Vice President of Quality Assurance of Darden Restaurants for 21 years. Ward is the Associate Head of the Science Department at North Carolina State University and has served in various organizations striving for improvements in food safety, including the Seafood HACCP Alliance Curriculum Development Committee and the NSF International Food Safety Advisory Council.

While many issues relevant to food GMPs were covered during the two meetings, some main themes emerged from these discussions. Most experts agreed that the food GMP modernization effort should not be sector-specific and should be focused on addressing a few important issues. These included the following:

- Improved, documented training with a minimum set of universal requirements,
- Recordkeeping in a few important areas, especially process control,
- Allergen control, with documented allergen control programs, including training and label review,
- Use of a guidance document to achieve compliance,
- Adding components of HACCP, such as controls, verification, and corrective action, and
- Positive incentive programs to encourage compliance.

These topics, as well as other points that were raised during the meetings, are discussed in detail below.

Training. The most frequently discussed topic during both meetings was training. All experts thought that training should be improved at food facilities. Most also concurred that training tends to be worse at small facilities. Nonetheless, Clingman noted management at large facilities are under the impression that there is nothing new to learn, which is problematic as well. Opinion on the length and frequency of training varied, but experts agreed that it should be tailored to the job of the employee. Cook suggested a one-time training session of 6 to 8 hours and 20 minutes of continuous training on a weekly basis. Hackney considered 2 days of training sufficient. Other specific recommendations for training mentioned by several experts included:

- Developing a minimum set of requirements (e.g., Ward mentioned identifying the important areas for training, those that have a direct impact on food safety) without being overly prescriptive or trying to differentiate by sector,

- Requiring documentation that shows that training took place,
- Requiring trainer certification,
- Requiring written SOPs for training (for consistency and inspection purposes), and
- Requiring training in allergens (only mentioned during first meeting).

Although some of the experts recommended manager training, Cook felt that top-level management would not have the time to commit to training. Cook emphasized that training needs to be highly visual, live, and ongoing. Clingman also mentioned the effectiveness of pocket-sized 3x5 cards in training, which can serve as constant reminders of key principles. While experts noted that these are effective methods, the consensus was that training should be adapted to the needs of each company and left to the manufacturer to customize. For example, Clingman noted that small plants would require different training from large plants. Certification of training programs by FDA was also mentioned as a possible option during the first meeting.

Recordkeeping. Another theme at both meetings was the importance of recordkeeping. Experts agreed that records are important in ensuring food safety outcomes, especially with respect to ensuring that the documented activities actually took place. These records include SOPs and documentation that SOPs were followed. Ward also noted the importance of SOPs in ensuring consistency of training.

Cook mentioned the importance of risk-based records. In his experience, when plants are overwhelmed by paperwork, they are more likely to fabricate records. He added that while SOPs are needed, they should not be punitive. In other words, firms should not be fined if they do not adhere to SOPs exactly as written. He also noted that the most critical records are process control records (e.g., water temperature).

Clingman mentioned the importance of records that are produced at the time of the activity versus those created after the activity has taken place. He noted that such post-activity records are not effective for ensuring that the activity occurs as intended.

Allergen control. Allergen training was discussed in detail in the first meeting. Cook and Hackney agreed that allergens are a very important issue and that training in this area is severely lacking. Records found to be critical for allergen control include label review records, letters of guarantee for raw materials, and a documented allergen control program, with training as the main component.

Both experts felt that a label review process would increase food safety, especially with respect to allergens. A requirement for a label review could be added to the processes and controls section of the food GMPs; it would detail how to match up the formula of the product to the ingredients stated on the label. Both experts emphasized that the label review process must be managed internally. According to Cook, medium to large plants currently conduct label reviews, whereas small plants typically do not. Hackney briefly discussed rework as another issue that should be addressed in GMPs with respect to allergen control.

Development of a guidance document. There was discussion at both meetings about the development of a guidance document to supplement and help explain the concepts in the food GMPs. Cook emphasized that manufacturers need clearly defined expectations, which the current food GMPs are lacking. These, he said, could be provided in a guidance document. Some experts would prefer a guidance document to a regulation because the former could provide detail not currently available in the food GMPs without becoming too prescriptive. Hackney used the example of the Seafood Hazard Guide (http://www.cfsan.fda.gov/~comm/haccp4.html) to show that some guidance documents are like regulations in their impact on manufacturer behavior. Creating a guidance document would not address the issue of enforceability, some meeting participants noted; others argued that a good guidance document might achieve a better food safety outcome with less resistance from industry. Cook suggested trying a guidance document first and then developing metrics based on the results, as he thinks there will be major resistance from industry to changing Part 110, especially with respect to recordkeeping.

Role of HACCP . HACCP was mentioned frequently by experts as being an effective way to ensure food safety. Cook and Clingman both noted that the increase in the use of HACCP in food manufacturing has increased because large, influential customers require it. Its role in the food GMP modernization effort is, however, debatable. A few experts liked the idea of a HACCP-based approach to food GMP modernization. During the May 26th meeting, Clingman and Ward suggested taking important pieces of HACCP and incorporating them into a new regulation. Clingman recommended taking the principles of controls, verification, and corrective action and renaming them as something other than

HACCP for the GMP modernization effort. Both Hackney and Cook noted that GMPs are needed as a base for HACCP, however, and that HACCP cannot substitute for GMPs.

Positive incentive programs. During the second meeting, Clingman brought up the concept of motivating food manufacturers with positive incentives to improve their practices beyond those dictated by GMPs. He recommended that FDA reward excellent performance instead of standard performance. As an example, he proposed allowing manufacturers to do self-audits after they have shown exemplary performance for a given period of time. FDA's own audits of such facilities could be reduced.

Clingman also suggested that FDA could certify an employee at a food manufacturing plant with a role in QA or food safety as an FDA inspector. This individual could then conduct official FDA inspections and provide documentation to FDA, and the plant could get reevaluated periodically for re-certification. Certified inspectors might be required to attend an annual meeting for continuing education and other updates. Eventually these individuals might be asked to conduct inspections in other food manufacturing facilities as well, once their reputation is well established. Along with these recommendations, Clingman also mentioned a similar program run by the National Marine Fisheries Services (NMFS) program for certifying seafood inspectors.

Other topics of discussion. Apart from the above, a few other topics were briefly addressed at these meetings. Pest management briefly came up at the end of the first meeting. Cook mentioned that manufacturers need to verify that their facilities are pest- and rodent-free and that this should be specified in a guidance document.

Internal audits and validation were brought up during discussions about recordkeeping in the first meeting. During the second meeting, audits were discussed in the context of providing a supervisory review. Section 4.2.4.1 provides the experts' recommendations on good examples of minimum standards.

During both meetings, the effectiveness of FDA inspections was discussed. Suggestions included training inspectors better and ensuring that the same training is provided to all. All experts noted that small manufacturers have more food safety problems than large manufacturers, with a few exceptions.

Given the difficulty of managing someone's personal hygiene, Clingman discussed solutions such as special soaps and gloves.

