GOOD MANUFACTURING PRACTICES (GMPs) FOR THE 21ST CENTURY – FOOD PROCESSING

FINAL REPORT

Prepared for
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740-3835

Prepared by
Eastern Research Group, Inc.
110 Hartwell Avenue
Lexington, MA 02421

In Partial Fulfillment of
Task Order 3 under Contract No. 223-01-2461

August 9, 2004

ACKNOWLEDGEMENTS

ERG would like to thank all the experts for their comments on and participation in the study upon which this report is based, including Dane Bernard, C. Dee Clingman, Peter Cocotas, Clifford Coles, Charles Cook, George Evancho, Cameron Hackney, John Manoush, Nancy Nagle, Robert Price, William Sanders, Robert Savage, William Sperber, Richard Stier, Tommy Shannon, Donn Ward, and Edmund Zottola.

This report was produced by ERG for FDA under task order 3 and ERG is solely responsible for its contents.

TABLE OF CONTENTS

LIST OF TABLES

EXECUTIVE SUMMARY

Since the last revision of food Good Manufacturing Practices (GMPs) almost 20 years ago, the food manufacturing industry has seen many changes, including newly recognized pathogens, more sophisticated technologies, and increased automation. While GMPs can control for many food safety problems, it is not clear that current GMPs adequately address these new developments. The food safety literature reviewed for this study shows that there continue to be food safety problems. The Food and Drug Administration (FDA) is currently evaluating its food GMPs regulations to ensure that they take today's technologies and food safety hazards into account.

Under contract to FDA, Eastern Research Group, Inc. (ERG) undertook this study comprising an extensive literature review and an expert elicitation of current food safety problems and the range of preventive controls needed to address them. The expert elicitation identified the most significant food safety problems, foods at high risk for these problems, and other major areas of concern. Based on the number of votes by experts who participated in the elicitation, "deficient employee training," "contamination of raw materials," "poor plant and equipment sanitation," and "poor plant design and construction" were ranked as the top four food safety problems faced by food manufacturers today. Results from the study also indicated that 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. The expert elicitation also showed that the needs of small and medium-sized food processors likely vary from larger processors, with smaller facilities generating higher risk scores than large facilities across all food safety problems and sectors considered.

The food safety experts who participated in the study recommended a range of preventive controls that could address most of the food safety problems faced by the food processing industry today. They did not, however, differentiate these preventive control recommendations by facility size despite the higher risk rankings of smaller facilities. The most frequently mentioned preventive controls with broad applicability across sectors and food safety problems included:

- *Training* – Ongoing and targeted training on issues ranging from allergen control, cleaning and sanitation procedures, incoming ingredient receipt protocol, and monitoring for employees, management, as well as 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 (i.e., swabs, organoleptic evaluations, and bioluminescence tests)

Post-study follow-up discussions with four of the experts also generated additional recommendations. While most experts agreed that food GMPs could be improved, opinions on how this should be done varied widely. Some experts indicated that GMPs were lacking in some areas, whereas others noted that the food GMPs should remain as written and that other approaches should be taken to encourage greater compliance. Recommendations made included:

- Revision of food GMPs in key areas, such as training,
- Addition of new requirements, including components of HACCP, allergen control, and recordkeeping,
- Issuance of a guidance document that would clarify GMPs and its expectations, and
- Institution of positive incentive programs, such as reduced inspections for select facilities that meet certain requirements.

Finally, ERG's literature review and comparative analysis of other GMPs (i.e., for pharmaceutical/biologic products and medical devices) and quality system programs revealed that the majority of preventive control recommendations echo the principles of these other GMPs regulations and quality systems. All of the programs reviewed, including International Organization for Standardization (ISO) 9001: 2000, American Society for Quality (ASQ) Q9004-3-1993 (Quality Management and Quality System Elements – Guidelines for Processed Materials), pharmaceutical GMPs, and medical device GMPs, have similar key provisions on training, audits, documentation, and evaluation/validation. A thorough comparison of the elements of food GMPs to these systems (see Appendix E) might aid FDA in its food GMPs modernization effort.

SECTION ONE

CURRENT FOOD GOOD MANUFACTURING PRACTICES

Current food good manufacturing practices (GMPs) are published in Title 21 of the Code of Federal Regulations, Part 110 (21 CFR 110). GMPs describe the methods, equipment, facilities, and controls for producing processed food. As the minimum sanitary and processing requirements for producing safe and wholesome food, they are an important part of regulatory control over the safety of the nation's food supply. GMPs also serve as one basis for FDA inspections.

The current GMPs are the result of an extended rulemaking process that spanned decades. The following section (Section 1.1) describes when, why, and how the food GMPs were developed and some of the obstacles that were overcome. Table 1-1 summarizes the major events that led to the development of GMPs as they are today. Section 1.2 provides a detailed discussion of the requirements in each of the five subparts of the GMP regulation, and concludes with a table (Table 1-2) outlining the main requirements.

1.1 The Development of Food GMPs

Food safety has been regulated since the mid-1800s and was mostly the responsibility of local and state regulators. However, the Pure Food and Drugs Act, passed by Congress in 1906, marked the first major federal consumer protection law with respect to food processing. The 1906 law prevented interstate and foreign commerce in misbranded or adulterated foods, drinks, or drugs. The intent of the Act was to prevent poisoning and consumer fraud. As more food products were manufactured in subsequent years, however, poor-quality food products and deceptive packaging continued to be produced due to loopholes in the law. Consumers were often unaware of what they were buying until products were opened. Therefore, in 1933, the FDA decided to overhaul the 1906 Act.

In 1938, after a battle about USDA jurisdictions with respect to the Act's enforcement, the Food Drug, and Cosmetic Act (FDCA) replaced the 1906 Act. The FDCA provided the necessary identity and quality standards to protect consumers from fraud. The FDCA provides the regulatory basis for today's food GMPs. Two sections of the FDCA are directly related to conditions in a facility where food has been manufactured.

- Section 402 (a)(3) specifies that food has been manufactured under such conditions that it is unfit for consumption.
- Section 402 (a)(4) considers that food may be adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health.

These provisions are unlike other parts of Section 402, in that they relate to the conditions of a facility where food is produced or stored. Thus, instead of having to prove that the food is adulterated, insanitary conditions are considered sufficient to show that the food might have become adulterated.

Given the FDCA's vagueness in establishing violations and thus, the difficulty of enforcing it, FDA began working on draft GMP regulations by the mid-1960s (although others had made the suggestion to do so as early as 1948). The objective of the GMP regulations was to describe general rules for maintaining sanitary conditions that must be followed by all food processing facilities to ensure that the statutory requirements of Section 402(a)(3) and (4) were met. After much industry involvement, including much debate about FDA's authority to adopt rules to carry out the provisions of the FDCA, the GMP regulations for food processing facilities were finally proposed in 1968 (see Table 1-1).

Three broad categories of interrelated issues arose during the development of the GMPs (Dunkelberger, 1995):

- Concern that the regulations were unduly stringent and especially burdensome for small food companies without necessarily improving the quality or safety of foods.
- Contention that the GMP regulations must prescribe conditions that "reasonably" relate to insanitary conditions that may contaminate food and render it injurious to health.
- Assertions that the regulations did not have the force of law.

These first two issues were resolved mostly through the use of more general terms, such as "adequate," "sufficient," and "suitable," rather than hard-line standards. FDA also used "shall" when the agency felt compliance was necessary and "should" when practices in the rule were less obviously related to the statutory requirements of the Act. The third issue became inconsequential when it was proved that FDA did have the statutory authority to promulgate the GMP regulations. The GMP regulations were finalized in April of 1969 and published as Part 128 of the Code of Federal Regulations (CFR). In 1977, Part 128 was recodified and published as Part 110 of the CFR.

The final GMP regulations were very broad, not specifying what exactly a facility must do to comply. This naturally created enforcement problems for the FDA. To address the ambiguity created by the umbrella GMPs, FDA next tried to develop industry-specific GMPs through the mid-1970s. By the late 1970s, however, FDA decided to improve the umbrella GMPs rather than adopting industry-specific GMPs. The revisions were finalized in 1986 and printed in 21 CFR 110. Specific GMPs were also included and printed in 21 CFR Parts 100 through 169 for:

- Quality control procedures for nutrient content of infant formula (21 CFR 106).
- Thermally processed low-acid canned foods in hermetically sealed containers (21 CFR 113).
- Acidified foods (21 CFR 114).
- Bottled drinking water (21 CFR 129).

In July of 2002, FDA formed a Food GMP Modernization Working Group to examine the effectiveness of current food GMPs given the many changes that have occurred in the food industry since 1986. The Working Group has been researching the impact of food GMPs on food safety, as well as on the impact (including economic consequences) of revised regulations. Part of the group's current effort, as of June 2004, is to find out which elements of the food GMPs are critical to retain and which should be improved. FDA is now holding public meetings to obtain the public comments to assist in this effort.

Table 1-1: Food GMP Development Timeline

Date	Milestone
1906	The Bureau of Chemistry passes the 1906 Pure Food and Drugs Act, prohibiting interstate commerce in misbranded and adulterated foods, drinks, and drugs
1933	FDA recommends revising the 1906 Pure Food and Drugs Act
1938	FDA passes the 1938 Federal Food, Drugs, and Cosmetics Act, which provides identity and quality standards for food
Mid 1960s	FDA decides to clarify the FDCA through GMP regulations
1968	FDA proposes food GMP regulations
1969	FDA finalizes food GMP regulations
Early 1970s	FDA considers promulgating industry-specific regulations
Late-1970s	FDA decides to revise the general GMPs rather than adopting industry-specific GMPs
1986	FDA publishes revised food GMPs
2002	FDA forms Food GMP Modernization Working Group
2004	FDA announces effort to modernize food GMPs

Source: Dunkelberger, 1995; FDA, 1981b.

1.2 Key Provisions of Food GMPs

The current GMPs consist of seven subparts, two of which are reserved. The requirements are purposely general to allow individual variation by manufacturers to implement the requirements in a manner that best suit their needs. Table 1-2 summarizes the five written subparts, which are discussed in further detail below.

1.2.1 General Provisions (Subpart A)

The general provisions in Subpart A of the food GMPs are divided into four sections. The first section defines much of the terminology used in describing GMPs. The terms "shall" and "should" are also defined to differentiate between when compliance is necessary ("shall") and when procedures and practices are not directly related to insanitary conditions as specified in Section 402(4)(a) ("should").

The section on personnel delineates plant and employee responsibilities with regard to personal hygiene. For example, personnel with diseases or other conditions that could contaminate food are to be excluded from manufacturing operations. The section also outlines expectations with respect to personal hygiene and cleanliness, clothing, removal of jewelry and other unsecured objects, glove maintenance, use of hair restraints, appropriate storage of personal items, and restrictions on various activities, such as eating and smoking. The section discusses the need for appropriate food safety education and training in very general terms. The subpart further mandates the assignment of supervisory personnel to ensure compliance.

Currently, establishments that only harvest, store, or distribute raw agricultural commodities are exempt from the requirements of Subpart A, although FDA reserves the right to issue special regulations to address this sector.

1.2.2 Buildings and Facilities (Subpart B)

Subpart B of the food GMPs outlines requirements for the maintenance, layout, and operations of food processing facilities.

Section 110.20 outlines the requirements for adequate maintenance of the grounds, including litter control, waste removal and treatment, and grounds maintenance and drainage. The subpart requires

that plants be designed and built to reduce the potential for contamination. Some detail is provided on how to achieve this, but the requirements are largely focused on the end result of a sanitary facility rather than specific practices. The language also includes many general terms to allow flexible implementation of the requirements.

Section 110.35 describes sanitary operations. Physical facilities, equipment, and utensils are to be sanitized in a way that protects against food contamination. Storage of cleaning materials and toxic materials permitted are outlined to prevent contamination with chemicals. The section also briefly addresses pest control and cleaning of various food contact surfaces, as well as the frequency of cleaning.

Section 110.37 describes the requirements for adequate sanitary facilities and controls, including the water supply, plumbing, toilet and hand-washing facilities, and rubbish and offal disposal. Some of the requirements of the section are fairly specific, such as the requirement of self-closing doors for toilet facilities, whereas others remain general, such as plumbing of adequate size and design.

1.2.3 Equipment (Subpart C)

Subpart C describes the requirements and expectations for the design, construction, and maintenance of equipment and utensils so as to ensure sanitary conditions. It also adds a specific requirement; an automatic control for regulating temperature or an alarm system to alert employees to a significant change in temperature. Other requirements of the subpart are fairly general and intended to prevent contamination from any source.

1.2.4 Production and Process Controls (Subpart E)

The first section of Subpart E lists the general sanitation processes and controls necessary to ensure that food is suitable for human consumption. It uses more general words (e.g., “adequate,” “reasonable,” etc.) and covers many aspects not discussed in previous subparts. This section also addresses the monitoring of physical factors (critical control points), such as time, temperature, humidity, pH, flow rate, and acidification.

The second section outlines very general requirements for warehousing and distribution. The section requires finished foods to be stored and distributed under conditions that protect against physical,

chemical, and microbial contamination. The container and the food must also be protected from deterioration.

1.2.5 Defect Action Levels (DALs) (Subpart G)

The last subpart of the food GMPs allows FDA to define maximum defect action levels (DALs) for a defect that is natural or unavoidable even when foods are produced under GMPs as set out in the other subparts of the regulations. Generally, these defects are not hazardous to health at low levels; they include rodent filth, insects, or mold. The DALs are defined for individual commodities and may be obtained by request from FDA, which produces a Handbook on Defect Action Levels for Food. They are also available from the FDA Web site (http://www.cfsan.fda.gov/~dms/dalbook.html). Table 1-3 provides examples of the maximum DALs for select food products. Manufacturers are expected to use quality control operations that reduce the level of the defect to the lowest possible levels. Those exceeding maximum DALs will be considered in violation of Section 402 (3)(a) of the FDCA.

The section bans blending of food with a defect level above a maximum DAL with other food. It also stresses that compliance with DALs does not excuse violations of Section 402(4)(a) of the FDCA or that of the other subparts of 21 CFR 110.

Table 1-2: Summary of 21 CFR Part 110: Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food

Subpart A. General Provisions		
Section 110.3	Definitions	Definitions of: • Acid foods/acidified foods • Adequate • Batter • Blanching • Critical control point • Food • Food-contact surfaces • Lot • Microorganisms • Pest • Plant • Quality control operation • Rework • Safe-moisture level • Sanitize • Shall • Should • Water activity
Section 110.5	Current good manufacturing practice	• Criteria for determining adulteration • Food covered by specific GMPs is also covered by umbrella GMPs
Section 110.10	Personnel	Requirements for: • Disease control • Cleanliness • Education and training • Supervision of personnel with regards to these requirements
Section 110.19	Exclusions	• Excluded operations (raw agricultural commodities) • FDA can issue special regulations to cover excluded operations
Subpart B. Buildings and Facilities		
Section 110.20	Plant and Grounds	• Description of adequate maintenance of grounds • Plant construction and design to facilitate sanitary operations and maintenance
Section 110.35	Sanitary Operations	Requirements for: • Cleaning/sanitizing of physical facilities, utensils, and equipment • Storage of cleaning and sanitizing substances • Pest control • Sanitation of food contact surfaces • Storage and handling of cleaned portable equipment and utensils
Section 110.20	Sanitary Facilities and Controls	Requirements for: • Water supply • Plumbing • Sewage disposal • Toilet facilities • Hand-washing facilities • Rubbish and offal disposal

Table 1-2: Summary of 21 CFR Part 110: Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food

Subpart C. Equipment		
Section 110.40	Equipment and Utensils	• Requirements for the design, construction, and maintenance of equipment and utensils
Subpart E. Production and Process Controls		
Section 110.80	Processes and controls	Delineates processes and controls for: • Raw materials and other ingredients • Manufacturing operations
Section 110.93	Warehousing and distribution	Storage and transportation of food must protect against contamination and deterioration of the food and its container
Subpart G. Defect Action Levels		
Section 110.10		• FDA has established maximum defect action levels (DALs) for some natural or unavoidable defects • Compliance with DALs does not excuse violation of 402 (a)(4) • Food containing defects above DALs may not be mixed with other foods

Source: Federal Register 51, 1986.