The issue of microbial testing was briefly raised during the second meeting. Ward commented that microbial testing would not be productive given the number of microbes and viruses that are of concern and the length of time it takes to obtain test results. He also noted that environmental sampling is conducted at large plants but generally not at small plants due to the expertise and financial investment required. Both Clingman and Ward agreed, however, that a plant that is visually clean generally does not require environmental testing. Ward commented that environmental testing usually verifies what you already suspect upon visual inspection. Clingman added that environmental testing is more relevant for certain food sectors than others.

Imports were raised as issues of concern by Clingman and Cook. No provision on how to modernize food GMPs to address this issue was discussed, however.

4.2.4.1 Additional Resources Recommended

A few experts recommend further reading for clarification and specifics on some of the topics discussed during the meetings. Most of these are described or available on the Internet, or were handed out during the meeting, as listed below:

Basic Standards:

- Supplier Food Safety Guidelines by C. Dee Clingman (handout at 5/26 meeting)

Training Requirements:

- Seafood HACCP
  http://www.cfsan.fda.gov/~lrd/fr951218.html
- Servsafe
  http://www.nraef.org/servsafe/?flag=lcd&level1_id=6&level2_id=1
- NSF International manual on food safety and quality expectations
  http://www.cookandthurber.com/2004_Expectations_Processing_Manual.pdf

Audits:

- NFPA internal audit document
  http://www.nfpa-safe.org/docs/NFPA-SAFE_Policies-and-Procedures-Manual.pdf
- Silliker third-party audits
  http://www.silliker.com/html/auditing_gmps.php

- Pizza Hut third-party audits

Allergen Control Programs:

- General Mills' and Kraft's SSOP documents for allergen control

4.2.4.2 Current Government Programs of Potential Interest

There are a number of existing government programs that FDA could study while preparing to modernize food GMPs. One type of program uses third party inspections, thus increasing the oversight of the governing body without incurring additional costs in most cases. An existing program of this nature is the FDA Center for Devices and Radiological Health Third Party Review Program. Under this program, FDA has accredited persons who are authorized to review 510(k)s—pre-market notifications for medical devices. Accredited persons conduct these reviews and forward them onto FDA, which makes a final determination on each application within 30 days. This program has been very successful, speeding up 510(k) reviews by 29 percent. The program has recently been extended to Class II medical devices. More information on the program can be found at http://www.fda.gov/cdrh/thirdparty/.

CDRH has also established a third-party inspection program, which allows accredited persons to inspect eligible manufacturers of Class I or II medical devices. The manufacturers must meet certain conditions in order to be inspected by an accredited person. More information on this program can be found at http://www.fda.gov/cdrh/ap-inspection/ap-inspection.html.

Positive incentive programs were mentioned by Clingman as a potential method for encouraging greater compliance. As noted earlier, NMFS runs one such program. The Occupational Safety and Health Administration (OSHA) also runs a positive incentive program, called the Voluntary Protection Program (VPP). Employers have to apply to the program and if they meet VPP requirements, they may join the program. Employers in the program are inspected regularly to ensure they continue to meet VPP requirements. The frequency of these inspections is reduced the longer the employer remains in the program, depending on which level of participation they have reached (Star, Merit, or Demonstration). Annual self-evaluations are required, the results of which are shared with OSHA. More information on the program can be found at http://www.osha.gov/dcsp/vpp/anniversary.html.

Similar programs are likely to be found at other government agencies. The ones noted above have shown great success and might be of special interest to FDA.

References

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Table 4-1: Expert Panel Members

Expert Name	Areas of Expertise
C. Dee Clingman	▪ Provides assistance with HACCP analysis, quality improvement, identifying hazards, and internal training ▪ Product inspection, product safety, sanitation training and certification, supplier inspections, and quality assurance audits for restaurants ▪ Registered Sanitarian ▪ President of CDC Global Quality & Safety
Peter Cocotas	▪ Developed HACCP plans for fast food restaurants, catering, meat, seafood, canned goods, fresh produce, beverages, and other products ▪ Certified as a third party auditor by the NFPA (National Food Processor's Association) SAFE Program ▪ Recognized as 3rd party auditor by Kroger, Albertson's, ConAgra, Campbell Soup, C.K.E. Enterprises, International Packaged Ice Association, Association of Food Industries, McDonald's, and others
Clifford M. Coles	▪ Contract testing and process assistance for major food companies ▪ Has several technical publications relating to microbiological and quality control issues in the food industry
Charles Cook	▪ 55 years in the food industry ▪ Directed product and process development, quality management, regulatory compliance, food safety, and product crisis activities ▪ Expert witness support in numerous food safety related litigation ▪ Chaired the AMI-HACCP Task Force ▪ Currently Adjunct Professor in the Department of Meat and Animal Science at the University of Wisconsin, Madison, Wisconsin
Cameron Ray Hackney	▪ Food microbiology, dairy processing, and food toxicology ▪ Chair of the National Academy of Sciences' Committee on Use of Scientific Criteria and Performance Standards for Safe Food ▪ Several publications on microbiology especially focusing on the seafood industry ▪ Dean of the Davis College of Agriculture, Forestry and Consumer Sciences, West Virginia University
John Manoush	▪ Low-acid canned foods, such as baked beans ▪ Provides customized training and technical assistance to food manufacturers implementing HACCP programs ▪ Assists in design of experiments, statistical process control, vendor and co-packer auditing, sanitation, and employee training ▪ Thoroughly knowledgeable in FDA GMPs, low-acid regulations, and AIB guidelines for sanitation and pest control ▪ 27 years as Manager of Quality and R&D for *B&M Baked Beans* ▪ Private consultant

Table 4-1: Expert Panel Members

Expert Name	Areas of Expertise
Nancy Nagle	▪ Specializes in produce food safety and good agricultural practices ▪ Provides expertise in Good Agricultural Practices, HACCP, and processing for the fresh produce industry ▪ Food Safety Advisor to the California Strawberry Commission ▪ Co-chair of the scientific task force that developed the "Voluntary Guidelines for Fresh Produce" for the Western Growers Association and the International Fresh-Cut Produce Association ▪ Adjunct professor and member of the Industry Advisory Committee for Chapman University, Food Science Department
Robert Price	▪ Extensive experience in implementing HACCP programs for the seafood industry ▪ Established the first successful statewide seafood technology program, the Seafood Technology Extension Program at the University of California Cooperative Extension at Davis ▪ Helped to implement the first set of federal food regulations geared specifically for the seafood industry; drafted the strategy for educating industry and inspectors on how to meet the new rules ▪ Led hundreds of workshops and training courses to educate consumers, industry workers, regulators and academics about seafood safety and safe seafood processing and handling techniques ▪ Created the Seafood Network Information Center (SeafoodNIC) at http://seafood.ucdavis.edu, a clearinghouse of information on seafood research, marketing, product development, news, and more that receives more than 6,300 hits a month from 40 countries
William Sanders	▪ 28 years of experience in the food industry devoted to technical management ▪ Development of quality control systems, training programs, and gap assessment processes ▪ Dry cereal, infant foods, frozen foods, low- and high-acid canned foods, milk, milk powders, acidified foods, pet foods, refrigerated foods, and beverages ▪ Currently Vice President of Quality Management and Regulatory Affairs at Nestle
Robert Savage	▪ Development of microbiological methods, QC sampling plans, thermal process schedules for low-acid canned foods, and troubleshooting microbiological problems ▪ While with FDA, active in the implementation of the first HACCP-based, low-acid canned food regulations, investigations of botulism outbreaks, product recalls and evaluations and audits of firms' compliance with FDA regulations both domestically and overseas ▪ Leading expert in thermal processing technology ▪ President, HACCP Consulting Group

Table 4-1: Expert Panel Members

Expert Name	Areas of Expertise
Tommy L. Shannon	▪ Over 40 years of food safety experience ▪ Led the development of process control, HACCP and auditing as proactive management processes for quality, food safety, and manufacturing reliability at Campbell Soup Company ▪ Recognized leader in HACCP development; worked with USDA, FDA, and various trade associations in HACCP protocol development and implementation ▪ Participated in HACCP Pilot Plant programs and in training programs for regulatory officials ▪ Retired as Vice President of Quality Assurance, Campbell Soup Company ▪ Owns a food safety and quality management consulting practice
William Sperber	▪ Over 30 years of experience in food microbiology ▪ Member of the National Advisory Committee on Microbiological Criteria for Foods ▪ Has worked with a number of other committees and associations in the field of food microbiology ▪ Industry advisor to the U.S. Delegation to the United Nations Codex Committee on Food Hygiene; member of the Conference for Food Protection, Council III; past chairman and executive committee member of the Food Microbiology Research Conference ▪ Senior Corporate Microbiologist at Cargill, Inc.
Richard Stier	▪ International experience in food safety (HACCP), food plant sanitation, quality systems, process optimization, GMP compliance, and food microbiology ▪ Canning, freezing, dehydration, deep-fat frying, aseptic systems, and seafood processing
Donn Ward	▪ Vice chair of the Seafood HACCP Alliance Curriculum Development Committee since 1995 ▪ From 1994 through 2000, vice chair of NSF International's Food Safety Advisory Council and from 1992 through 1998, member of the National Advisory Committee on Microbiological Criteria in Foods ▪ Served on the U.S. Delegation to Codex Alimentarius Commission's Food Hygiene Committee ▪ Associate Head of the Food Science Department, North Carolina State University
Edmund A. Zottola	▪ Extensive industry and consulting experience in food safety, food microbiology, microbial control in food processing, sanitation, GMPs, and HACCP ▪ Published over 100 research articles in refereed J=journals, as well as another 100 general interest publications including extension bulletins, pamphlets, fact sheets, and articles in trade journals ▪ Involved with HACCP since 1971, and with GMPs since 1972 ▪ Presented short courses and seminars on research topics given above, food safety, food regulations, HACCP and GMPs ▪ Professor emeritus, food microbiology, Department of Food Science and Nutrition, University of Minnesota ▪ President of Lansi Bay consulting company

Table 4-2: Summary of Q1 Responses: Applicability of Food Safety Problem by Sector

Food Safety Problem	Not a problem		Baked goods		Dairy		Frozen		Refrigerated		Shelf-Stable		Meat and poultry		Total # of Votes w/o Meat & Poultry
Poor plant design and construction	0	(0%)	10	(63%)	11	(69%)	12	(75%)	14	(88%)	8	(50%)	14	(88%)	55
Deficient employee training	0	(0%)	11	(69%)	13	(81%)	15	(94%)	15	(94%)	11	(69%)	14	(88%)	65
Poor employee hygiene	0	(0%)	10	(63%)	12	(75%)	13	(81%)	13	(81%)	7	(44%)	13	(81%)	55
Difficult-to-clean equipment	0	(0%)	8	(50%)	11	(69%)	10	(63%)	13	(81%)	8	(50%)	13	(81%)	50
No preventive maintenance	1	(6%)	9	(56%)	10	(63%)	10	(63%)	12	(75%)	9	(56%)	11	(69%)	50
Contamination of raw materials	0	(0%)	12	(75%)	11	(69%)	14	(88%)	14	(88%)	10	(63%)	14	(88%)	61
Contamination during processing	0	(0%)	9	(56%)	11	(69%)	13	(81%)	13	(81%)	10	(63%)	13	(81%)	56
Post-process contamination at manufacturing plant	0	(0%)	9	(56%)	10	(63%)	9	(56%)	13	(81%)	9	(56%)	13	(81%)	50
Contamination by reworked product	1	(6%)	6	(38%)	9	(56%)	7	(44%)	11	(69%)	6	(38%)	12	(75%)	39
Lack of equipment parts reconciliation after repairs	7	(44%)	7	(44%)	6	(38%)	7	(44%)	7	(44%)	7	(44%)	8	(50%)	34
Lack of crisis management protocol	3	(19%)	12	(75%)	12	(75%)	12	(75%)	12	(75%)	12	(75%)	12	(75%)	60
Lack of knowledge of welding standards	4	(25%)	2	(13%)	8	(50%)	4	(25%)	7	(44%)	5	(31%)	7	(44%)	26
Poor pest control	2	(13%)	11	(69%)	9	(56%)	10	(63%)	12	(75%)	10	(63%)	10	(63%)	52
Lack of equipment knowledge	2	(13%)	10	(63%)	9	(56%)	12	(75%)	11	(69%)	11	(69%)	9	(56%)	53
Inadequate cooling	0	(0%)	2	(13%)	10	(63%)	8	(50%)	13	(81%)	4	(25%)	11	(69%)	37
Biofilms	0	(0%)	4	(25%)	13	(81%)	10	(63%)	12	(75%)	6	(38%)	14	(88%)	45
Use of unpotable water	6	(38%)	6	(38%)	7	(44%)	5	(31%)	7	(44%)	6	(38%)	7	(44%)	31
Stagnant water due to dead ends in plumbing	1	(6%)	5	(31%)	12	(75%)	8	(50%)	11	(69%)	10	(63%)	9	(56%)	46
Condensate on pipes and other equipment	0	(0%)	7	(44%)	10	(63%)	11	(69%)	15	(94%)	6	(38%)	12	(75%)	49
Poor plant and equipment sanitation	0	(0%)	13	(81%)	12	(75%)	15	(94%)	14	(88%)	14	(88%)	15	(94%)	68
Inadequate glass cleanup policy	4	(25%)	7	(44%)	8	(50%)	8	(50%)	10	(63%)	11	(69%)	8	(50%)	44
Lack of product recovery protocol	3	(19%)	11	(69%)	10	(63%)	11	(69%)	11	(69%)	10	(63%)	11	(69%)	53
Incorrect labeling or packaging	1	(6%)	13	(81%)	9	(56%)	12	(75%)	13	(81%)	11	(69%)	10	(63%)	58
Lack of chemical control programs	0	(0%)	1	(6%)	1	(6%)	1	(6%)	1	(6%)	1	(6%)	1	(6%)	5
Lack of allergen control programs	0	(0%)	1	(6%)	1	(6%)	1	(6%)	1	(6%)	1	(6%)	1	(6%)	5
Total number of votes	**35**		**196**		**235**		**238**		**275**		**203**		**262**		**1,147**