Table 1-3: Maximum Defect Action Levels for Selected Food Products

Food Product	Maximum Defect Action Level
Allspice (ground)	• Average of 30 or more insect fragments per 10 grams • Average of 1 or more rodent hairs per 10 grams
Broccoli (frozen)	• Average of 60 or more aphids, thrips, and/or mites per 100 grams
Cocoa beans	• More than 4% of beans by count are moldy • More than 4% of beans by count are insect-infested or insect-damaged • More than 6% of beans by count are insect-infested or moldy (**NOTE: Level differs when both filth and mold are present)** • Average of 10 mg or more mammalian excreta per pound
Pitted olives	• Average of 1.3 percent or more by count of olives with whole pits and/or pit fragments 2 mm or longer measured in the longest dimension
Pineapple juice	• Average mold count of 15% or more • Mold count of any 1 subsample is 40% or more
Tomatoes (canned)	• Average of 10 or more fly eggs per 500 grams • 5 or more fly eggs and 1 or more maggots per 500 grams • 2 or more maggots per 500 grams

Source: FDA, 2004.

References

Dunkelberger, Edward. 1995. The statutory basis for the FDA's food safety assurance programs: From GMP, to emergency permit control, to HACCP. *Food and Drug Law Journal 50*. 357-383.

Federal Register 51. 1986. Part 110—Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. *Federal Register 51*. June 19. http://www.cfsan.fda.gov/~lrd/cfr110.html.

Food and Drug Administration (FDA). 1981a. The Story of the Laws Behind the Labels Part I: 1906 Food and Drugs Act . *FDA Consumer*. June.

Food and Drug Administration (FDA). 1981b. The Story of the Laws Behind the Labels Part II: 1938 Federal Food, Drugs, and Cosmetics Act. *FDA Consumer*. June.

Food and Drug Administration (FDA). 1999. Milestones in U.S. Food and Drug Law History. *FDA Backgrounder*. May 3.

FDA. 2004. *The Food Defect Action Levels*. Center for Food Safety and Applied Nutrition. Revised May 1998. http://www.cfsan.fda.gov/~dms/dalbook.html.

Gould, Wilbur A. 1994. *CGMPS/Food Plant Sanitation*. CTI Publications, Inc: Baltimore, MD.

Junod, Suzanne White. 1999. *The Rise and Fall of Federal Food Standards in the United States: the Case of the Peanut Butter and Jelly Sandwich*. Society for the Social History of Medicine. Spring Conference. April 9.

SECTION TWO

LITERATURE REVIEW OF COMMON FOOD SAFETY PROBLEMS AND APPLICABLE CONTROLS

This section presents ERG's literature review of preventive controls for microbiological, chemical, and physical food safety problems in the food processing industry. Microbiological safety hazards cause most of the foodborne illnesses and include pathogenic bacteria, viruses, and parasites. Historically, pathogenic bacteria have been the most prevalent food safety hazard, with viral cases following closely behind according to the most recent CDC report on the etiology of foodborne illness (CDC, 2004). Chemical food safety hazards vary widely, but the most common problems cited in the literature include contamination with pesticides, allergens, and natural toxins, including scrombotoxins found in fish and mycotoxins found in crops. Foreign objects, or physical safety hazards, are the least likely to affect large numbers of people and usually are easily recognized.

Many of the microbiological food safety problems discussed in the literature can potentially be addressed by good manufacturing practices (GMPs) codified in 21 CFR 110, such as proper employee hygiene, adequate training, and effective cleaning and sanitizing of the manufacturing equipment and environment. For example, niche environments, which are sites within the manufacturing environment that can harbor bacteria, are a significant cause of post-processing contamination but difficult to reach with average cleaning and sanitizing procedures. Food plants that put in a greater than average effort must identify and eliminate niches by taking apart equipment in order to minimize the risk of post-processing contamination from niche environments. Others take an even more stringent approach by applying a post-package pasteurization method, virtually eliminating the risk of post-processing contamination due to niche environments.

Many chemical food safety problems are also addressed by following good manufacturing practices, such as pest control and proper storage. The rigor of the controls in place varies by plant, however. Further, some food safety problems, such as allergen control, may be better addressed by a Hazard Analysis and Critical Control Point (HACCP) plan in addition to GMPs. Physical hazards may also be better controlled by a HACCP plan. Controls may include foreign body detection systems, such as metal detectors, in addition to putting preventive measures in place.

Table 2-1 summarizes the range of problems associated with each type of hazard as identified in the literature. The following three sections provide a more detailed overview of each hazard and the preventive controls to address each problem, as noted in the literature. Each section also includes a summary flowchart that highlights the potential problems, the relevant CFR section or guidance that addresses each problem, the industry/product covered, and the types of preventive controls typically recommended to eliminate or minimize the type of food safety hazard risk posed. Finally, Section 2.4 discusses other issues to consider when evaluating food safety controls, in addition to GMPs.

2.1 Microbiological Safety

The microbiological safety hazards include pathogenic bacteria, viruses, and parasites. Some of the problems that lead to the contamination of food with these microorganisms at the processor level can be easily remedied with improved employee training programs and effective hygienic practices. Others are more difficult to control, such as post-processing contamination with *Listeria monocytogenes*, a pathogen that is ubiquitous in the processing environment.

Inefficient hygienic practices among employees. Employee hygiene is paramount to plant sanitation and is one of the leading causes of food contamination (Higgins, 2002). One of the challenges that food processors have to overcome is how to motivate employees to comply with hygienic practices. Training is one step in the process, but is often not enough to ensure employee compliance. Companies have adopted several aids to ensure employee compliance. For example, Atlanta's Buckhead Beef Company requires workers to key in their Social Security Numbers to activate the hand sanitizer dispensers on the plant floor. The company then uses the collected data to impose financial reprisals on employees found to be deficient in hand-sanitizing practices. Other controls include a sensor-equipped towel that prevents the cross-contamination that can occur with hand cranks. These units also count the number of towels dispensed. A signal dispenser that beeps when users have washed their hands sufficiently is also available to ensure adequate hand-washing time.

Language barriers. Current training programs, even those that include Spanish signage and instructional manuals, can be inadequate if the first language of plant employees is one other than English or Spanish. Even Spanish training materials can be problematic due to dialectical differences in translations. Some industry experts therefore recommend a picture-and-symbol approach to training to overcome language barriers (Higgins, 2002).

Table 2-1. Range of Processor-Level Problems by Type of Food Safety Hazard Posed

Microbiological Safety
Inefficient employee hygiene practices
Language barriers
Ineffective training of employees
Biofilms
Niche environments
Plant renovations
Ineffective use of cleaning agents/disinfectants
Lack of sanitary equipment design
Reactive instead of routine maintenance
Ineffective application of sanitation principles
Internalization of pathogens in fruit
Contamination of raw materials
Post-processing contamination
Chemical Safety
Raw material contamination with pesticides
Indiscriminate spraying of facilities against pests
Mistaken identity of pesticides
Spillage of pesticides
Adding too much of an approved ingredient
Raw material contamination with an allergen
In-line cross-contamination with an allergen
Contamination by utilization of rework
Cross-contamination from maintenance tools
Cross-contamination from conveyor belts
Incorrect labeling or packaging
Older equipment (more difficult to clean)
Raw material contamination with natural toxins
Mycotoxin infestation due to drought
Mycotoxin infestation due to insect damage
Mycotoxin infestation due to delayed harvesting
Mycotoxin infestation due to mechanical damage
Mycotoxin infestation due to moisture/heat
Patulin production in apples
Corrosion of metal containers/equipment/utensils
Contamination with cleaner/sanitizer residue
Adding too much of an approved ingredient
Physical Safety
Foreign matter in raw materials
Poorly maintained equipment/lines
Light fixture breakage
Foreign matter introduction during storage

Ineffective training of employees. Although effective training is crucial to ensuring that sanitation standards are met, it is not clear that current training methods are sufficient. In the third Annual Best Manufacturing Practices Survey conducted by the *Food Engineering* magazine in 2002, a panel of food manufacturing professionals rated employee training as the lowest among all food safety measures in terms of effectiveness (Gregerson, 2002). Employee training that companies conduct may be too generic. For example, external consultants may not be familiar enough with a plant's operations and requirements to give effective advice. Other impediments to effective training might include training the wrong people, not training enough people, or not providing enough training (Blackburn and McClure, 2002).

Biofilms. Biofilms occur when bacteria form a slime layer upon a surface and provide an environment for pathogens to proliferate. The adhesion of pathogenic bacteria to a biofilm is a food safety hazard because the biofilm can detach and become a significant source of food contamination. Cleaning to remove biofilms prior to sanitation is often sufficient to prevent this problem. However, studies have shown that attached bacteria may survive conventional cleaning methods (Austin and Berferon, as cited in Stopforth et al, 2002). Adequate cleaning prior to sanitizing is therefore paramount to controlling this problem. Further, coating drains and equipment parts with antimicrobial material can counteract biofilms although it does not eliminate the need for proper cleaning and sanitizing (Higgins, 2003).

Niche environments. Niche environments are sites within the manufacturing environment where bacteria can get established, multiply, and contaminate the food processed. These sites may be impossible to reach and clean with normal cleaning and sanitizing procedures. Examples include hollow rollers on conveyors, cracked tubular support rods, the space between close-fitting metal-to-metal or metal-to-plastic parts, worn or cracked rubber seals around doors, and on-off valves and switches (Tompkin, 2002). Tompkin (2002) provides an extensive list of potential niches. Manufacturers must identify and eliminate niches. Microbiological sampling of the environment and equipment can detect a niche. Third-party validation of test results might be useful to further establish confidence in environmental sampling results. Further, sanitary equipment design can help prevent niches (AMI, 2003). Proper maintenance to keep equipment parts from providing potential niches is also essential.

Plant renovations. Outbreaks of listeriosis have been linked to environmental contamination of food caused by plant renovations (FDA/CFSAN, 2001a). While no data were identified in the literature on this issue, plant renovations are likely to require revisions in standard operating procedures (SOPs) to prevent contamination due to changes in processes.

Ineffective use of cleaning agents and disinfectants. Different cleaning agents vary in their ability to remove different soil types (Blackburn and McClure, 2002). Thus, the correct choice of cleaning agent is essential to ensure effective cleaning in a food processing facility. The efficacy of disinfectants is dependent on microbial species, pH, presence of biofilms, temperature, concentration, and contact time (Stopforth et al., 2002; Blackburn and McClure, 2002). Stopforth et al. (2002) found that commonly used disinfectants were not as effective as desired, possibly due to inadequate pre-cleaning steps. While there were no examples in the literature of plants having problems with this issue, the potential for ineffective sanitation is clearly present. Food manufacturers should always confirm the efficacy of their cleaning and disinfection programs with tests from the supplying companies or in-house trials (Blackburn and McClure, 2002).

Lack of sanitary equipment design. Good hygienic design of equipment prevents or minimizes microbiological contamination of food. The materials used for food processing equipment should be easily cleanable. As noted earlier, niche environments are known sources of pathogens; surfaces also deteriorate with age, and this abrasion makes cleaning more difficult (Blackburn and McClure, 2002). For cleaning and sanitation to be effective, all parts of the equipment should be readily accessible. Another way to improve equipment hygiene is to use antimicrobial coatings on equipment parts (Higgins, 2003).

Reactive rather than routine/predictive maintenance. In the Best Manufacturing Practices Survey conducted by *Food Engineering* magazine in 2001, 56 percent of respondents reported having routine preventive programs (Gregerson, 2002). Only 8.5 percent of respondents noted having predictive maintenance programs; the remaining respondents described their programs as reactive in nature, i.e., "run it 'til it breaks." Reactive maintenance can result in food contamination before a failure is identified. Niches can develop or controls can become defective in processing equipment that is not routinely maintained. For example, in 1994, a *Listeria monocytogenes* outbreak was linked to the use of defective processing equipment in the production of chocolate milk (FDA/CFSAN, 2001a).

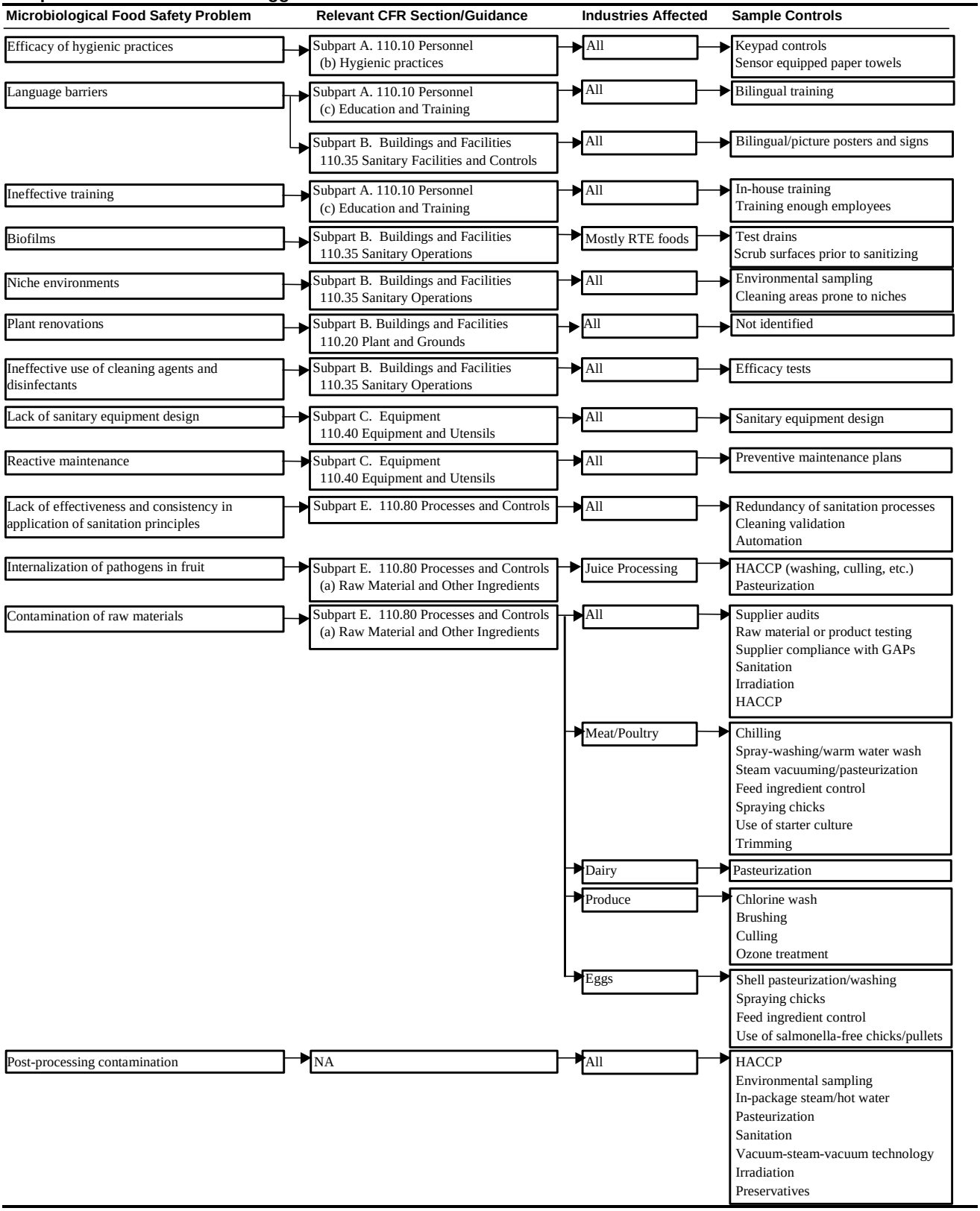
Ineffective application of sanitation principles. It may be difficult for a food processor to apply sanitation principles consistently and effectively to each batch of product. Food processors have found that improving the effectiveness of sanitation principles is dependent on using redundant processing controls (FDA/CFSAN, 1999c). Validation of cleaning processes may also be necessary. Automation that makes it unnecessary for humans to conduct the cleaning, such as robotic spray washers, may also improve sanitation. The extent to which these practices are used in the industry is unclear and should be explored with industry experts.