Table 4-3: Number of Votes by Food Safety Problem

Food Safety Problem	Number of Votes	
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%)
Not selected	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%)

Table 4-4: Food Subsectors Identified for Risk Scoring by Food Safety Problem

		Food Safety Problem									
Food Sector	**Food Subsector**	**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 or Packaging**
Baked goods	Bakery snacks	1	1			1	1	1	1	1	1
	English muffins					1					
	Fresh bread and rolls	1		1		1	1				
	Pastry/donuts	1	1	1	1	1	1	1	1	1	
	Pies/cakes	1	1	1	1	1	1	1	1	1	1
	All other	1	1	1	1	1	1	1	1	1	1
Dairy	Butter	1			1						1
	Cheese	1	1	1	1	1	1	1	1	1	1
	Cottage cheese	1	1	1	1	1	1	1	1	1	1
	Creams/creamers	1	1	1	1	1	1	1	1		1
	Milk	1	1	1	1	1	1	1	1	1	1
	Sour cream	1		1	1	1	1	1	1		1
	Yogurt	1	1	1	1	1	1	1	1	1	1
	All other	1	1	1	1	1	1	1	1	1	1
Frozen	Frozen appetizers/snack rolls	1	1	1	1	1	1	1	1	1	1
	Frozen baked goods	1	1	1	1	1	1	1	1		1
	Frozen breakfast food	1	1	1	1	1	1	1	1		1
	Frozen coffee creamer	1	1	1	1	1	1	1	1		
	Frozen cookies	1	1	1	1	1	1	1	1		1
	Frozen corn on the cob				1	1					
	Frozen desserts/toppings	1	1	1		1	1		1	1	
	Frozen dinners/entrees	1	1	1	1	1	1	1	1	1	1
	Frozen dough	1	1	1	1	1	1	1	1		
	Frozen fruit	1	1	1	1	1	1	1	1		
	Frozen novelties	1	1	1	1	1	1	1	1	1	1
	Frozen pasta	1	1	1	1	1	1	1	1		
	Frozen pies	1	1		1	1	1	1	1	1	1
	Frozen pizza	1	1	1		1	1	1	1	1	1
	Frozen plain vegetables		1	1	1	1	1	1	1		
	Frozen pot pies	1	1	1	1	1	1	1	1	1	1
	Frozen potatoes/onions	1		1	1	1					
	Frozen prepared vegetables	1	1	1	1	1	1	1	1	1	
	Frozen seafood	1	1	1	1	1	1	1	1	1	1
	Frozen side dishes	1	1	1	1	1	1	1	1	1	1
	Ice cream/sherbet	1	1	1	1	1	1	1	1	1	1
	Frozen juices	1	1	1	1	1	1	1	1	1	

Table 4-4: Food Subsectors Identified for Risk Scoring by Food Safety Problem

		Food Safety Problem									
Food Sector	Food Subsector	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 or Packaging
Frozen (cont.)	All other	1	1	1	1	1	1	1	1	1	1
Refrigerated	Baked goods	1	1	1	1	1	1	1	1	1	1
	Cheesecakes	1	1	1	1	1	1	1	1	1	1
	Deli-salads	1	1	1	1	1	1	1	1	1	1
	Desserts	1	1	1		1	1	1	1	1	1
	Dough/biscuit dough	1	1	1	1	1	1	1	1	1	1
	Egg substitutes	1	1	1	1	1	1	1	1	1	1
	Entrée/side dishes	1	1	1	1	1	1	1	1	1	1
	Fresh cut fruits and vegetables	1	1	1	1	1	1	1	1	1	1
	Juice/beverage	1	1	1	1	1	1	1	1	1	1
	Juice/drink concentrate	1	1	1	1	1	1	1	1	1	1
	Lard	1	1	1	1	1		1	1		1
	Lunches	1	1	1	1	1	1	1	1	1	1
	Margarine/spreads/butter blend	1	1	1	1	1		1	1		1
	Pasta	1	1	1	1	1	1	1	1	1	1
	Pickles/relish	1	1	1	1	1	1	1	1	1	1
	Pizza	1	1	1	1	1	1	1	1	1	1
	Refrigerated dips	1	1	1	1	1	1	1	1	1	1
	Tortilla/eggroll/wonton wrap	1	1	1	1	1	1	1	1	1	1
	Salad dressing	1	1	1	1	1	1	1	1	1	1
	Seafood - packaged	1	1	1	1	1	1	1	1	1	1
	Seafood - unpackaged	1	1	1	1	1	1	1	1	1	1
	Spreads	1	1	1	1	1	1	1	1	1	1
	All other	1	1	1	1	1	1	1	1	1	1
Shelf-stable	Aseptic juices	1	1	1	1	1	1	1	1	1	
	Baked beans						1	1			
	Baking mixes		1	1	1	1		1	1		1
	Baking needs								1		1
	Baking nuts		1			1	1		1	1	1
	Bottled juices	1	1	1			1	1	1	1	
	Bottled water	1	1	1	1		1	1	1		
	Breadcrumbs/batters	1	1	1				1	1		
	Canned juices	1	1	1			1	1	1	1	
	Canned/bottled fruit	1		1			1	1		1	
	Caramel/taffy apple kits										
	Carbonated beverages									1	
	Chocolate candy		1	1	1	1	1	1	1		1

Table 4-4: Food Subsectors Identified for Risk Scoring by Food Safety Problem

		Food Safety Problem									
Food Sector	**Food Subsector**	**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 or Packaging**
Shelf-stable	Cocktail mixes									1	
(cont.)	Cocoa mixes		1					1	1	1	
	Coffee										
	Coffee creamer	1	1	1		1	1	1	1	1	1
	Cold cereal			1	1		1	1	1		1
	Cookies	1						1	1	1	1
	Crackers							1	1	1	
	Croutons	1						1	1	1	1
	Dessert toppings	1	1			1					1
	Dinners	1	1	1		1	1	1	1	1	1
	Dip	1	1	1		1	1	1	1	1	
	Dried fruit		1	1	1		1	1	1	1	1
	Drink mixes		1		1	1	1	1	1	1	
	Dry beans/vegetables		1	1				1			1
	Dry fruit snacks		1						1	1	1
	Evaporated/condensed milk	1		1	1	1	1	1			
	Flour/meal		1				1				
	Frosting		1						1		1
	Gelatin/pudding mixes			1			1	1	1		
	Gravy/sauce mixes	1	1	1	1	1	1	1			1
	Gum										
	Hot cereal										
	Ice cream cones/mixes	1	1		1						1
	Instant potatoes	1					1	1	1		
	Isotonics	1						1			
	Jellies/jams/honey		1	1	1	1			1		1
	Juice/drink concentrate		1		1	1				1	
	Marshmallows										
	Mayonnaise	1	1	1		1	1				
	Mexican foods	1		1	1	1	1	1	1		1
	Mexican sauce				1	1		1			
	Milk flavoring/drink mixes		1	1				1	1		1
	Mustard and ketchup										
	Non-chocolate candy			1							1
	Non-fruit drinks			1							
	Oriental food	1		1	1		1	1	1		1
	Pancake mixes					1			1		1

Table 4-4: Food Subsectors Identified for Risk Scoring by Food Safety Problem

		Food Safety Problem									
Food Sector	**Food Subsector**	**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 or Packaging**
	Pasta						1	1	1		
	Peanut butter		1						1		1
	Pickles/relish/olives				1					1	
	Pizza products	1	1			1	1	1	1		
	Popcorn/popcorn oil			1	1						
	Powdered milk	1	1	1	1	1	1	1	1	1	
	Rice		1								
	Rice/popcorn cakes		1						1	1	
	Salad dressings	1		1		1	1	1	1		1
	Salad toppings		1						1	1	
	Salty snacks										1
	Sauce	1	1			1	1	1			
	Seafood	1	1	1	1	1	1	1	1	1	1
	Shortening and oil			1	1						
	Snack bars/granola bars		1						1	1	1
	Snack nuts/seeds		1						1		1
	Soup	1		1	1		1	1			1
	Spaghetti/Italian sauce			1	1						
	Spices/seasonings		1	1					1		
	Stuffing mixes		1						1		
	Sugar										
	Sugar substitutes										
	Syrup/molasses										
	Tea bags/loose		1	1							
	Tea instant tea mixes		1					1	1		
	Tea ready-to-drink								1		
	Tomato products										
	Vegetables	1	1					1	1	1	
	Vinegar									1	
	Weight control/nutrition liquid/powder		1	1	1				1		1
	Weigh control candy/tablets			1					1		1
	All other	1	1		1	1	1	1	1	1	1

Note: “1” indicates that the sector has been selected for individual risk scoring by one or more experts.

Table 4-6: Overall Risk Scores and Factor Risk Scores By Sector, General Risk Category

Risk Factors	Food Sectors				
	Baked Goods	**Dairy**	**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."

Table 4-7: Overall Risk Scores and Factor Risk Scores By Sector, Allergen Risk Category

Risk Factors	Food Sectors				
	Baked Goods	**Dairy**	**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."

Table 4-8: Average Standardized Scores for the Ten Risk Problems By Sector, General Risk Category

Risk Problem	Food Sectors				
	Baked Goods	**Dairy**	**Frozen**	**Refrigerated**	**Shelf-Stable**
Poor plant design and construction	-0.218	0.608	0.239	1.041	-0.458
Deficient employee training	0.000	0.671	0.177	1.088	-0.479
Poor employee hygiene	0.460	0.474	0.128	1.134	-0.494
Difficult-to-clean equipment	0.458	0.756	0.394	1.021	-0.574
No preventive maintenance	0.068	0.783	0.147	0.579	-0.325
Contamination of raw materials	-0.415	0.660	0.218	0.849	-0.380
Contamination during processing	-0.268	0.900	0.188	0.865	-0.414
Post-process contamination at plant	-0.242	0.955	-0.152	0.483	-0.192
Poor plant and equipment sanitation	-0.266	0.731	0.315	1.027	-0.488
Incorrect labeling or packaging	-0.311	0.358	-0.071	0.900	-0.279

Note: The numbers reported in this table reflect standardized scores. ERG standardized the values for these variables to be consistent with the values reported for the factor analysis.

Table 4-9: Average Standardized Scores for the Ten Risk Problems By Sector, Allergen Risk Category

Risk Problem	Food Sectors				
	Baked Goods	**Dairy**	**Frozen**	**Refrigerated**	**Shelf-Stable**
Poor plant design and construction	0.214	0.165	0.245	1.173	-0.489
Deficient employee training	1.425	0.157	0.469	0.648	-0.493
Poor employee hygiene	0.181	0.337	0.204	0.773	-0.365
Difficult-to-clean equipment	0.984	-0.187	0.600	0.834	-0.520
No preventive maintenance	0.286	0.585	0.346	0.626	-0.399
Contamination of raw materials	0.042	-0.147	0.378	0.451	-0.252
Contamination during processing	0.365	-0.016	0.380	0.794	-0.404
Post-process contamination at plant	-0.260	-0.376	-0.180	0.528	-0.048
Poor plant and equipment sanitation	0.660	0.150	0.387	0.776	-0.443
Incorrect labeling or packaging	0.047	-0.222	0.107	0.567	-0.194

Note: The numbers reported in this table reflect standardized scores. ERG standardized the values for these variables to be consistent with the values reported for the factor analysis.

Table 4-10: List of Preventive Controls Recommended for the Top Four Food Safety Problems

Deficient Employee Training	Contamination of Raw Materials	Poor Plant and Equipment Sanitation	Poor Plant Design and Construction
3x5 pocket-sized cards to remind employees of a few vital hazards	Document all activities	Assign accountability for plant and equipment sanitation	A sanitary design control program
Conduct audits (in-house, by third party, of GMPs, or not specified	All transport carriers and warehouses should be inspected	Audit of outside cleaning companies	Better overall flow to prevent cross-contamination
Base training efforts on Vulnerability Assessment Report	Antibiotic testing	Awareness of new sanitation technologies such as ozone and chlorine dioxide	Better understanding of process flow concepts
Improve training on process control and pathogen monitoring	Self inspection (by department or individual)	County extension programs that offer consulting services	Building, construction, and equipment companies and engineers need to be trained in sanitary design criteria
Better use of chemical supplier expertise	Audit and inspection emphasis should be placed on offshore-sourced raw materials	Conduct cross-department inspections	Clearly defined expectations
Bilingual training (in-house or not specified)	Better controls on raw agricultural practices, e.g., foreign object control	Dedicated cleanup crew	Conduct audits (internal or third-party, GMP, of plant design, construction, and grounds, to correct deficiencies, twice a year, or not specified)
Conduct brief training sessions periodically	Better overall pest management	Develop SSOPs for all equipment	Consultants (use for advice or not specified)
Make use of county and IFT extension programs	Certificates of analysis/supplier guarantees	Documentation (of hygiene and sanitation activities, procedure, sign-offs on SSOPs, signed and verified records of activities, or not specified)	Contract out the fix, with firms that specialize in food plant design, or not specified
Develop in-house training programs (for new employees, using input from employees and QA team, or not specified)	Change suppliers if needed	Documented bilingual procedures	Control condensation
Develop monthly meetings with employees to train (short duration or not specified)	Clean/decontaminate raw materials when possible	Efficacy of sanitation process should be quantitatively measured by pre-op and op micro counts, organoleptic evaluations, by bioluminescence, swabs, or ATP)	Develop "Mr. Clean" attitude in personnel
Directed, work-area or product-specific training, with input from and approved by plant operations management	Color code according to risks	Use performance as criteria in employee review	Develop plant upgrades/expansion plans to reduce this problem
Hold discussion groups on training issues	Develop specifications for all products and make sure specs are achieved outside GMP audit at least yearly	Employee training	Develop priority list for areas needing revision and/or specific operational practices necessary due to design issues

Table 4-10: List of Preventive Controls Recommended for the Top Four Food Safety Problems