Internalization of pathogens in fruit. Fruit is usually contaminated by direct or indirect contact with animal feces. Studies have shown that pathogens can infiltrate fruit through damaged or decayed areas or through the flower end of the fruit (FDA/CFSAN, 1999a; FDA/CFSAN, 1999b; FDA/CFSAN, 1999c). While employing best control practices—such as not using dropped fruit, removing damaged fruit, and washing/brushing fruit prior to processing—minimizes these risks, the problem can only be controlled with some certainty by a kill step, such as pasteurization. Other possible controls are listed in the *FDA Report of 1997 Inspections of Fresh, Unpasteurized Apple Cider Manufacturers* and listed again in the annotated bibliography.

Contamination of raw materials. Many pathogens, like *E. coli* and *Salmonella*, enter the food processing environment via raw materials contaminated with those pathogens. A number of studies have shown that methods currently in place to prevent this are not sufficient (FDA/CFSAN, 1999a; FDA/CFSAN, 1999b; FDA/CFSAN, 1999c; Riordan et al., 2001; Tilden et al., 2002). Raw material contamination can affect any industry, but is more common in industries that use animal-derived products or products at risk of cross-contamination by animal feces. There are numerous preventive controls available to address the hazard. Some controls minimize the risks of raw material contamination (i.e., ensuring that raw material suppliers comply with good agricultural practices) and others (i.e., irradiation, pasteurization) involve a kill-step to eliminate any pathogens.

Post-processing contamination. Products can also be contaminated if the post-processing environment, utensils, or equipment have been contaminated with a pathogen. This issue is especially relevant to the pathogen *Listeria monocytogenes*, due to its hardiness and pervasiveness in the environment. Effective controls against post-process contamination include eliminating the pathogen from the post-processing environment by using environmental sampling to eliminate niches, effective sanitation, and various in-package pasteurization methods. Use of preservatives, such as nisin, to slow down the growth of *Listeria monocytogene* are also becoming more common.

Figure 2-1: Microbiological Safety Problems, Related CFR Section or Guidance, Industries Affected, and Sample Preventive Controls Suggested



2.2 Chemical Safety

Chemical safety hazards include intentionally added chemicals (e.g., allergens), unintentionally added chemicals (e.g., cleaners and solvents), and natural toxins (e.g., mycotoxins). Chemicals can also contaminate food through corrosion of metal processing equipment/utensils and residues of cleaning chemicals left on processing equipment. Further, adding too much of an approved ingredient, such as a vitamin in vitamin-fortified products, may compromise the safety of foods.

Raw material contamination with pesticides. FDA has found that roughly 1 percent of sampled domestic produce has pesticide residue in violation of EPA standards (FDA/CFSAN, 2002). While the incidence of contamination is low, consumers remain concerned about pesticide residues. Aside from washing and testing the produce, manufacturers can select produce from organic suppliers to avoid raw material contaminated with pesticides. Other alternative farming systems, such as low-input sustainable agriculture (LISA) and integrated pest management, are also control options at the farm level (Moulton, 1992). These systems, which use much less pesticide than conventional agricultural systems, rely on biological, chemical, cultural, and physical principles and tools to control pests throughout the farming operation. Other preventive control options may include genetic engineering with resistance against pests or developing safer chemicals (Moulton, 1992).

Indiscriminate spraying of facilities against pests. Chemicals can contaminate food if pesticides against insects and rodents are used indiscriminately in a processing facility. Therefore, food experts generally recommend that pest control be performed only by professionals to avoid residues in food (Folks, 2001).

Mistaken identity of pesticides. Food can become contaminated with pesticides if pesticide container labels are misread or when products are stored in containers that have had another use. The best way to control the risk of mistaken identity is to store pesticides away from food ingredients, keep an inventory of pesticides, and store the products in their original containers (Tybor, 1990; Folks, 2001; Bryan, 1997).

Spillage of pesticides or other chemicals. Pesticides should be handled like poisons to avoid potential spillage. Storing chemicals away from food and packaging materials will minimize accidental spillage of pesticides and other chemicals (Tybor, 1990). Further, processors should only use food-grade lubricants and greases in manufacturing.

Corrosion of metal containers/equipment/utensils. Metal poisoning can occur when heavy metals leach into food from equipment, containers, or utensils. When highly acidic foods (e.g., citrus fruits, fruit drinks, fruit pie fillings, tomato products, sauerkraut, or carbonated beverages) come into contact with potentially corrosive materials, the metals can leach into the food (Tybor, 1990). One solution to the problem is to use appropriate, non-corrosive materials in food processing.

Residue from cleaning and sanitizing. If equipment and other food handling materials are not rinsed well, then residue from detergents, cleaning compounds, drain cleaners, polishers, and sanitizers can contaminate a food product. This problem can best be controlled by properly training personnel about cleaning and sanitizing (Folks, 2001; Tybor, 1990).

Accidentally adding too much of an approved ingredient. Some substances, such as preservatives, nutritional additives, color additives, and flavor enhancers, are intentionally added to food products. But adding an approved ingredient in inordinate amounts by accident—such as adding too much nitrite to cured meat—can result in a toxic product (Bryan et al., 1997). Thus, Tybor (1990) recommends that nitrite be stored in a locked cabinet and weighed and bagged separately before being added to any product. Nutritional safety issues can also arise when product labels' nutrition information is incorrect. Thus, it can be dangerous to public health when too little or too much of a specified nutrient is added. For example, malnutrition can occur if infant formula does not deliver the expected nutrient content during its shelf life. Due to the risk involved, infant formula quality control procedures and labeling requirements are addressed outside of GMPs in 21 CFR 106 and 107, respectively. There are also many examples of nutritional food safety issues arising when too much of a nutrient gets added to a product unintentionally. For example, some vitamins that are added to fortified foods (such as Vitamin A) are known to be toxic at high doses. And iron, a necessary dietary component, can cause severe illness and death if too much is ingested. Controlling chemicals by keeping an inventory of additives minimizes the occurrence of this type of contamination (Folks, 2001).

Natural toxins. Food can be contaminated with naturally occurring chemicals that cause disease. Toxins such as mycotoxins (discussed further below) and marine toxins are naturally produced under certain conditions. Given that these toxins generally occur in raw materials, especially crops and seafood, manufacturers should require suppliers to certify hat the products they purchase are free from natural toxins.

Cross-contamination with allergens on production lines. A product can become cross-contaminated with allergens on the production line. To minimize the risk of cross-contamination, equipment must be cleaned and sanitized to remove all traces of allergens when the next run includes product that should not contain allergens (Minnesota Department of Agriculture, 2003). Wash-down techniques may need adjustment to ensure that they remove allergens as well as pathogens (Higgins, 2000). Rinsing with water only or only cleaning at the end of the day is not adequate (FDA/CFSAN, 2001a). Some equipment may need to be disassembled to be cleaned. The cleaning process should be verified by visual inspection. Enzyme-linked immunosorbent assay (ELISA) tests can also help verify cleaning procedures (Deibel et al., 1997; Morris, 2002). Manufacturers may choose to physically separate lines for allergen- and nonallergen-containing products (Morris, 2002). This may be too costly for most plants; scheduling longer production runs to minimize changeovers, with allergen-containing product runs scheduled at the end of the day, may be a more suitable alternative (Deibel et al., 1997; FDA/CFSAN, 2001b; Floyd, 2000; Gregerson, 2003; Minnesota Department of Agriculture, 2003; Morris, 2002). Crossover points on production lines, including conveyor belts that transport products, should be enclosed to prevent cross-contamination. Physical detachments and lockouts can be used for equipment common to allergen- and nonallergen-containing foods (Deibel et al., 1997). Maintenance tools should be color-coded to prevent cross-contamination (FDA/CFSAN, 2001b; Morris, 2002). Allergenic materials should be stored separately from nonallergenic materials, with dedicated utensils and containers. Putting all of the ingredients for a specific batch on a pallet before taking them to the processing area, or "staging," will also minimize the risk of cross-contamination. Line clearance, such as removing all the ingredients from the production area and checking for cleanliness, can also help prevent cross-contamination (Floyd, 2000). Product can also be tested for the presence of allergens, although this does not appear to be a common industry practice (FDA/CFSAN, 2001a). Finally, allergens should be evaluated as part of a hazard analysis, and a HACCP plan or similar approach can be taken to identify process areas that are at high risk for contamination with allergens (Morris, 2002).

Raw material contamination with allergens. When controlling a production process for allergens, manufacturers must maintain a close working relationship with suppliers of raw materials. The ingredient specification should provide assurance that the product is allergen free (Deibel et al., 1997; FDA/CFSAN, 2001c). Manufacturers should also obtain full ingredient lists from their suppliers (Deibel et al., 1997; Gregerson, 2003). Reconditioned ingredients and oils should not be purchased (Minnesota Department of Agriculture, 2003). The manufacturer should also audit suppliers each year to determine other products that are run on the same production line, whether any allergenic processing aids or rework have been used in the product, and whether any contamination from other common equipment could have occurred

(Gregerson, 2003). A training program may be necessary to educate suppliers about allergen control, especially if suppliers have not implemented an allergen control plan (Deibel et al., 1997, Minnesota Department of Agriculture, 2003).

Contamination with allergens by utilization of rework. Proper use of rework is essential to prevent contamination of product with allergens. A documented rework plan should be available. Rework areas, equipment, and containers must be clearly identified and documented, as well as the rework itself (Deibel et al., 1997; Gregerson, 2003). This can be done through the use of color tags, plastic liners, or bar coding.

Not declaring an allergen on labeling. Unavoidable product contamination with allergens may occur if it is impossible to verify that all residue has been removed from a line or if other controls cannot be put in place (Floyd, 2000). A good manufacturing practice includes reviewing the labeling to ensure that the allergen is declared. However, a study of inspections conducted by FDA/ CFSAN (2001a) indicated that many firms do not have label review policies. Further, a large percentage of these manufacturers had undeclared allergens in their products. Controls to prevent this problem can include removing old label and packaging inventories from plants, verifying labels by scanning bar codes, and conducting label audits (FDA/CFSAN, 2001b; FDA/CFSAN, 2001c; Minnesota Department of Agriculture, 2003).

Older equipment. Effective cleaning is paramount to controlling allergen contamination. Older equipment, however, may not be designed to verify cleaning with a visual inspection (Deibel et al., 1997). As noted in the section on microbiological issues and controls, all parts of the equipment should be readily accessible and visible for cleaning and sanitation to be effective. Further, equipment surfaces should not harbor allergens. Gregerson (2003) reports one such case in which cross-contamination with allergens occurred due to the surface nicks on the processing table. Thus, sanitary equipment design is necessary to ensure proper removal of allergens from equipment.

Infestation of mycotoxins due to drought. Toxigenic fungi, or mycotoxins, are found primarily in foods of plant origin, although they can also pass through the food chain in milk and meat. Drought can encourage the growth of mycotoxins in certain crops. For example, drought stress can cause aflatoxin, a type of mycotoxin, to grow in corn and treenuts (Moss, 2002). Drought can be minimized through adequate irrigation schedules (Park et al., 1999). Thermal and chemical treatments are also available for use on crop that is already affected by mycotoxins (Park et al., 1999). Thermal inactivation, however, is

not effective on certain types of mycotoxins, such as aflatoxin. Chemical treatments, such as ammoniation and activated carbons and clays, are other possible controls (Boutrif, 1999; Horne et al., 1989; Park et al., 1999; Suttajit, 1989).

Infestation of mycotoxins due to damage. Insect damage is associated with high levels of mycotoxin infection, as is mechanical damage from harvesters (Boutrif, 1999; Moss, 2002; Park et al., 1999). Diseases, such as ear rot in corn, also cause damage that leaves the crop susceptible to mycotoxin infestation (Moss, 2002). Delayed harvesting can also make crops more susceptible to disease due to higher moisture levels (Park et al., 1999). Damage to the product, whether through insect feeding or mechanical harvesters, provides a potential entry point for the mold that produces the mycotoxin. Controls available include pest management to prevent insect damage, breeding cultivars that are resistant to pest damage, timely harvesting, hand picking or electronic sorting to remove damaged crops, and thermal or chemical treatment as noted above (Boutrif, 1999; Moss, 2002; Park et al., 1999; Suttajit, 1989). Possible biological control of insects and diseases in the field is also being investigated (Moss, 2002).

Infestation of mycotoxins due to moisture/heat during storage. Post-harvest storage that protects the product from heat and moisture is essential to prevent mycotoxin infestation (Boutrif, 1999). Grains should be dried as soon as feasible, and storage under modified atmospheric conditions is desirable (GASCA/CTA, 1997). Products should be dried rapidly to less than 10 percent moisture (Park et al., 1999). Products can also be sampled for mycotoxins during storage (Boutrif, 1999). Methods include visual inspection with black light, ELISA tests, and complex laboratory analysis using high-pressure liquid chromatography (Horne et al., 1989). While prevention with proper storage conditions is the best way to control mycotoxin infestation, thermal and chemical inactivation, as described earlier, can control any mycotoxins that do form under storage.

Patulin production in apples. Patulin is a mycotoxin that is produced by a number of molds associated with fruit spoilage (Bisessur et al., 2001). Control methods often used in the production of apple juice include using tree-picked apples, culling apples, washing apples, charcoal treatment, chemical preservation using sulfur dioxide, gamma radiation, fermentation, trimming of fungus-infected apples, and clarification methods (Bisessur et al., 2001; Jackson, et al., 2003).