Deficient Employee Training	Contamination of Raw Materials	Poor Plant and Equipment Sanitation	Poor Plant Design and Construction
Documentation of training activities	Documented handling policies	Reduce employee turnover	Develop programs for short and long-term fixes
Use performance as criteria in employee review	Employee training on what to look for when receiving incoming ingredients	Environmental sampling (involving QC lab, daily sanitation tests, or not specified)	Develop understanding of GMPs in all employees including the boss; clean up plant so that it complies with GMPs
Employee mentoring programs (e.g., match employees with same language/ethnicity)	Ensure that the storage areas are clean and maintained appropriately	Formal sanitation program with clear-cut responsibilities defined	Evaluate design issues and potential effects on food safety
Evaluate effectiveness of training	Establish criteria for prevention of contamination of raw materials	GMP audits (internal or external, monthly or annually, or not specified)	Greater sanitation
Food safety reminders on paystubs and websites	FDA Website for recalls	Hand washing facilities in processing area (sensors or not specified)	Head of maintenance has had training in sanitary design
Food safety training of all new employees with minimum quarterly refresher	GMP audits (internal or external; of storage areas, monthly with response from management, or not specified)	Have personnel sign off when SSOPs completed	Implement programs designed to compensate for the design flaws, e.g., more frequent cleanup, more people on the line
Formal training policy	GMPs	Improved worker training	Improved flow and better/easier access to equipment
GMPs	Greater frequency of port inspection	In-house audits of sanitation	Inspection by certified third party
Good orientation programs	Implement programs within the plant to prevent contamination of products with materials from the outside of packaging.	In-house training (by outside consultants or not specified)	Limit condensation
HACCP	Improved monitoring of incoming raw materials	Interactive training	Limit downtime
Handwashing	Incoming inspection and approval programs	Keypad controls	Limit splash
Training in temperature control, monitoring equipment, hygiene, GMP, and overall food safety risk	Sampling and testing (in-house, more frequent, periodic, or not specified)	Make sure there is sufficient time to clean	Monthly meetings to discuss problems and how to make corrections, involving all personnel including management and maintenance
Improved thermal process focus	Metal detectors or filters (in bulk transfer operations or not specified)	Management commitment and involvement	New equipment if needed
Improved training on pathogen monitoring	Mandatory handwashing or glove use	More involvement by the chemical suppliers for training and education (e.g., teaching programs)	Obtain input from buyers and their QA/sanitation/food safety people

Table 4-10: List of Preventive Controls Recommended for the Top Four Food Safety Problems

Deficient Employee Training	Contamination of Raw Materials	Poor Plant and Equipment Sanitation	Poor Plant Design and Construction
Industry affiliation training programs	Multiple tanks for bulk liquids to ensure separation of lots	Ongoing cleaning (sweeping, etc.) during production operations	Owner/operator must address
In-house training (specific or general, by insurance carrier, consultant, or not specified)	Provide segregated storage (separate raw materials from finished products)	Outside training of personnel responsible for monitoring	Reconfigure, correct, repair, or fix problems
Use of broad range of training materials and learning aids, such as CD-ROM, online learning, equipment labeling, food safety icons	Review past audits of suppliers	More effective pathogen monitoring schemes and more pathogen monitoring	Relocate to a less risk area or move concerned area
Make training a part of supervisor's performance rating	Personal hygiene training (see training for detail)	Pay and other incentives for employees to practice good sanitation	Review by technically competent and experienced resource to identify problem areas and construction constraints
Management commitment/responsibility	Program for rotation and code tracking of raw materials	Improve definition of sanitation expectations and process: define "clean"	Sanitation records
Training on monitoring equipment	Proper cleaning and sanitizing of bulk carriers	Provide proper tools and supplies for adequate sanitation	Sign off on corrections
Seminars (monthly, by specialist from outside company, or not specified)	Proper in-house storage	Routine cleaning and sanitizing of refrigerators, coiling coils, and compressors	SSOPs
Use outside consultants who understand adult education	Purchasing of fresh produce from growers utilizing GAPs programs	Make sanitation a core corporate value	Stricter in-process controls can be used to help compensate
Ongoing verbal exampling and reinforcement of training concepts	Conduct random microbiological verification of lots	Signed and verified records	The sanitary design criteria must be implemented
Outside training courses	Raw material specifications (and product specifications appropriate to the product)	SSOPs (written, for each piece of processing equipment and processing areas, with signoff logs, or not specified)	Training
Posters and use of reminder icons in critical areas of plant	Maintain receiving records	Tech group training in auditing and evaluation of sanitation effectiveness	University extension services
Provision of learning aids, such as video and other visuals (NFPA and other professional organization video programs)	Sanitation at farms and milking operations	Employ technical staff	Use professionals on all redesigns
Training refresher courses	Separate or designated employees for tasks	Third-party auditing/training of tech and management group.	Weld (when possible or not specified)
Repetition in training of concepts taught	Separate personnel by job function (raw vs. processed)	Audits (third-party or in-house)	

Table 4-10: List of Preventive Controls Recommended for the Top Four Food Safety Problems

Deficient Employee Training	Contamination of Raw Materials	Poor Plant and Equipment Sanitation	Poor Plant Design and Construction
Review and update in-house training programs quarterly	Separate raw ingredients and finished product and processing	Train employees (in-house and by outside consultants, entirely in-house, interactively, verbally, or not specified)	
Set up plant training committee, with guidance from HR or training department and plant operations as coordinators	Supplier audits	Training programs for management supervision and cleaning personnel with focus on cleaning technique, cleaning and sanitation compounds, and how to evaluate performance	
Training on specific allergen controls and specific cleaning and sanitation procedures	Supplier training	Use contract cleaners	
Test all employees, including management, for understanding and proficiency	Third-party audits of raw materials	Use detergent	
Training based on show and tell examples of basic food safety practices, with use of graphics and icons	Training	Use sanitizers in condensate pans	
Training booklets, USDA publications	Use of irradiated or pasteurized ingredients	Use video film for training	
Training in learning to read and write English	Use of processed materials vs. raw material where appropriate	Validate the procedures being used to clean and sanitize the plant	
Training in specific dairy issues	Use pre-process treatments to prevent contamination from raw materials	Visual daily inspections	
Training tailored to management personnel above and beyond operational employees (managers/supervisors)—trained in GMPs, sanitation, HACCP, allergens	Use risk assessment to identify potential hazards	Weekly sanitation tests	
Written training guidelines	Vendor qualification/supplier certification, especially for specific pathogen and chemical sensitive raw materials (based on third-party or in-house audit, conduct FOIA inquiries, call current customers)	Written cleaning and sanitation procedures that are developed by corporate staff or preferably by the companies that supply the cleaning/sanitation chemicals and systems.	