Figure 2-2: Chemical Safety Problems, Related CFR Section or Guidance, Industries Affected, and Sample Preventive Controls Suggested

Chemical Food Safety Problem	Relevant CFR Section/Guidance	Industries Affected	Sample Controls
Pesticides: Raw material contamination with pesticides	Subpart E 110.80 Processes and Controls (a)(1) Raw materials and other	All	Organic production systems Integrated pest management Low-input sustainable agriculture Development of safer chemicals Genetically engineered pest-resistant plants Washing and testing produce
Pesticides: Indiscriminate spraying of facilities against pests	Subpart B 110.35 Sanitary Operations (c) Pest control	All	Professional pest control
Pesticides: Mistaken identity of pesticides	Subpart B 110.35 Sanitary Operations (b) (2) Storage of toxic chemicals	All	Maintain pesticides in original containers Keep inventory of pesticides in a secure, supervised area, separated from food
Pesticides: Spillage of pesticides	Subpart B 110.35 Sanitary Operations (b)(2) Storage of toxic chemicals	All	Store pesticides away from food/packaging Handle like poison Use only food-grade greases and lubricants
Metals: Corrosion of containers/equipment/utensils	Subpart E 110.80 Processes and Controls (b)(7) Manufacturing operations	All	Use equipment that does not corrode with acidic foods
Cleaning chemicals: Residue from cleaning and sanitizing	Subpart B 110.35 Sanitary Operations (a) General maintenance	All	Train personnel about cleaning and sanitizing
Approved ingredients: Accidentally adding too much of an approved ingredient	Subpart E 110.80 Processes and Controls	All	Keep an inventory of additives
Toxins: Natural toxins	Subpart E 110.80 Processes and Controls (a)(3) Raw materials and other ingredients	Various crops and seafood	Certification of product by supplier
Allergens: Cross-contamination with allergens on production line	Federal Food, Drug and Cosmetics Act Section 402 (a)(4) Insanitary conditions	All	Adequate cleaning and sanitizing Separate production lines Run allergen-containing product at end of day Long production runs Verification of cleaning Physical lockouts or detachments Staging areas Line clearance Color code maintenance tools Employee training Crossover points should be contained HACCP
Allergens: Raw material contamination with allergen	Federal Food, Drug and Cosmetics Act Section 402 (a)(4) Insanitary conditions	All	Maintain close working relationship with supplier On-site audits of material suppliers Allergen training for suppliers Ensure that suppliers have implemented documented an allergen prevention plan Do not purchase reconditioned ingredients HACCP
Allergens: Contamination by utilization of rework	Federal Food, Drug and Cosmetics Act Section 402 (a)(4) Insanitary conditions	All	Clearly identify and document rework Documented rework plan HACCP
Allergens: Incorrect labeling or packaging	Federal Food, Drug and Cosmetics Act Section 402 (a)(4) Insanitary conditions	All	Verify labels and packaging with bar code scanners Discard old labels and packaging Conduct label audits HACCP Label verification policies and procedures

Figure 2-2 cont.: Chemical Safety Problems, Related CFR Section or Guidance, Industries Affected, and Sample Preventive Controls Suggested

Chemical Food Safety Problem	Relevant CFR Section/Guidance	Industries Affected	Sample Controls
Allergens: Older equipment harder to clean	Federal Food, Drug and Cosmetics Act Section 402 (a)(4) Insanitary conditions	All	Sanitary equipment design
Mycotoxins: Infestation due to drought	Subpart E 110.80 Processes and Controls (a)(3) Raw materials and other ingredients	Various crops (mostly grains, corn, peanuts, treenuts)	Adequate irrigation schedules Chemical/thermal inactivation
Mycotoxins: Infestation due to insect damage	Subpart E 110.80 Processes and Controls (a)(3) Raw materials and other ingredients	Various crops (mostly grains, corn, peanuts, treenuts)	Pest management Breed cultivars resistant to pest damage Electronic sorting Handpicking Chemical/thermal inactivation Biological control in the field Timely harvesting
Mycotoxins: Infestation due to moisture/heat during storage	Subpart E 110.80 Processes and Controls (a)(3) Raw materials and other ingredients	Various crops (mostly grains, corn, peanuts, treenuts)	Controlled atmospheric storage Dry grain as soon as possible Chemical/thermal inactivation Testing/sampling for mycotoxins
Mycotoxins: Patulin production in apples	Subpart E 110.80 Processes and Controls (a)(3) Raw materials and other ingredients	Apple juice	Charcoal treatment Sulfur dioxide treatment Gamma irradiation Fermentation Clarification methods (pressing, centrifugation, fining, enzyme treatment, and filtration) Use tree-picked and culled apples

2.3 Physical Safety

Materials that do not belong in food, like glass or metal, cause physical safety hazards. A physical safety hazard is any extraneous object or foreign matter in food that can cause injury or illness in the person consuming the product (Folks, 2001). Rocks, metal, wood, and other objects are sometimes found in raw ingredients. Further, contamination can occur during transport, processing, and distribution of foods due to equipment failure, accidents, or negligence (Institute of Medicine/National Research Council, 1998). Separation equipment should be used to separate the foreign bodies from the product. Detection methods include metal detectors, x-ray machines, and optical systems (Wallin and Haycock, 1998).

Foreign matter in raw materials. Sources of foreign matter in raw materials can include nails from pallets and boxes, ingested metal from animals, harvesting machinery parts, elements from the field, veterinary instruments, caps, lids, closures, and more (Wallin and Haycock, 1998). Mechanical harvesters will often collect more than the product. Processors can include separation equipment, such as destoners, air cleaners, magnets, screens, sieves, traps, scalpers, and washers as part of their production lines. For example, grain processors use four screens to remove foreign materials (Stier, 2001). Foreign matter in

raw materials can be controlled with raw material inspections and vendor certifications or guarantees from suppliers. X-ray technology is also available to examine incoming material (Folks, 2001).

Poorly maintained equipment and lines. Pieces of equipment can break off and enter food products during processing if equipment is poorly maintained. Routine or preventive maintenance and other periodic checks of equipment can minimize the risk from this safety issue. Risk is further minimized with the use of metal detectors and x-ray machinery. Proper calibration of equipment and minimizing contact between pieces of machinery is also helpful (Folks, 2001; Stier, 2001).

Lighting fixture/other glass breakage. Glass can be controlled by having a glass breakage policy, such as throwing away all food and containers within 10 feet of the incident (Stier, 2001). Light fixtures can be protected so that if they break, the glass does not spill out (Folks, 2001). Other controls include examining of empty glass containers visually or cleaning a container with water or compressed air and inverting the container to remove any shards. Capping equipment should be properly calibrated and lines should be monitored for evidence of glass breakage. X-ray technology can also be helpful in identifying glass pieces in food (Olson, 2002).

Human factors. Production line workers can be a major source of contamination. For example, jewelry can fall off or break, fingernails can break, and pens can fall into food. Jewelry removal is required under GMPs. If pens are metallic, a metal detector can detect them. Production workers' fingernails should be cut short and gloves should be worn under certain processing conditions.

Introduction of foreign matter during storage. Pests can enter products during storage, leaving remnants behind. Effective pest control is the solution. It can include preventive measures such as filling in all non-functional openings in a building; fully sealing doors, windows, and vents; protecting intake points with filters or grills; and protecting drains and other facility intakes and exits. Professional extermination is needed once pests have established. UV light traps can also be used, although they need to be designed to prevent further contamination from the tray that collects the insect remains (Wallin and Haycock, 1998).

Figure 2-3. Physical Safety Problems, Related CFR Section or Guidance, Industries Affected, and Sample Preventive Controls Suggested

Physical Food Safety Problem	Relevant CFR Section/Guidance	Industries Affected	Sample Controls
Foreign matter in raw materials	Subpart E 110.80 Processes and Controls (b)(8) Measures against extraneous material GAPs	All	Raw material inspection and specification Vendor certification/letters of guarantee Destoners Magnets Screens Washers X-ray technology
Poorly maintained equipment and lines	Subpart E 110.80 Processes and Controls (b)(8) Measures against extraneous material Subpart E 110.40 Equipment and Utensils (a) Maintenance	All	Metal detectors X-ray technology Proper maintenance and calibration of detection equipment Controlling contact between pieces of machinery Passing product through separation equipment
Light fixture or other glass breakage	Subpart E 110.80 Processes and Controls (b)(8) Measures against extraneous material Subpart E 110.20 Plant and Grounds (5) Lighting	All	Shield light Glass breakage policy Glass scanners Monitoring lines for glass breakage Proper adjustment of capping equipment Visual examination of containers Cleaning containers with water/compressed air and inverting X-ray technology
Introduction of foreign matter during storage	Subpart B 110.35 Sanitary Operations (c) Pest Control	All	Pest control

2.4 Other Considerations

There is a wide range of issues related to the safety and wholesomeness of food in addition to GMPs. These should be considered in addition to the problems identified at the food processing level when evaluating the effectiveness of food GMPs. They include the following and are discussed in more detail below:

- New trends contributing to foodborne illness,
- Most common causes of foodborne illness,
- High-risk foods, and
- Role of market incentives

New trends contributing to foodborne illness. A number of recent trends contribute to the incidence of foodborne illness. For example, in recent years, there has been an increase in consumer

purchases of ready-to-eat (RTE) foods, made popular by the busy lifestyles of people today. Many cases of foodborne illness are caused by RTE foods that were cross contaminated with pathogenic bacteria. Since RTE foods are generally not cooked prior to consumption, the likelihood of foodborne illness is high when these products are contaminated.

Another alerting trend is the increase in new and drug-resistant infectious foodborne agents since the GMPs were last revised. *Listeria monocytogenes* and *Cryptosporidium* are examples of newly recognized agents that has been of great concern in the last few years. Some pathogens have also shown antimicrobial resistance, such as *Campylobacter jejuni* and *Salmonella typhimurium* DT104. There is also evidence of well-known viruses, such as hepatitis A and *Salmonella entertidis*, appearing in new foods like produce (Institute of Medicine/National Research Council, 1998). The evolution of these new agents and new vehicles transmitting known pathogens makes prevention of food contamination a moving target for those in charge of ensuring food safety.

The aging population in the United States is another trend of concern: this group is at higher risk for developing illness from contaminated food. As the baby boomer generation enters their retirement years, one can expect this trend to become even more pronounced. These and other changes over time significantly increase the risk of contracting foodborne illness, necessitating a new look at food GMPs in light of these factors.

Most common causes of foodborne illness. Pathogenic bacteria are the most commonly reported agents of foodborne illness, closely followed by viruses (CDC, 2004). Further, most reported cases of foodborne illness are attributable to poor handling at the home or at retail food establishments rather than failures at the food processing level (CDC, 2000). It is not possible to determine (with certainty) the cause of foodborne illness in roughly 50 percent of all foodborne illness cases. Moreover, many foodborne illness cases go unreported.

High-risk foods. The level of risk to public health varies by type of food. Some food products, such as refrigerated RTE foods, have a higher risk of being contaminated by pathogenic bacteria (e.g., *Listeria monocytogenes*) than others, such as frozen RTE products (NFPA, undated). Further, FDA/CFSAN (2001a) has also shown in their *Listeria monocytogenes* risk assessment that the level of risk varies for different types of RTE foods. Therefore, from a risk perspective, indiscriminate application and/or recommendation of controls and policies may unduly burden manufacturers as well as the FDA and in some cases lead to inadvertent outcomes. For example, under the current zero-tolerance policy of

the Food Safety and Inspection Service (FSIS) for *Listeria monocytogenes*, when a plant's testing program detects *Listeria monocytogenes* on plant equipment, the plant is required to recall all product produced on that line during the period of contamination. FSIS may also obtain test data if a plant has a suspected problem with *Listeria monocytogenes.* While there is a consensus in the industry that aggressive environmental monitoring is essential to controlling *Listeria monocytogenes*, Tompkin (2002) argues that the zero-tolerance policy discourages, rather than encourages, the RTE food industry from confirming the presence of *Listeria monocytogenes* in their environmental sampling programs. Many companies may conduct less (rather than more) aggressive environmental monitoring and product testing to avoid regulatory conflict.

Role of market incentives. FSIS is required to inspect meat and poultry slaughtering and processing plants carcass by carcass. As a result of the continuous inspection requirements, FSIS's inspection budget is four times that of FDA (Institute of Medicine/National Research Council, 1998). The lack of inspection resources may contribute to less enforcement of food safety statutes under FDA's jurisdiction. Given the lack of resources, it is important to evaluate the role of other, non-regulatory incentives that encourage food safety. For example, food safety problems can be a major liability for manufacturers of brand name products. If food is said to be unsafe, these manufacturers can face a huge public relations crisis that will negatively affect their bottom line (Ballenger and Ollinger, 2003). Consumers may also shun an entire category of food (Institute of Medicine/National Research Council, 1998). Most producers of branded products, therefore, invest more to ensure the safety of the food they produce. Grocery stores and wholesalers also require strict food safety controls from their suppliers to protect their reputations. For example, USDA's Economic Research Service (ERS) researchers recently surveyed 1,000 slaughtering plants and found that contractual agreements covering food safety standards result in higher levels of food safety with regards to equipment, testing, dehiding, sanitation, and operating procedures (Ballenger and Ollinger, 2003). A similar study for FDA-regulated products may yield comparable results.

References

American Meat Institute (AMI). 2003. Sanitary Equipment Design. *AMI Fact Sheet.* March.

Ballenger, Nicole, and Michael Ollinger. 2003. Weighing Incentives for Food Safety in Meat and Poultry. *Amber Waves.* USDA/ERS, Washington, DC. April.

Bissessur, J., K. Permaul, and B. Odhav. 2001. Reduction of Patulin During Apple Juice Clarification. *Journal of Food Protection.* Vol. 64, No. 8.

Blackburn, Clive de W., and Peter J. McClure. 2002. *Foodborne Pathogens: Hazards, Risk Analysis, and Control*. CRC Press, Washington, DC.

Boutrif, Ezzeddine. 1999. Minimizing Mycotoxin Risks Using HACCP - The Cracker. *International Tree Nut Council.* September.

Bryan, Frank L., John J. Guzewich, and Ewen C.D. Todd. 1997. Surveillance of Foodborne Disease III. Summary and Presentation of Data on Vehicles and Contributory Factors; Their Value and Limitation. *Journal of Food Protection.* Vol. 60, No. 6: 701-714.

CDC. 2004. 2002 Summary Statistics: The Total Number of Foodborne Disease Outbreaks by Etiology. *Foodborne Outbreak Response and Surveillance Unit.* http://www.cdc.gov/foodborneoutbreaks/us_outb/fbo2002/summary02.htm.

CDC. 2000. Surveillance for Foodborne Disease Outbreaks—United States, 1993–1997. *MMWR Surveillance Summaries.* Vol. 49 (SS01):1-51. March 17.

Deibel, Kurt, Tom Trautman, Tom DeBoom, William H. Sveum, George Dunaif, Virginia N. Scott, and Dane T. Bernard. 1997. A Comprehensive Approach to Reducing the Risk of Allergens in Food. *Journal of Food Protection.* Vol. 60, No. 4: 436-441.

FDA/CFSAN. 2002. Food and Drug Administration Pesticide Program: Residue Monitoring 2000. Washington, DC. May.

FDA/CFSAN. 2001a. *Draft Assessment of the Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods*. January.

FDA/CFSAN. 2001b. *Seafood HACCP Alliance HACCP Training Curriculum Manual: Hazards – Biological, Chemical, and Physical (Chapter 2)*. November.

FDA/CFSAN. 2001c. *Analysis and Evaluation of Preventive Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-cut Produce*. September 30.

FDA/CFSAN. 1999a. *Potential for Infiltration, Survival, and Growth of Human Pathogens within Fruits and Vegetables*. November.

FDA/CFSAN. 1999b. *Preliminary Studies on the Potential for Infiltration, Growth, and Survival of Salmonella enterica Hartford and Escherichia coli O157:H7 Within Oranges*. November.

FDA/CFSAN. 1999c. *Report of 1997 Inspections of Fresh, Unpasteurized Apple Cider Manufacturers*. January.

Floyd, Bruce M. 2000. Battling Allergen Contamination. *Food Product Design.* December.

Folks, Heather, and Dennis Burson. 2001. *Food Safety: Chemical Hazards*. University of Nebraska Cooperative Extension.

GASGA/CTA. 1997. Mycotoxins in Grains. *Technical Leaflet*. No. 3. June.

Gregerson, John. 2003. Plain Talk About Allergen Management. *Food Processing.* January 29.

Gregerson, John. 2002. Third Annual Best Manufacturing Practices Survey. *Food Engineering.* February.

Gould, William A. 1994. *CGMP's/Food Plant Sanitation*. CTI Publications, Inc., Timonium, MD.

Higgins, Kevin T. 2003. Food Safety: Say Goodbye to the Burn. *Food Engineering.* January.

Higgins, Kevin T. 2002. The Culture of Clean. *Dairy Foods.* November.

Higgins, Kevin T. 2000. A Practical Approach to Allergen Control. *Food Engineering.* July.

Horne, C.W., L.L. Boleman, C.G. Coffman, J.H. Denton, and D.B. Lawhorn. 1989. Mycotoxins in Feed and Food Producing Crops. *U.S. National Dairy Database.* http://www.mda.state.mn.us/dairyfood/mfgallergens.htm.

Institute of Medicine. 2001. Food Safety Policy, Science, and Risk Assessment: Strengthening the Connection. *Food Forum Workshop Proceedings.* National Academy Press, Washington, DC.

Institute of Medicine/National Research Council. 1998. *Ensuring Safe Food.* National Academy Press, Washington, DC.

Jackson, Lauren S.,, Tina Beacham-Bowden, Susanne E. Keller, Chaitali Adhikari, Kirk T. Taylor, Stewart J. Chirtel, and Robert I. Merker. 2003. Apple Quality, Storage, and Washing Treatments Affect Patulin Levels in Apple Cider. *Journal of Food Protection*. Vol. 66, No. 4.

Minnesota Department of Agriculture. 2003. Managing Food Allergen Risks. http://www.mda.state.mn.us/dairyfood/mfgallergens.htm.

Morris, Charles E. 2002. Best Practices for Allergen Control. *Food Engineering.* March.

Moss, Maurice. 2002. Toxigenic Fungi. In *Foodborne Pathogens: Hazards, Risk Analysis and Control* edited by Clive de W. Blackburn and Peter J. McClure. Woodhead Publishing Limited and CRC Press LLC. Boca Raton, FL.

Moulton, Curtis J. 1992. Reducing Pesticide Residues in Food. *Food Safety and Quality.* June.

Muth, Mary K., Shawn A. Karns, and Donald W. Anderson. 2001. *Analysis of Hazard Analysis Critical Control Point (HACCP) Survey Data*. RTI. Prepared for FDA Center for Food Safety and Applied Nutrition. May.

NFPA/AMI/NTF/NCC/NMA/NAMP/SMA/AAMP. 2000. *Meat and Poultry Listeria Reassessment Survey*. Presentation provided to ERG by Jenny Scott, Senior Director, Food Safety Programs, National Food Processors Association, on May 27, 2003.

National Food Processors Association (NFPA). Undated. *Industry Position on Control of Listeria Monocytogenes, With Emphasis on Meat and Poultry Products*. National Food Processors Association. www.nfpa-food.org.

Olson, Alan R. 2002. Hard or Sharp Objects. *Compendium of Fish, Fishery Product Processes, Hazards, and Controls.* October.

Park, Douglas L., Henry Njapau, and E. Boutrif. 1999. Minimizing Risks Posed by Mycotoxins Utilizing the HACCP Concept. *Food, Nutrition, and Agriculture.* No. 23.

Riordan, D. C. R., G. M. Sapers, T. R. Hankinson, M. Magee, A. M. Mattrazzo, and B. A. Annous. 2001. A Study of U.S. Orchards To Identify Potential Sources of *Escherichia coli* O157:H7. *Journal of Food Protection.* Vol. 64, No. 9: 1320-1327.

Stier, Richard F. 2001. Foreign Materials in Foods: Are They Really Dangerous? *Market Pulse.*

Stopforth, J.D., J. Samelis, J. N. Sofos, P. A. Kendall , and G. C. Smith.. 2002. Biofilm Formation by Acid-Adapted and Nonadapted *Listeria monocytogenes* in Fresh Beef Decontamination Washings and Its Subsequent Inactivation with Sanitizers. *Journal of Food Protection.* Vol. 65, No. 11: 1717-1727.

Suttajit, Maitree. 1989. Prevention and Control of Mycotoxins. *Mycotoxin Prevention and Control in Foodgrains.*

Tilden, John Jr., Wallace Young, Ann-Marie McNamara, Carl Custer, Barbara Boesel, Mary Ann Lambert-Fair, Jesse Majkowski, Dur Vaga, S. B. Werner, Jill Hollingsworth, and J. Glenn Morris. 2002. A New Route of Transmission for *Escherichia coli*: Infection from Dry Fermented Salami. *American Journal of Public Health.* Vol. 85, No. 8: 1142-1145.

Tompkin, R.B. 2002. Control of *Listeria monocytogenes* in the Food Processing Environment. *Journal of Food Protection.* Vol. 65, No. 4: 709-725.

Tybor, Phillip T., William C. Hurst, A. Estes Reynolds, and George A. Schuler. 1990. Preventing Chemical Foodborne Illness. *The University of Georgia College of Agricultural and Environmental Sciences Cooperative Extension Service.* November. http://www.ces.uga.edu/pubcd/b1042-w.html.

Wallin, P., and P. Haycock. 1998. Good Manufacturing Practice (GMP). In *Foreign Body Prevention, Detection, and Control.* Blackie Academic and Professional, London.

SECTION THREE

PREVIOUS SURVEYS OF MANUFACTURING PRACTICES IN THE FOOD INDUSTRY

In the last few years, a number of surveys have evaluated the state of current manufacturing practices in the food industry. Although most of these surveys are limited in scope, the combined data may assist FDA in identifying various areas of concern and in supporting its own findings regarding food safety practices of the industry. For example, results from several of the surveys indicate that small manufacturers are less likely to have certain food safety practices in place than larger manufacturers. The importance of employee training also appears to be a common theme in some of the survey results.

Table 3-1 summarizes the characteristics of eight industry surveys identified, including survey mode, sample size, and response rate. The following sections discuss the findings of each survey in more detail.

3.1 Meat and Poultry *Listeria* Reassessment Survey

The Meat and Poultry *Listeria* Reassessment Survey was designed to determine the industry response to a 1999 Federal Register (FR) Notice requesting that meat and poultry plants reassess their Hazard Analysis and Critical Control Point (HACCP) plans for *Listeria monocytogenes* (*Lm)* contamination control (Federal Register 64, 1999). The survey was sponsored by the American Association of Meat Processors (AMI), National Chicken Council (NCI), National Meat Association (NMA), North American Meat Processors (NAMP), American Meat Institute (AMI), National Food Processors Association (NFPA), and National Turkey Federation (NTF), whose members answered a three-page questionnaire on their response to the 1999 FR Notice. Survey respondents included mostly small or very small establishments. Only one-third of the survey respondents were large establishments.

Survey results showed that almost all establishments (98 percent) responded to the 1999 FR notice with a reassessment of their HACCP plans for *Lm* contamination control. More than a third of the responding plants indicated adding critical control points. In addition, roughly two-thirds of plants reported having end-product testing programs for *Lm* and almost all plants (90 percent) reported using environmental testing. Among all responding plants, very small plants conducted the least testing. Survey

Table 3-1: Industry Surveys of Manufacturing Practices

Year	Mode	Sample Frame	Response Rate
Meat and Poultry *Listeria* Reassessment Survey (NFPA et al., 2000)			
2000	Mail	Trade group member companies	91% (277/303)
Evaluation Report *Listeria* Reassessment (USDA/FSIS, 2000)			
2000	Email	30 Randomly selected large and small food plants	NA
Food Processing 2002 Manufacturing Trends Survey (Ennen, 2002)			
2002l	Email	Readers	NA
Food Processing 2003 Manufacturing Trends Survey (Ennen, 2003)			
2003	Email	Readers	NA
Food Processing 2004 Manufacturing Trends Survey (Fusaro, 2004)			
2004	Email	149 Readers from circulation list	NA
3rd Annual Best Manufacturing Practices Survey (Gregerson, 2002)			
2002	Mail	Readers	13% (130/1,000)
2nd Annual Best Manufacturing Practices Survey (Morris, 2001b)			
2001	Mail	Readers	13% (132/1,000)
1st Annual Best Manufacturing Practices Survey (Morris, 2000a)			
2000	Mail	Readers	11% (112/1,000)
A Survey of Automation Practices in the Food Industry (Ilyukhin et al., 2001a)			
2001	Mail	U.S. food manufacturers (as well as system integrators and equipment suppliers)	54% (27/50)
A Survey of Control System Validation Practices in the Food Industry (Ilyukhin et al., 2001b)			
2001	Mail	U.S. food manufacturers (as well as system integrators and equipment suppliers)	54% (27/50)
A Survey on the Use of Computer-Integrated Manufacturing in Food Processing Companies (Aly, 1989)			
1989	Mail	Food processing companies in central California	32% (31/98)
FDA HACCP Survey (Muth et al., 2001)			
2001	Mail/phone	U.S. food manufacturers and repackagers	32% (595/1,142)
Survey of Practices of Maryland Cider Producers (Senkel et al., 1999)			
1999	Mail	U.S. cider producers	100% (11/11)

results also showed that the majority of plants respond in some way when environmental testing limits are exceeded, most commonly by intensifying sanitation. Overall, while most manufacturers had appropriate programs in place prior to the reassessment, many refined their programs as part of reassessment.

3.2 *Listeria* Reassessment—Evaluation Report

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) also conducted a short study of 30 randomly selected large and small plants to investigate activities undertaken in response to the 1999 FR Notice. For the study, FSIS supervisory inspection personnel were questioned by email regarding the actions of plants they inspected.

All 30 of the large and small establishments sampled reviewed their HACCP plans in response to the notice, discussed the notice with plant personnel, and documented their reassessment in their hazard analyses. Approximately three-fourths of the establishments modified their HACCP plans. Of these, half of the plants added or modified critical control points in their HACCP plans, a third added or modified verification activities, and one-fourth added or modified corrective actions. Establishments also viewed *Lm* as a sanitation issue, with about two-thirds of the establishments reviewing their sanitation standard operating procedures (SSOP) programs.

Outside of HACCP and SSOP plans, almost half of plants had taken actions in response to the 1999 FR Notice, such as training, product or environmental testing, adding sanitizers, developing abatement programs, adding floor foamers and citric acid, modifying packaging rooms, adding footbaths, increasing handwashing, providing special clothes, conducting repairs to improve sanitation, doing new construction, and increasing anti-microbial additives. According to the survey, approximately two-thirds of the establishments conduct some form of environmental testing at a minimum on a weekly basis. Fewer than two-thirds typically conduct product testing once per quarter.

3.3 *Food Processing* Magazine's Annual Manufacturing Trends Survey

Each year, *Food Processing* magazine surveys food manufacturing professionals regarding their beliefs about important upcoming issues in the industry and plans for the following year. We reviewed the last three surveys available.

In the 2002 and 2003 surveys, food safety was the top and growing concern, with the events of September 11 having accelerated these concerns. The 2002 survey did not cover many food safety practices, but reported that many of the respondents were increasing security at their plants by securing physical facilities and improving employee identification and surveillance. In 2003, improving security was also a top concern, with 78 percent intent on improving facility security. Roughly half of those

surveyed have added surveillance initiatives and increased background checks during that year. In addition, while the majority of respondents reported responding to the current food safety concern with employee training, roughly three-quarters indicated an intent to either institute a HACCP plan or modify their existing HACCP plan. More than half of the respondents indicated that their companies planned to improve pest control and that they have augmented or will be augmenting, sanitation equipment.

In the 2004 survey, food safety continued to be the top concern for manufacturers. Almost all respondents reported that they would take additional steps to improve food safety, with the majority of respondents mentioning training as the most important factor in improving sanitation. Many respondents also mentioned HACCP programs and improved pest control. Sanitary equipment and rapid microbial detection systems were mentioned less frequently, but many manufacturers use them. Other steps undertaken by food processors to improve food safety included reevaluation of HACCP programs (6.8 percent), improved traceback to suppliers (3.5 percent), bioterrorism training (3.4 percent), and more metal detection (2.7 percent).

3.4 *Food Engineering* Magazine's Annual Best Manufacturing Practices Surveys

Each year, *Food Engineering* magazine surveys its readership to determine current best manufacturing practices. We reviewed the last three surveys available.

Overall, survey results were very similar from year to year. An analysis of survey responses showed that supervised on-the-job training is the most widely used training method in the industry. Other popular methods included onsite classroom training, vendor training programs, and cross-training in various skills. The number of plants practicing reactive maintenance is relatively high across all survey years, oscillating between slightly less than and somewhat more than one-third from year to year. In all years, however, the majority of plants surveyed applied preventive or predictive maintenance programs. In 2000, survey results indicate that HACCP has been voluntarily implemented in more than two-thirds of plants in each industry segment other than meat and poultry, in which HACCP is mandated. However, fewer than 10 percent of plants with HACCP programs had people appointed to manage the HACCP plans; half the plants that did have such managers were meat processors.

The 2002 survey also asked respondents to comment on the efficacy of the practices in use, in addition to providing information on best practices. As might be expected, most respondents (84 percent) characterized their reactive maintenance programs as inefficient. Meanwhile, more than half (56 percent)

of those practicing routine preventive maintenance considered their programs efficient. While anti-microbial treatments and rapid microbial detection systems were not frequently used, plants that used these systems rated them very highly. HACCP programs were rated as very useful, although less so than anti-microbial treatments and rapid microbial detection systems. Few of those employing voluntary HACCP programs expressed disappointment with the programs (2 percent compared to 14 percent of those that implemented mandated HACCP programs). Contrary to other findings, training was only found to be very useful by one-third of plants using it to improve food safety. On the other hand, sanitary equipment was found to be very useful by more than half of plants that recently added such equipment to their locations.

3.5 A Survey of Control System Validation Practices in the Food Industry

Digital control systems, which have increased in use in recent years, require proper validation to prevent serious failures. Ilyukin et al. (2001a) attempted to determine who conducts control system validation at food manufacturing plants and how it is done with an industry survey.

While validation of control systems should be part of a good manufacturing practice program, less than a third of food plants responding to the survey considered themselves responsible for control system validation. The majority of food plants surveyed delegated this responsibility to a third party, such as an equipment supplier, system integrator, or consulting firm. While most food plants that reported not having validation plans would like to establish such plans, up to a quarter indicated that they would never develop them.

Moreover, less than a fifth of food plants reported requesting validation records from the third-party who conducted the validation. Most equipment suppliers and system integrators reported keeping these records and could provide them to their customers. Slightly more than 10 percent of food manufacturers generated and kept validation records themselves. Training on control systems was conducted either by manufacturers (29 percent) or by third-party firms. Roughly one-third of plants surveyed had formal control system maintenance plans in place, and the rest had informal plans.