Table 4-11: List of Preventive Controls Recommended for the Next Three Food Safety Problems

No Preventive Maintenance	Difficult-to-Clean Equipment	Post-Process Contamination at Manufacturing Plant
Assign accountability (to individual or not specified)	A sanitary design control program	Adequate design of the process flow to take the product most effectively from the end of the "process" into packaging
Assign to a department	Additional of kill-step at end of processing	Allergen controls
Assign to a position description	All equipment should be certified as acceptable for use in food plants	Avoid all human contact with finished goods
At minimum, apply preventive maintenance program to food contact or processing equipment	Apply in-depth evaluation of cleaning practices until repairs made	Better overall understanding of post-retort handling of cans/bottles
Clearly defined expectations	Assign accountability to department	Conduct audits (GMP, in-house or third-party, or not specified, of controls or processes)
Comprehensive maintenance program is essential to food processing plants (large or small)	Assign accountability to individual	Configure product flow to prevent cross-contamination
Conduct audits (third-party, GMP, of facility, of maintenance plan, of processing equipment, or not specified)	Better process control schools	Control traffic patterns
Develop program and stick to it	Bilingual training if needed	Dedicated equipment
Documentation	Cleaning areas prone to niches	Denial of pest access and proper pest monitoring and control programs
Emergency maintenance logs	Conduct audits (in-house or third-party, GMP, of plant and grounds, SSOPs, or not specified)	Develop management controls to prevent post-processing contamination
Equipment manufacturer develop programs and training for maintenance personnel	Conduct regularly scheduled cleaning	Documented handling policies
Establish a preventive maintenance program (on critical equipment, critical infrastructure, internal, or not specified)	Consulting with manufacturer before purchase	Documented sanitation programs
Having production sign that they accept the repaired equipment back into service or sign off when repairs are completed	Contract out cleaning	Employee awareness through education and training
Identification of repairs needed	Document training	Environmental and processing area sampling
Identify critical equipment parameters and initiate monitoring programs	Effectiveness of cleaning is verified and pre-operational inspections are done	Finished product inspection program
Maintenance plan	Employee training (new hires, cleanup crew, equipment specific, in-house programs, or not specified)	GMPs
Maintenance request systems	Environmental sampling and testing (increase frequency, for pathogens, or not specified)	HACCP (establish, utilize to identify potential hazards, reassess)
Management review	Examine equipment & develop plans to upgrade hard to clean units	Immediate final packaging of finished goods
Monitoring and documentation of preventive maintenance process	Extra cleaning during breaks	Improve raw and cooked process flow

Table 4-11: List of Preventive Controls Recommended for the Next Three Food Safety Problems

No Preventive Maintenance	Difficult-to-Clean Equipment	Post-Process Contamination at Manufacturing Plant
Monthly inspections	General ease of equipment cleaning needs to be improved	Improved pathogen monitoring on dry dairy products
Parts reconciliation program	GMPs	Incubation program (for aseptic or retorted only)
Planned and documented maintenance programs	HACCP	Involvement of sanitation chemical suppliers
Records (of emergency and routine repairs/services, maintenance activities, or not specified)	Head of maintenance has had training in sanitary design	Limit personnel access
Repair trending and tracking	Identify better equipment designs for future purchases	Maintain equipment
Signed and verified records	Identify via competent and experienced resource—develop specific cleaning procedures	Maintenance of air handling systems
Terminate ongoing employee offender	Implement a monitoring program to assess the actual risks	Microbiological monitoring or sampling of finished and packaged product
Training	Improve expectations relative to materials and design	Ozone air fogging of environment during off hours
Use a third party to evaluate	Improvement of CIP capabilities (better line flow design for equipment or not specified)	Package must be intact
Use of metrics to evaluate efficacy of preventive maintenance	Installations conducted by equipment manufacturer	Packaging inspection program
Utilize computer preventive maintenance program (such as MP2 system; other software is available)	Knowledge of the equipment harborage sites	Positive filtered air pressure in packaging areas
	Label equipment with proper cleaning instructions	Product sampling
	Management responsibility, review, and follow-up	Proper cleaning and sanitizing and documentation of valving and design
	Meetings (monthly training meetings or short duration meetings)	Proper environmental controls
	Microbial sampling	Proper seaming/sealing of containers and routine monitoring of same
	Design or purchase easier-to-clean equipment	Proper storage
	Purchase the right equipment for the task	Proper valving and design to ensure pasteurized milk is not contaminated on cold side
	Repair, replace, or return equipment to manufacturer	Rewards for good job
	Review and update training programs quarterly	Routine cleaning of refrigeration systems such as compressors, fans, and condensate collectors
	Rewards for doing good job	Sanitation practices (for packaging and sealing areas, product contact surfaces and equipment, or not specified)
	Sanitation tests (daily or weekly)	Segregate all raw and finished goods
	Signed and verified records	SSOPs (written with signed and verified records or not specified)

Table 4-11: List of Preventive Controls Recommended for the Next Three Food Safety Problems

No Preventive Maintenance	Difficult-to-Clean Equipment	Post-Process Contamination at Manufacturing Plant
	Sign-off on cleaning	Sufficient monitoring programs for environmental conditions
	SSOPs (for equipment, difficult cleaning, written, or not specified)	Temperature control must be appropriate for product
	Surface sampling	Terminal kill-step in process
	Taking equipment apart to clean	Trash handling and product handling systems and personnel for unprocessed and processed areas of the production
	Use video tapes for training and other visuals	Warehouses and transport carriers must meet GMP expectations
	Utilize suppliers who provide support services	
	Verification of efficacy of cleaning using swabs or ATP tests	

Table 4-12: List of Preventive Controls Recommended for the Remaining Three Food Safety Problems

Contamination During Processing	Poor Employee Hygiene	Incorrect Labeling or Packaging
Allergen control program (with process scheduling or not specified)	3x5 pocket-sized cards to remind employees of a few vital hazards	Two approvers for in-process label and packaging changes
Integrated Pest Management	Adequate restroom facilities and equipment (based on the number of employees, including handwashing and sanitizing stations, clean locker rooms and showers, centralized handwashing, warm water at handwashing stations, or not specified)	Adherence to approved formulas and suppliers
Assign department for self-inspection	Automated handwashing stations/keypad controls and sensor-equipped towel dispensers	All labeling material should be pre-approved by third party
Assign individual for self-inspection	Base training efforts on Vulnerability Assessment Report	Allergen control programs such as production scheduling, proper cleaning, and ingredient handling
Clearly defined expectations, i.e., food code	Clearly define expectations	Allergen identification system for all inbound ingredients
Color code risks	Communication	Batching programs and record keeping
Condensate control through proper air circulation	Conduct audits (include operating personnel, management, and maintenance, third-party GMP review, internal audits, or not specified)	Careful inventory and verification of label status
Conduct audits (in-house, third party, GMP, of systems and processing lines and areas, or not specified)	Define minimum standards	Check labels and product daily—all shifts
Configure product flow to prevent cross-contamination	Develop training materials and procedures internally, using input from employees and QA team	COA for all inbound raw materials
Define process capability	Develop training programs that emphasize the importance of employee hygiene	Conduct audits (third-party, of label compliance or performance, or not specified)
Develop appropriate control measures to prevent contamination	Directed, work-area-specific training, with input from and approved by plant operations management	Define expectations as to ingredient declaration
Develop preventive maintenance program	Disciplinary actions	Define when cleanup is needed to prevent carryover into non-allergen product
Training (improved existing training, temperature control training, personnel hygiene training, or not specified)	Discuss personal hygiene during monthly meetings	Develop control programs for scheduling formulations without allergens first in production day
Employment of certified food safety manager	Discussion groups	Develop label management control on issuing, storing, and disposition of obsolete labels
Environmental monitoring and control	Documentation of training or written training guidelines	Develop label review process with at least two persons involved
Environmental sampling	Emphasize personnel hygiene when hiring	Develop label/product documentation at beginning of shift and checks on each new container
Equipment maintenance (routine, preventative, or not specified)	Employee mentoring (by matching employees with same language/ethnicity or not specified)	Development of labeling expectations