3.6 Automation Practices in the Food Industry

Ilyukhin et al. (2001b) conducted a survey of food manufacturers, system integrators, and equipment suppliers to determine the state of automation practices in the food industry. The majority (59 percent) of food manufacturers reported that their plants were mostly automated. Ilyukhin (2001b) found that the level of automation was correlated with annual production. Almost all plants with smaller annual production volumes reported a desire to increase automation. The biggest obstacles to automation reported were time and cost.

The level of automation varied by operation. Among the responding plants, processing was automated at 94 percent of food manufacturing operations and packaging was automated at 82 percent. Automation was used in less than half of the plants surveyed for raw material processing, post process handling and inspection, and warehousing and storage. The type of automation used (type of processor, software, sensors, transmission technology, etc.) varied widely. Almost a quarter of food manufacturing plants used computer integrated manufacturing for HACCP.

3.7 Survey on the Use of Computer-Integrated Manufacturing in Food Processing Companies

Aly (1989) conducted a survey of 98 food processing companies located between Sacramento and Fresno in central California. The questions in the survey addressed eight key computer-integrated manufacturing (CIM) functions, namely accounting, production planning, distribution management, computer-aided manufacturing, quality control, materials handling, maintenance scheduling, and design.

Of the CIM functions surveyed, the three most commonly used were accounting (98.6 percent), production planning (77.4 percent), and distribution management (45.2 percent; this category includes such functions as order processing, sales inventory, shipping, and invoicing). Computer-aided manufacturing was used by less than half of companies, with most using it to monitor package weights. A very small number used robots. Further, while the percentage using CIM in quality control was small, more use of this CIM function is expected in this area in the future due to current emphasis on quality. Only a small minority use the other CIM functions surveyed. Aside from the eight functions addressed in the survey, CIM functions used by a small number of survey participants included engineering, scheduling, and process control. Survey results also indicated that 66.7 percent of companies not currently using CIM in their plants are considering use of CIM in the future. Cost has been an obstacle for the majority of companies.

3.8 FDA HACCP Survey

In 1998, FDA conducted an industry survey to determine HACCP practices of food manufacturing facilities in six FDA-regulated industries. For the survey, each of the six industries was further stratified into large and small plants. Plants were contacted by phone and asked questions about their HACCP plans (including training, planning, and implementation), the level of documentation of sanitation practices and procedures, performance of microbiological testing and other monitoring practices, and verification of specific sanitation procedures such as pasteurization.

The survey found significant differences between small and large plants. In general, large plants were more likely to have HACCP practices, sanitation processes, or other food safety procedures in place than small plants. HACCP training was also more likely in large plants. In plants that conduct HACCP training, managers and quality control personnel were the most often trained, but production workers were also trained in over half of plants. Training was most often administered by an industry trade group. Surveys results also indicated that large plants are more likely to be familiar with HACCP than small ones. At the time the survey was conducted (1998), more than half of the plants surveyed had not implemented HACCP and had no intention to do so if not required by FDA. Overall, about 76 percent of plants had written sanitation programs and 78 percent had written records that verified sanitation inspections. Small plants were unlikely to have these systems in place.

3.9 Survey of Maryland Cider Producer Practices

In 1999, Senkel et al. (1999) conducted a survey to evaluate the manufacturing practices of Maryland cider producers. Eleven cider producers were mailed a survey, which included questions about raw material sourcing and sanitation controls. Cider producers were then invited to a training program focused on *E. coli* contamination, HACCP, sanitation procedures, and GMPs.

The survey indicated that the majority of cider producers purchase some or all of their apples from neighboring states. A few make use of windfall apples, using only washers/scrubbers to clean them. While many (7 out of 11 producers) reported washing and brushing apples only prior to milling, a few also reported sanitizing apples after cleaning and before milling. Most producers reported using the traditional hydraulic press with rack and cloths. A few producers use preservatives, but only one reported pasteurizing the cider. None allow fermentation of the cider before distribution or sale and almost all

refrigerate the finished product at temperatures between 0.6 and 7.2 Celsius. While all producers reported washing and sanitizing equipment, a few did not always sanitize equipment between uses.

Evaluation after the training program indicated that producers implemented controls from the HACCP plans, but did not adapt any GMPs, or SSOPs, or keep any monitoring records. While none of the major pathogens were found in in-line samples, generic *E. coli* was found. Given that the generic *E. coli* was not found on the raw materials, in-plant processing contamination likely occurred, indicating a need for GMPs and SSOPs in addition to HACCP controls to ensure product safety.

References

Aly, Nael A. 1989. A Survey on the Use of Computer-Integrated Manufacturing in Food Processing Companies. *Food Technology.* March 1989.

Ennen, Steve. 2002. Food Security. *Food Processing*. February 2002.

Ennen, Steve. 2003. Safety Tops Concerns for Coming Year. *Food Processing*. January 1.

Federal Register 64. 1999. *9 CFR Parts 416 and 417: Listeria Monocytogenes Contamination of Ready to Eat Products.* Food Safety and Inspection Service, U.S. Department of Agriculture. Federal Register 64 (101). May 26, Wednesday.

Fusaro, Dave. 2004. Annual Manufacturing Trends Survey: Manufacturing Concerns for a Scary New World. *Food Processing*. January 12.

Ilyukhin, Sasha V., Timothy A. Haley, and Rakesh K. Singh. 2001a. A Survey of Automation Practices in the Food Industry. *Food Control.* Vol. 12: 285-296.

Ilyukhin, Sasha V., Timothy A. Haley, and Rakesh K. Singh. 2001b. A Survey of Control System Validation Practices in the Food Industry. *Food Control.* Vol. 12: 297-304.

Morris, Charles E. 2002. 3rd Annual Best Manufacturing Practices Survey. *Food Engineering*. February 2.

Morris, Charles E. 2000. Best Manufacturing Practices. *Food Engineering.* February 1.

Morris, Charles E. 2001. Best Manufacturing Practices. *Food Engineering.* February.

Muth, Mary K., Shawn A. Karns, and Donald W. Anderson. 2001. *Analysis of Hazard Analysis Critical Control Point (HACCP) Survey Data*. RTI. Prepared for FDA Center for Food Safety and Applied Nutrition. July.

NFPA/AMI/NTF/NCC/NMA/NAMP/SMA/AAMP. 2000. *Meat and Poultry Listeria Reassessment Survey*. Presentation provided to ERG by Jenny Scott, Senior Director, Food Safety Programs, National Food Processors Association (NFPA) on May 27, 2003.

Senkel, I. Arthur, Robin A. Henderson, Beverly Jolbitado, and Jianghong Meng. 1999. Use of Hazard Analysis Critical Control Point and Alternative Treatments in the Production of Apple Cider. *Journal of Food Protection.* Vol. 62: 778-785.

USDA/FSIS. 2000. *Evaluation Report Listeria Reassessment.* http://www.fsis.usda.gov/OPPDE/PEIS/Reports/OPPDE/Listeria_Re.htm.

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

Kim, Jae-on, and Charles W. Mueller. 1978. *Introduction to Factor Analysis: What It Is and How to Do It*. Sage Publications: Beverly Hills, CA.

Linstone, Harold A., and Murray Turoff. 2002. *The Delphi Method: Techniques and Applications*. Addison-Wesley: Reading, MA.

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%

APPENDIX A

ANNOTATED BIBLIOGRAPHY ON FOOD SAFETY PROBLEMS AND RECOMMENDED PREVENTIVE CONTROLS

Table A-1: Summary of Literature Findings on Microbiological Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
AMI, 2003	Meat and poultry	Manufacturing equipment design	The processing equipment should be of sanitary design. ▪ It must be cleanable down to the microbiological level ▪ It must be made of compatible materials ▪ It must be accessible for inspection, maintenance, cleaning, and sanitation ▪ It must be self-draining (i.e., does not allow for product or liquid collection) ▪ It must have its hollow areas hermetically sealed ▪ It must be free of niches ▪ It must have sanitary operational performance ▪ It must have its maintenance enclosures hygienically designed ▪ It must be hygienically compatible with other plant systems ▪ It must have a validated cleaning and sanitizing protocol
BBC News, 2002	Prepared foods	Cooks and chefs with long and/or artificial finger nails	Short and clean finger nails
Beauchat and Ryu, 1997	Fresh produce	Pathogen contamination through ▪ Contact with soil, raw or improperly composted manure, irrigation water containing untreated sewage, or contaminated wash water ▪ Contact with animals, insects, unpasteurized products of animal origin, and contaminated surfaces	▪ Treatment of produce with chlorinated water (may not eliminate pathogens completely) ▪ Control of potential points of contamination in the field, during harvesting, processing and distribution, retail markets, at food-service facilities, and at home
Bell and Kyriakides, 2002a	Not specified	Not specified	▪ Effective hygiene ▪ Routine pathogen monitoring ▪ Steam pasteurization ▪ GAPs ▪ Microbiological testing ▪ Chlorine washing ▪ Challenge studies to determine the critical control points ▪ Segregation of raw materials from in-process and finished products ▪ Effective cleaning and disinfection

Table A-1: Summary of Literature Findings on Microbiological Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
Bell and Kyriakides, 2002b	Not specified	Not specified	▪ Controlling the feed of food animals and poultry ▪ Effective hygiene ▪ Routine pathogen monitoring ▪ Steam pasteurization ▪ GAPs ▪ Microbiological testing ▪ Chlorine washing ▪ Challenge studies to determine the critical control points ▪ Segregation of raw materials from in-process and finished products ▪ Effective cleaning and disinfection
Bell and Kyriakides, 2002c	Raw and processed foods	▪ Product manufactured with no processing stage to kill the organism ▪ Product with few or no preservatives ▪ Post-process contamination ▪ Poor personnel handling practices	▪ Monitoring and testing the product ▪ Washing produce with chlorine ▪ Segregation of raw and processed materials ▪ Effective cleaning and sanitation ▪ Environmental sampling and cleaning ▪ Routine monitoring of cleaning efficiency
Belluck and Drew, 1998	Lettuce	▪ Open shed ▪ Unchlorinated wash water ▪ Unsanitary employee practices	Not specified
Berne, 1997	All foods	Not specified	▪ Good employee hygiene ▪ Ensurance of adequate hand washing through the use of automated hand washing systems ▪ Use of color-coded cleaning materials ▪ Use of pathogen detection and cleaning validation testing systems
Best, 2000	Meat and eggs	In-plant construction activities	▪ Avoidance of sample compositing during testing ▪ Testing during operations to reflect true-life conditions ▪ Nonrandomized testing ▪ Vaccination ▪ Competitive exclusion ▪ In-the-shell pasteurization
Brandt, 1999	Hot dogs	Risk of post-processing contamination with *Listeria monocytogenes*	▪ Revised plant procedures ▪ Packaging innovations ▪ Addition of key ingredients, such as sodium nitrite, sodium lactate, sodium diacetate, polyphosphates, organic acids, smoke flavoring, and bacteriocins, such as nisin and pediocin

Table A-1: Summary of Literature Findings on Microbiological Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
Bryan et al., 1997	Processed foods	▪ Raw product/ingredient contaminated by pathogens ▪ Cross-contamination from raw ingredient of animal origin ▪ Bare-hand contact by food handler ▪ Handling by an intestinal carrier of enteric pathogens ▪ Inadequate cleaning of processing or preparation equipment ▪ Storage in contaminated environment	No specific controls suggested
Calicioglu et al., 2002	Soudjouk-style sausage	Natural fermentation may not eradicate *E. Coli* in the absence of controlled fermentation, post-fermentation cooking, and/or ambient-storage processing step	Use of a starter culture
Chmielewski and Frank, 2003	Processed foods	▪ Biofilm formation ▪ Infrequent cleaning of environmental surfaces, such as storage tank and pump exteriors, and walls and ceilings	▪ Biofilm development control via nutrient and water limitation, equipment design, and temperature control ▪ Use of chemical and physical force combination during cleaning ▪ Appropriate sanitizer selection ▪ Microbial load monitoring with plating of swabbing solution, contact plates, and the dipstick technique
Cliver, 1999	Fruits and vegetables Grains Dairy products Meat Poultry Fish	▪ Human errors in handling ▪ Pests and rodents ▪ Temperature abuse during handling	▪ Cold storage and appropriate selection of packaging for fruits and vegetables ▪ Pasteurization for milk ▪ Irradiation and dipping in a trisodium phosphate solution for poultry ▪ Proper handling and routine monitoring for toxins for fish
Cramer, 2003	Processed foods	▪ Microbiological (pathogens) hazards ▪ Physical (glass, metal shavings, wood) hazards ▪ Chemical (allergen cross contamination) hazards	▪ Adherence to the basic elements of sanitary design, including facility site selection, grounds and dust control, pest control, basic facility flow, plant materials, and equipment ▪ Cross-functional training of staff in sanitary facility and equipment design
Curiel, 2003	Processed foods	Increased probability of microbial contamination due to mild preservation technologies	Sanitary equipment design
Deibel, 2001	Not specified	Biofilm formation	▪ Effective cleaning and sanitation that combines physical and chemical methods ▪ Use of peroxide and peroxide-containing sanitizers instead of chlorine, iodophors, and most quaternary ammonium compounds

Table A-1: Summary of Literature Findings on Microbiological Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
Donnelly, 2002/2003	Smoked seafood RTE meat and poultry soft cheeses raw milk Mexican-style cheeses	▪ Listeria contamination due to niche environments ▪ Improper placement of drains	▪ Use of advanced chemical sanitizers to clean and sanitize surfaces ▪ Rotation of chemical sanitizers ▪ Employee-gowning protocols ▪ Easily cleanable boots ▪ Segregation of raw materials and food production areas ▪ Use of foot baths ▪ Foaming sanitizers and hand-washing systems ▪ Product reformulation ▪ Electronic pasteurization ▪ High-pressure processing (HPP)
Doyle E., 1999	Meat and poultry	Listeria	▪ Use of organic acids, other preservations, or bacteriocins in product formulation ▪ Application of additional process steps, such as thermal process, irradiation, high pressure, pulsed electric fields, electrolyzed oxidizing water, ultraviolet light, and ultrasound ▪ Use of modified atmosphere packaging (MAP)
Doyle, 2000	Foods of animal and plant origin	▪ Animals and animal manure used for foods are a leading source of food borne pathogens ▪ Imported foods	▪ Education of producers ▪ Implementation of HACCP systems at the point of production
Drew and Belluck, 1998	Apple juice	▪ Use of decayed apples possibly have been in contact with deer feces ▪ Inadequate quality control	▪ HACCP ▪ Pasteurization
Ennen, 2003	Processed foods	Not specified	▪ HACCP training and implementation of date/lot/batch coding, metal detection and x-ray machines ▪ Audit programs ▪ Process control and plant improvements training ▪ Locking of milk tankers for security ▪ Increased production line sampling and improved clean-out procedures ▪ Intervention processes for carcass beef, E. Coli test and hold programs ▪ HACCP/FDA inspections/AIB audits ▪ Research and development ▪ Personnel training
Erickson, 1995	Mayonnaise and mayonnaise dressing	▪ Use of unpasteurized eggs ▪ Wet environmental areas	▪ Use of pasteurized eggs ▪ GMPs ▪ Good hygienic practices

Table A-1: Summary of Literature Findings on Microbiological Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
ERS, 2001a	Meat and poultry	Not specified	▪ Animal or meat testing for pathogens, ▪ Knife sterilization and temperature, airflow, and other process controls ▪ Improved evisceration and hide, hair, and feather removal techniques ▪ Employee work methods and empowerment for food safety decisions ▪ Production line layouts that minimize cross-contamination ▪ Pathogen testing of equipment and plant environment ▪ Use of labor-saving equipment that reduces cross-contamination ▪ Rate at which workers' hands, tools, and equipment are sterilized ▪ Management strategies, like the Hazard Analysis and Critical Control Points (HACCP) system ▪ Steam pasteurization and/or vacuuming ▪ Hot water sprays ▪ Use of Chlorinated water and other sanitizers to disinfect product, work surfaces, and equipment ▪ Competitive exclusion (poultry) ▪ Automation of manual processes
ERS, 2001b	Meat and poultry	Pathogens	Irradiation
FDA/CFSAN, 2001a	Selected RTE foods	▪ Plant renovations ▪ Use of defective processing equipment ▪ Inadequate pasteurization	Maintenance of food safety controls and strengthening of existing controls
FDA/CFSAN, 2001b	Seafood	▪ Bacteria (sporeformers and nonsporeformers) ▪ Viruses due to poor hygienic practices ▪ Worms and protozoa	▪ Good personal hygiene ▪ Elimination of insufficiently treated sewage to fertilize crops ▪ Freezing (parasite control)
FDA/CFSAN, 2001c	Fresh and fresh-cut produce	▪ Manure and biosolids ▪ Water for agricultural uses ▪ Improper postharvest packing, cooling, and storage practices	▪ Temperature control ▪ Physical removal of microorganisms ▪ Use of effective GRAS cleaning agents ▪ Ozone treatment ▪ Irradiation ▪ Biocontrol
FDA/CFSAN, 1999a	Fruits and vegetables and juices	▪ Contamination of damaged/decayed sites on the rind of fruits that pathogens may infiltrate via insects and birds or immersion in cold contaminated water ▪ Equipment cross contamination during processing	No specific controls recommended in the study

Table A-1: Summary of Literature Findings on Microbiological Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
FDA/CFSAN, 1999b	Oranges	*Salmonella Enterica Hartford* and *E. Coli* O157:H7 can be internalized in the fruit at infiltration levels of 3 percent or higher	Refrigeration reduces the survivability of *E. Coli* but not of *S. Hartford*
FDA/CFSAN, 1999c	Fresh unpasteurized apple cider	▪ Contamination through direct/indirect contact with animal feces during growing and harvesting of apples ▪ Pathogen migration through the flower end or breaks in the apple skin	▪ Culling ▪ Initial washing ▪ Prompt processing or refrigerated holding ▪ Final culling, washing, and brushing ▪ A closed processing system ▪ Equipment sanitation ▪ Environmental sanitation ▪ Employee hygiene ▪ Implementation of HACCP ▪ Pasteurization ▪ UV treatment ▪ High pressure sterilization ▪ Electric resistance heating ▪ Aseptic packaging ▪ Ultrafiltration ▪ Pulsed electric field ▪ Electromagnetic fields ▪ Pulsed light ▪ Ozone treatment ▪ Hot water rinses ▪ Irradiation ▪ Freezing and thawing ▪ Redundant processing controls ▪ Use of sanitizer dips and sprays and preservatives ▪ Microbiological testing of products
Floyd, 1999	RTE foods and some microwaveable products	▪ Areas with standing water ▪ Drains and floors ▪ Dry-cleaned operations	▪ Testing of areas that have a potential to contaminate the processing/packaging areas or adjacent spaces ▪ Environmental testing ▪ Equipment testing to validate the cleaning process ▪ Monitoring of the effectiveness of clean-up and sanitizing procedures ▪ Validation of changes to cleaning procedures ▪ Swabbing of dry-cleaned operations areas ▪ Testing of packaging material and packaging area
Food Quality Magazine, 1997	Not specified	Inadequate sanitation	Automated handwashing stations with boot dips
Gagliardi et al., 2003	Melons	Contaminated wash water	Focusing on water quality as an important control point at the farm and at processing and packing facilities

Table A-1: Summary of Literature Findings on Microbiological Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
Gregerson, 2002	Processed foods	Not specified	▪ On-the-job training of employees ▪ Cross training of employees ▪ Bonus programs, including benefits packages (medical, dental) and good work conditions ▪ Routine preventive and/or predictive maintenance schedules ▪ Antimicrobial treatments ▪ Rapid microbial detection systems
The Hartford, 1999	Shell eggs	Not specified	▪ Voluntary quality assurance programs, including cleaning and disinfecting hen houses between flocks, strict rodent control, washing of eggs, refrigeration between transport and storage, biosecurity measures, mortality monitoring, use of salmonella-free chicks and pullets ▪ In-shell pasteurization ▪ Irradiation ▪ Spraying of hatched chickens with Preempt ▪ Implementing HACCP
Hegenbart, 1996	Dairy foods Fruits and vegetables Grains Fish and seafood	▪ Pathogenic bacteria ▪ Toxins and carcinogens ▪ Mycotoxins ▪ Parasites and viruses	▪ Sanitation of the milking facility (dairy) ▪ Cleaning of the cows' udders prior to milking (dairy) ▪ Thermostatic control of milk holding tanks (dairy) ▪ Frequent changing of the bedding materials in holding pens (poultry) ▪ Feed testing (poultry) ▪ Competitive exclusion (poultry) ▪ Use of herbicides and pesticides (plants) ▪ Adequate irrigation and pest protection (crops) ▪ Post harvest cooking and/or freezing (seafood)
Higgins, 2003	Food and beverages	Post-processing contamination	▪ In-package sterilization ▪ Steam vacuuming ▪ Organic acid sprays ▪ Washes and Rinses ▪ Thermal pasteurization ▪ Irradiation ▪ Ultra high pressure pasteurization ▪ Coating drains or equipment parts with antimicrobial agents ▪ Cleaning and sanitizing surfaces

Table A-1: Summary of Literature Findings on Microbiological Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
Higgins, 2002	Dairy products	▪ Language barriers among plant employees ▪ Ineffective employee training ▪ Poor hygienic practices among employees	▪ Bilingual training ▪ Picture- and symbol-based approach to training and instruction ▪ Keypad controls on hand sanitizers that enable the collection of data on handwashing practices of employees ▪ Sensor-equipped paper towel dispensers to replace hand cranks ▪ Contour mapping and/or spatial analysis to identify any infestation hot spots in the plant
Higgins, 2001	Processed foods	▪ Reactive maintenance ▪ Lack of integration between operations and maintenance ▪ Lack of integration among CMMS, condition-based monitoring, and enterprise asset management systems	▪ Institution of a workable maintenance plan where predictive maintenance is applied to the most critical assets ▪ Integration of CMMS, monitoring, and enterprise asset management systems
Hoffman et al., 2002	Raw and smoked fish	*L. monocytogenes* strains may persist in a plant for years. Thus, environmental contamination is separate from that of incoming raw materials.	Regular *L. monocytogenes* testing of drains and molecular subtyping of isolates obtained
Holah and Thorpe, 2002	Not specified	▪ Ovens designed to drain into high-risk areas ▪ Leakage of sumps under ovens into high-risk areas	▪ Separation of processing areas from non-processing areas and high-risk from low-risk areas ▪ Monitoring and controlling cleaning and disinfection programs to prevent biofilms ▪ Intensive periodic cleaning in addition to routine cleaning ▪ Use of multiple cleaning products for specific operations ▪ Monitoring the efficacy of cleaning and disinfecting agents ▪ Microbiological testing
Ilyukhin et al., 2001	All processed foods	Control system failures as a result of inadequate control system validation measures	Formal and comprehensive training and maintenance programs for manufacturing equipment and control system
Jahncke and Herman, 2001	Cold-smoked finfish	▪ Improper refrigeration controls ▪ *Listeria monocytogenes* and *C. botulinum* spores present on fish ▪ Cross-contamination with *L. monocytogenes* during slicing and cutting	▪ Properly storing fish so that their internal temperature is less than 40 degrees Fahrenheit ▪ Thawing frozen fish under sanitary conditions ▪ Temperature control of the brine solution during brining ▪ Removal of thick and large parts ▪ Strict adherence to SSOPs and GMPs
Keller et al., 2002	Apple cider	▪ Certain processing areas, such as apple mills and tubing for pomace, and juice transfer, may harbor contaminants even after cleaning and sanitation ▪ Use of poor quality ingredients ▪ Poor sanitation ▪ Reuse of uncleaned press cloths	No specific controls recommended in the study

Table A-1: Summary of Literature Findings on Microbiological Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
Kindle, 2001	Not specified	▪ Wood-covered door frames that corrode over time ▪ Doors that unnecessarily remain open	Doors made of corrosion-resistant material
Krysinki, 1992	Not specified	▪ Effectiveness of sanitizers depends upon the surface being cleaned; polyester/polyurethane is most difficult to sanitize ▪ Effectiveness of biofilm removal with cleaners depends on the surface being cleaned; polyester/polyurethane is most difficult to clean	▪ Clean surfaces prior to sanitization for complete biofilm removal ▪ Combine GMPs with HACCP
Kuhn, 1995	Not specified	▪ Inadequate hand washing practices ▪ Lack of cleaning validation	▪ Automated hand-washing machines ▪ ATP bioluminescence monitoring ▪ Portable sanitation equipment
Kuntz, 1992	Not specified	▪ Molds ▪ Yeast ▪ Viruses ▪ Bacteria	▪ Prevention of contamination by proper cleaning of manufacturing equipment, ▪ Removal of microorganisms by washing, trimming, centrifuging, and filtration ▪ Removal of oxygen by applying a vacuum, or the replacement of oxygen by gases, such as nitrogen or carbon dioxide ▪ High or low temperature treatments depending on the type of food product ▪ PH control ▪ Control of water activity levels via cooking, baking, or dehydration ▪ Use of preservatives or inhibitory substances that have Generally Recognized as Safe (GRAS) status ▪ Irradiation
Morris, 2000a	Processed foods	Not specified	▪ Routine preventive and/or predictive maintenance schedules ▪ HACCP ▪ Pay-for-skills programs where the responsibility goes to the workers ▪ On-line standard plate count (SPC) ▪ Automated batch control

Table A-1: Summary of Literature Findings on Microbiological Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
Morris, 2000b	Processed foods	▪ Weak prerequisite programs, including SSOPs, GMPs, QA programs, consumer complaint monitoring, environmental monitoring, vendor certification, and allergen management ▪ Half-way HACCP programs due to lack of upper-management commitment ▪ Release of product despite CCP violations ▪ Inclusions of quality components in HACCP that dilute its effectiveness ▪ Weak CCP validations and hazard analyses ▪ Inadequate/inefficient documentation ▪ Inadequate training ▪ Lack of continuous improvement	No specific controls recommended in the study
Mortimore, 2003	Not specified	▪ Wrong perception of the value and complexity of HACCP implementation ▪ Traditional and/or hierarchical organizational structure ▪ Lack of expertise in hazard analysis and risk evaluation ▪ Lack of motivation and failure to develop the right attitude and skills for system maintenance	▪ Education about food borne illness and trends ▪ Education on how HACCP is a minimal system that ensures maximum control ▪ Education on how HACCP can help reduce sanitation costs and down time, lengthen shelf life, improve efficiency, and reduce waste
Murphy et al., 2003	Fully-cooked vacuum-packed chicken breast meat	Existence of *Listeria monocytogenes*	▪ In-package steam pasteurization ▪ In-package hot water pasteurization
Neff, 1999	Frozen vegetables	Ineffectiveness of chlorine (widely used to decontaminate process water) under certain circumstances	▪ Peroxyacetic acid ▪ Ozone ▪ Ultraviolet radiation
NFPA, undated	RTE foods	*Listeria monocytogenes*	▪ Applying a validated listericidal process where appropriate, ▪ Purchasing from suppliers with a *Listeria* control program, ▪ Minimizing the potential for recontamination, ▪ Adopting new technologies as soon as they are available, and ▪ Implementing an environmental monitoring program for *Listeria* spp. to verify that the control program is effective. ▪ In-package pasteurization ▪ Ionizing radiation ▪ Product reformulation with *L. monocytogenes* inhibitors

Table A-1: Summary of Literature Findings on Microbiological Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
Paulson, 1996	Not specified	▪ Gloves with poor barrier characteristics ▪ Ineffective hand washing among employees ▪ Hand contact with contaminative surfaces, such as mucous, blood, soil, urine, or feces	▪ Washing hands prior to donning gloves ▪ Ongoing employee training and education ▪ Institution of a quality control program ▪ Environmental disinfection/sanitation program ▪ Restriction of tasks among employees to prevent cross contamination
Raloff, 1998	Pasteurized egg products Hot dogs Poultry summer sausage Meat products	*Listeria monocytogenes* and *Clostridium*	Addition of bacteriocins to the food product
Riordan et al., 2001	Fresh fruit	Internalization of microflora in the fruit, especially in those that have been dropped and/or damaged	▪ Exclude dropped or damaged fruit from those that are designated for the production of unpasteurized juice or for the fresh or fresh-cut market ▪ Locate orchards away from potential sources of contamination, such as pastures
Rushing and Fleming, 1999	Acidified foods	Not specified	Maintenance of an adequately low pH of 4.6 or below throughout the food
Senkel et al., 1999	Apple cider	▪ Lack of specific GMP, sanitation standard operating procedures, and sanitation monitoring records ▪ Lack of adherence to GMPs and HACCP	▪ Ensuring conformance to GMP and sanitation procedures ▪ Ensuring conformance to HACCP
Siddiqi, 2001	Not specified	Pathogen transmitting pests, such as rodents, roaches, and flies	▪ An integrated pest management program that relies on inspection, monitoring, establishing action threshold levels, and implementing first non-chemical and then chemical measures ▪ Communication and education ▪ Computer-aided monitoring ▪ Nonvolatile nonrepellant insecticide formulations
Snowdon and Cliver, 1996	Honey	▪ Yeasts and spore-forming bacteria ▪ Coliforms ▪ Cross-contamination ▪ Insanitary equipment and buildings	Routine microbiological testing, including standard plate counts, yeast counts, bacterial spore-former assays, and coliform counts
Sommers et al., 2002	Ham	Existence of *Listeria innocua*	▪ Vacuum-steam-vacuum technology ▪ Ionizing radiation
Stier, 2002	Not specified	▪ Construction projects ▪ Increases in production volume	Evaluation of how changes affect one's operation and taking steps to ensure that food safety is not compromised in the process
Stopforth et al., 2002	Fresh beef	Biofilms on equipment surfaces to which *Listeria monocytogenes* cells can attach and persist despite washing and sanitizing	Correct sanitizer selection as each sanitizer has an optimal working environment in which it is most effective

Table A-1: Summary of Literature Findings on Microbiological Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
Thimothe et al., 2002	Raw, whole, and processed crawfish	Presence of *Listeria monocytogenes* and *Listeria* ssp. in drains and some employee contact surfaces	▪ Heat treatment during processing ▪ Practices preventing post-processing contamination (not specified)
Thomas et al., 2002	Cooked potato products	*Bacillus* and *Clostridium*	Addition of nisin to the product formulation
Tilden et al., 2002	Dry fermented salami	Presence of *E. Coli* O1576:H7 on raw meat used in manufacturing salami	Not specified
Tompkin et al., 2002	RTE processed foods	▪ Product testing is insufficient to indicate the mode of contamination ▪ Errors in food handling ▪ Establishment of a pathogen in a niche which is impossible to reach and clean with normal cleaning and sanitizing procedures	▪ Environmental and equipment testing to detect niches ▪ Inclusion of sampling sites that are good indicators of control, such as food contact surfaces ▪ Weekly or more frequent sampling of the food processing environment ▪ Improvements in equipment design to make cleaning more effective and to minimize breakdowns and repairs ▪ Increased use of post-packaging pasteurization with irradiation, hot water, steam, and high pressure
USDA/FSIS, 2002	Beef	Cattle is an important reservoir for *E. Coli* O157:H7	▪ Post-slaughter antimicrobial decontamination methods, including spray-washing, steam-vacuuming, steam pasteurization, warm water wash, trimming, lactic acid decontamination ▪ Chilling and temperature control for finished product storage