Table 4-12: List of Preventive Controls Recommended for the Remaining Three Food Safety Problems

Contamination During Processing	Poor Employee Hygiene	Incorrect Labeling or Packaging
Facility equipment layout	Employee supervision	Eliminate potential cross-contamination during processing
Glass breakage procedures	Employee training (new employees, in-house, outside, on personal sanitation and hygiene, on food safety, or not specified)	Employee training (proper labels, label/formulation control, importance of using appropriate labeling, or not specified)
GMPs	Enforce employee hygiene work rules	Formal process for approval of labels and printed packaging
HACCP (utilization, establishment, implementation, reassessment, or not specified)	Food safety reminders on paystubs and websites	HACCP (establishment of CCP, risk assessment review, and reassessment)
Handling practices	Formal training policy	Inspection and documentation of all labels used in production
Improved CIP capability	GMPs	Isolated storage for all allergen-containing ingredients
Improved equipment design	Good orientation programs	Label development critical, involve management, quality control, production, warehouse personnel
Limit personnel access	Hand wash signs posted	Label inventory control system
Mandatory handwashing or glove use protection and protocol	Impress on the employees the need to keep clean personally, as well as keep plant clean	Labeling allergens is most critical
Metal detection (with magnets and screens or not specified)	Laboratory testing	Mandatory sample label attachment to production records
Microbial sampling	Management commitment	Monitor as part of packaging CCP
Monthly meetings for management and employees	Managers set good examples	Off-shore-produced product of great concern
More reliance on prerequisite programs	Monitor efficacy—develop metrics	Packaging engineering
Plant management to do self-inspection	Monitoring of employees (including handwashing stations)	Preoperations label review and documentation before production can begin
Positive filtered air pressure in packaging areas	Provide ongoing verbal examples and reinforcement/repetition of training concepts	Programs to approve all labels
Pre-operational inspections of processing lines/equipment	Policy that all personnel will adhere to hygiene codes	QC label monitoring program during production
Prevent crossover of personnel from raw to finished products	Posters (bilingual or not specified)	Records
Preventive maintenance	Prepare demonstrations of the effects of poor hygiene	Removal of outdated/old/obsolete labels (removal program or not specified)
Process awareness	Provide aprons or coats (for critical employees) and uniform and shoes	Review finished packaging
Proper cleaning and sanitation of equipment and product contact surfaces	Regular re-training of existing employees	Review and verify labels (when new supplier, by routine inspections, upon receipt, at time of use, or not specified)
Proper cleaning and system design and construction	Seminars	Review process (internal, of label and on-line packing, or not specified)

Table 4-12: List of Preventive Controls Recommended for the Remaining Three Food Safety Problems

Contamination During Processing	Poor Employee Hygiene	Incorrect Labeling or Packaging
Properly designed and documented cleaning and sanitizing programs	Set up plant training committee, with guidance from HR or training department and plant operations as coordinators	Scanning bar codes or using on-line bar code scanners
Record logs	Signed and verified records	SSOPs
Sampling	SSOPs (written or not specified)	Third-party marketplace compliance verification
Sanitary design program	State Public Health training handouts	Independent technical review of all labels
Segregation of processes, operations, products, product line, staging areas, and storage for raw and finished products	Supervision	Verify labels and maintain records
Separate or designated employees for tasks	Training based on show and tell examples of basic food safety practices, with use of graphics and icons	
Sign off to make sure task is completed	Training in reading and writing English	
SSOPs (operational, written with signed and verified records, or not specified)	Training with supervision on floor responsible for performance, not QA	
Traffic control between processed, WIP, and raw material	Understanding needs	
Use follow-up operational management	Use of broad range of training materials, such as video training tapes, CD-ROM, online learning, equipment labeling, booklets, food safety icons (in critical areas of plant or not specified)	
Use covers on open food containers/equipment	Visible handwashing checks	
	Vulnerability Assessment Report by outside food safety expert	

Table 4-13: Top Five Commonly Mentioned Preventive Controls by Food Safety Problem

Food Safety Problem	Most Frequently Mentioned Controls	Count [a]
Deficient employee training	Audits (third-party or in-house)	6
	In-house training	6
	Bilingual training	6
	Use video tapes for training and other visuals	4
	Documentation of training activities	3
Contamination of raw materials	Supplier audits	8
	Supplier qualification/certification	7
	Raw material and product specifications	6
	Testing or inspecting raw materials	5
	Segregation of storage	4
Poor plant and equipment sanitation	Training	9
	Audits (third-party or in-house)	7
	SSOPs	6
	Documentation of sanitation activities and procedures	5
	Sanitation evaluation and monitoring	4
Poor plant design and construction	Audits (third-party or in-house)	7
	Fix problems and reconfigure plant design	2
	Use outside consultants or others specialized in plant design	2
	Contract out repair and design work	2
	Correct, reconfigure, or repair equipment	2
No preventive maintenance	Preventive maintenance programs	9
	Audits (third-party or in-house)	5
	Records/documentation of maintenance	4
	Assign accountability	2
	Sign off on repaired equipment	2
Difficult-to-clean equipment	SSOPs	8
	Training	7
	Environmental sampling and testing	5
	Audits (third-party or in-house)	5
	Repair, replace, or return equipment	3
Post-process contamination at manufacturing plant	Audits (third-party or in-house)	6
	Environmental sampling	4
	SSOPs	4
	Training	3
	Sanitation practices	3
Contamination during processing	Audits (third-party or in-house)	10
	Training	7
	Segregation or processes, products, and storage	6
	HACCP	4
	Equipment maintenance	4
Poor employee hygiene	Training	9
	Audits (third-party or in-house)	7
	Adequate facilities and equipment	5
	Automated handwashing and towel dispensers	4

Table 4-13: Top Five Commonly Mentioned Preventive Controls by Food Safety Problem

Food Safety Problem	Most Frequently Mentioned Controls	Count [a]
Poor employee hygiene (cont.)	Broad range of training media and materials	4
Incorrect labeling or packaging	Label review/verification	8
	Audits (third-party or in-house)	5
	Training	5
	HACCP	3
	Removal of outdated labels	3

[a] Total number of experts that included the control in question in their list of preventive controls for the food safety problem.

Table 4-14: Types of Records Recommended as Preventive Controls

Record Type [a]	Count	Percent
Cleaning and sanitation	13	87%
Corrective action documentation	1	7%
Equipment maintenance records	11	73%
Labeling and packaging	5	33%
Personnel records	9	60%
Receipts of incoming ingredients, raw materials	3	20%
Supplier audits	10	67%
Warehousing/inventory/storage records	2	13%