Table A-1: Summary of Literature Findings on Microbiological Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
USDA/FSIS, 2001	Meat and poultry	▪ Food contact surface contamination between the cooking and packaging steps ▪ Cross contamination ▪ Reservoirs of *L. monocytogenes*, including floors and drains, standing water, ceilings and overhead pipes, refrigeration condensation units, recess or hollow material, air filters, and open bearings	▪ Dry cleaning ▪ Pre-rinsing equipment ▪ Foaming and scrubbing ▪ Rinsing ▪ Visual inspection of equipment ▪ Cleaning walls and floors ▪ Sanitizing ▪ Drying ▪ Environmental and contact surface testing to determine the effectiveness of cleaning and to identify potential sources of contamination ▪ Rotating sanitizers periodically ▪ Alternating between alkaline and acid-based detergents to avoid soapstone or hard water buildups and formation of biofilms ▪ Plant design to eliminate traffic flow between RTE and raw product areas ▪ Use of dehumidifiers and drip pans in RTE areas ▪ Smooth, sealed, and moisture-free ceilings and walls ▪ Filtered air supply ▪ Light fixtures that do not harbor dirt or moisture ▪ Environmental testing of non-food contact surfaces, food contact surface testing, and product testing ▪ Regular validation of test results by a third party
Walker et al., 2003	Not specified	Lack of hygiene knowledge among food handlers	Not specified
Young, 2003	Not specified	Equipment that is not designed to be cleaned with the help of automation	▪ Automated sanitation systems ▪ Transfer of sanitation duties from the third to second or first shifts and to better-trained employees ▪ Use of ozone (instead of chlorine) as disinfectant

Table A-2: Summary of Literature Findings on General Chemical Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
Bryan et al., 1997	All foods	▪ Natural toxins ▪ Spillage of chemicals ▪ Indiscriminate spraying of chemicals ▪ Misreading labels ▪ Adding too much of an approved ingredient ▪ Leaching of toxic containers or pipelines due to acidic foods	No specific controls recommended
FDA/CFSAN, 2001	All foods	Chemical hazards occur: ▪ Naturally (e.g., mycotoxins, allergens, and marine toxins) ▪ From intentionally added chemicals (e.g., preservatives, and nutritional and color additives) ▪ From unintentionally added chemicals (e.g., pesticides, veterinary drugs, toxic elements, and cleaning/sanitizing chemicals)	No specific controls recommended
Folks and Burson, 2001a	All foods	Raw materials may be contaminated with: ▪ Pesticides ▪ Antibiotics ▪ Hormones ▪ Toxins ▪ Fertilizers ▪ Fungicides ▪ Heavy metals ▪ PCBs During processing, contamination can occur with: ▪ Preservatives ▪ Flavor enhancers ▪ Color additives ▪ Peeling aids ▪ Defoaming agents ▪ Pesticides ▪ Cleaners/sanitizers	▪ Store chemicals separately from food and packaging materials ▪ Thoroughly rinse cleaning agents and sanitizers from equipment ▪ Only use USDA-approved chemicals ▪ Pest control should be performed by professionals ▪ Pest control residues in food should be controlled ▪ Inventory should be kept of chemicals, colorings, and additives ▪ Conduct audits of chemicals used ▪ Train employees adequately about chemical use ▪ Test product in-house for residues
Jahncke and Herman, 2001	Cold-smoked fish	▪ Temperature abuse of Scrombotoxin-susceptible fish	▪ Certification of proper time and temperature handling on vessel ▪ Sensory evaluation ▪ Analytical testing ▪ Refrigerated at 40 F or less ▪ Rapid cooling of the product after cold-smoking process

Table A-2: Summary of Literature Findings on General Chemical Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
Moulton, 1992	All food	▪ Pesticide residue	▪ Organic production systems ▪ Integrated pest management ▪ Low input sustainable agriculture (LISA) ▪ Development of safer chemicals ▪ Genetically-engineered, pest-resistant plants
Tybor et al., 1990	Various	▪ Metal poisoning from food handling equipment and utensils due to corrosion ▪ Pesticide spills ▪ Indiscriminate spraying of facilities with pesticide ▪ Improper storage or mistaken identity of pesticides ▪ Incomplete washing of produce ▪ Adding too much of intentional food additives ▪ Unintentional food additives	▪ Use equipment and utensils that do not corrode with citrus fruits, fruit drinks, fruit pie fillings, tomato products, sauerkraut, and carbonated beverages ▪ Store and secure pesticides away from food products ▪ Handle pesticides like poisons ▪ Avoid indiscriminate application of pesticides ▪ Use trained and certified personnel in application of pesticides ▪ Avoid use of empty cleaning chemical containers for food storage ▪ Properly train personnel about cleaning and sanitizing ▪ Use only approved food grade lubricants and greases ▪ Maintain chemicals in original containers ▪ Read and follow instructions on labels ▪ Keep inventory of chemicals in a secure, supervised area

Table A-3: Summary of Literature Findings on Allergen-related Chemical Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
CSPI, 2001	Processed foods	▪ Modification of product recipe without changing the label ▪ Not separating production runs ▪ Not cleaning machines properly between runs	▪ Cross-checking ingredients on labels ▪ Separate production runs ▪ Clean machinery properly
Deibel et al., 1997	Processed foods	▪ Raw material contamination ▪ Allergen contamination from products containing allergens run on same production line ▪ Improper use of rework ▪ Cross-contamination from maintenance tools ▪ Incorrect labeling or packaging ▪ Cross-contamination from conveyor belts ▪ Inadequate cleaning between allergen-containing product run and nonallergen-containing product runs ▪ Older equipment difficult to clean ▪ Lack of employee training	An allergen prevention plan that includes: ▪ A close working relationship with material suppliers ▪ On-site audits of material suppliers ▪ Allergen training for suppliers ▪ Longer run times that minimize changing products ▪ Scheduling the allergen-containing product at the end of the run ▪ Covering transport belts to prevent ingredients from falling ▪ Identifying and documenting rework ▪ Color coding maintenance tools or specifying proper cleaning procedures ▪ Verifying labels and packaging (e.g., with bar code scanners) ▪ Physical detachments or lockouts for equipment with high-contamination risk ▪ Enclosure of line crossover points ▪ Verification of cleaning between allergen and nonallergen runs ▪ ELISA tests ▪ Employee training
FDA/CFSAN, 2001d	Ice cream, bakery, and candy	▪ Omittance of raw ingredients that are potential allergens from label ▪ Failure of label review policies ▪ Contamination of product by utilization of rework ▪ Use of common utensils ▪ Allergen and nonallergen runs were not scheduled or sequenced ▪ No dedicated equipment for allergen runs ▪ Inadequate cleaning of lines (rinsing with water only or cleaning at end of day only) ▪ Lack of training in allergen control	▪ Effective label review policies ▪ Scheduling production of allergen-containing products at the end of production runs ▪ Proper use of rework ▪ Equipment and system design considerations ▪ Thorough cleaning of lines after running allergen-containing products ▪ Effective management of label inventory ▪ Control of ingredients from suppliers ▪ Training of employees in allergen control

Table A-3: Summary of Literature Findings on Allergen-related Chemical Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
FDA/CFSAN, 2001e	All foods	Food allergens enter food by means of: ▪ Misformulation ▪ Improper scheduling ▪ Use of rework ▪ Improper sanitation ▪ Cross-contamination	▪ Minimize equipment exposure to allergens ▪ Designate and label equipment for use with specific products ▪ Enclose equipment ▪ Avoid crossovers of production lines ▪ Add allergens near the end of a process ▪ Schedule longer run times ▪ Run nonallergen-containing products before allergen-containing products ▪ Produce allergen-containing products on a separate day than other products ▪ Adequate control on rework ▪ Discarding old labels and packaging materials ▪ Conduct label audits ▪ Appropriate sanitation ▪ Training on allergens and sanitation
FDA/CFSAN, 2001f	Fish and fisheries products	Food and color allergens in foods	▪ Declare the presence of an allergen ▪ Test for residue of an allergen ▪ Require supplier certification ▪ Review label of raw materials
Floyd, 2000	All foods	▪ Lack of product scheduling ▪ Lines are not separated ▪ Raw material contamination may be beyond a manufacturer's control ▪ Poor equipment design ▪ Lack of employee training	▪ Employee training ▪ Scheduling of production runs ▪ Separation of allergenic and nonallergenic products, with dedicated bins, scoops, and weighing buckets ▪ Staging areas (putting all ingredients for a specific batch on a pallet before processing) ▪ Line clearance after allergen processing ▪ Verification with test kits ▪ Design plant to avoid dust carryover ▪ Improved equipment design ▪ Add warning to label as last resort

Table A-3: Summary of Literature Findings on Allergen-related Chemical Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
Gregerson, 2003	All foods	▪ Poor sanitation ▪ Use of common utensils ▪ Reuse of baking parchments ▪ Use of table with surface nicks that caused cross-contamination ▪ Raw material contamination ▪ Lack of dedicated lines or allergenic product scheduling at end of day ▪ Lack of proper identification of materials	▪ Obtain full ingredient list from suppliers ▪ Investigate whether any allergenic processing aids/rework has been incorporated into the product ▪ Investigate possible product carryover from common equipment ▪ Replacement of non-functioning or non-characterizing allergens ▪ Allergenic products should be run on dedicated lines or scheduled at end of day ▪ Long run times for allergenic products to minimize product carryover ▪ Rework areas, equipment, and containers should be clearly identified through use of color tags, bar codes, etc. ▪ Equipment should be made of sanitation friendly material, like stainless steel ▪ ELISA tests
Higgins, 2000	All foods	▪ Inadequate washdown ▪ Too many changeovers, ▪ Scheduling allergen-containing products before non-allergen containing products ▪ Poor equipment design ▪ Products shipped in wrong package ▪ Lack of line separation	▪ Proper washdown techniques ▪ Longer production runs ▪ Scheduling allergen-containing products for the end of the day ▪ Sanitary equipment design ▪ UPC scanners to ensure correct packaging ▪ Add allergens at the end of the line ▪ Focus on 8 common allergens ▪ Validate allergen-control program with testing kits of in-process and finished foods

Table A-3: Summary of Literature Findings on Allergen-related Chemical Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
Minnesota Department of Agriculture, 2003	Processed foods	▪ Poor equipment design ▪ Crossover of conveyor lines ▪ Allergen addition point not isolated on line ▪ Re-feed systems are not dedicated ▪ Raw material contamination ▪ Product lines are not dedicated or allergenic products are not run last ▪ Inadequate sanitation ▪ Incorrect labeling or packaging ▪ Contaminated maintenance tools ▪ Lack of employee education	▪ HACCP ▪ Consider non-allergenic substitutes ▪ Add allergenic ingredients at end of process ▪ Sanitary equipment design ▪ Allergen addition point of line should be isolated ▪ Re-feed systems should be dedicated ▪ Product should be contained on line ▪ Eliminate crossover of conveyor lines ▪ Ensure suppliers have implemented and documented an allergen plan ▪ Products with allergens should be run at one time or at the end of a production run ▪ Adequate cleanup is required between runs ▪ All rework should be clearly labeled ▪ Labels should be verified ▪ Outdated packaging material should be removed from plant ▪ Sanitation practices should be validated using sight, bioluminescence, and ELISA tests ▪ Check maintenance tools for cross-contamination ▪ Employee training
Morris, 2002	All products	▪ Lack of dedicated lines or not adding allergenic product at end of process ▪ Crossover of conveyor lines ▪ Contaminated maintenance tools ▪ Too many changeovers ▪ Poor sanitation ▪ Lack of employee training	▪ Eliminate allergens if possible ▪ Add allergenic ingredient at end of process ▪ Dedicate production line to allergenic products ▪ Cover conveyors ▪ Seal off allergen addition points on line ▪ Color code maintenance tools ▪ Audits and documentation should be required of raw material suppliers ▪ Longer production runs with minimal changeovers for high-volume products ▪ When changeovers are necessary, products containing allergens can be scheduled last in the production cycle ▪ Discard old packaging ▪ ELISA tests ▪ HACCP ▪ Employee training

Table A-4: Summary of Literature Findings on Mycotoxin-related Chemical Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
Moss, 2002	Cereals, legumes, oilseeds, treenuts, milk, meat, coffee, cocoa, fruits, spices	▪ Insect damage ▪ Drought ▪ High water activity ▪ Mold growth	For preventing aflatoxin contamination: ▪ Preventing insect damage ▪ Alleviating drought stress ▪ Reducing water activity in product For preventing ochratoxin A contamination: ▪ Prevention of mold growth at every stage of production For preventing patulin contamination: ▪ Removal of moldy apples ▪ Treatment with charcoal or sulfur dioxide For preventing fumosin contamination: ▪ Breed cultivars resistant to insect damage and ear rot ▪ Biological control in the field
Bissessur et al., 2001	Apple juice	Production of patulin in apple juice	▪ Charcoal treatment ▪ Chemical preservation using sulfur dioxide ▪ Gamma irradiation ▪ Fermentation ▪ Trimming of fungus-infected apples ▪ Clarification methods (including pressing, centrifugation, fining, enzyme treatment, and filtration)
Boutrif, 1999	Tree nuts	▪ Drought ▪ Insect infestation ▪ Delayed harvesting ▪ Mechanical damage ▪ Moisture and heat during storage ▪ Immature kernels	▪ Timely harvesting ▪ Pesticides ▪ Minimize mechanical damage ▪ Electronic sorting to remove immature, damaged, or mold infested kernels ▪ Handpicking to remove immature, damaged, or mold infested kernels ▪ Chemical/heat inactivation of mycotoxins ▪ Proper storage to protect from moisture and heat
GASGA/CTA, 1997	Grains	▪ Insect damage ▪ Temperature stress ▪ High water activity	For field fungi: ▪ Protection from insect damage ▪ Protection from temperature stress For storage fungi: ▪ Dry grain as soon as feasible ▪ Store under modified atmospheric conditions ▪ Protect from damage and insects ▪ Sample for fungi

Table A-4: Summary of Literature Findings on Mycotoxin-related Chemical Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
Horne et al., 1989	Grains	▪ Droughts ▪ Temporary storage conditions ▪ High moisture storage conditions ▪ Immature or broken kernels	▪ Detect mycotoxin with black light ▪ ELISA tests ▪ Other screening programs ▪ Storage facilities with 13 percent moisture content ▪ Anhydrous ammonia treatment ▪ Shaking out immature or broken kernels
Jackson, et al, 2003	Apple cider	▪ Damaged fruit ▪ Dropped apples ▪ Washing inadequate for high levels of contamination	▪ Use tree-picked apples ▪ Cull apples ▪ Washing (not for high levels of contamination)
Park et al, 1999	Crops	▪ Insect damage ▪ Drought ▪ Lack of timely harvesting ▪ High moisture storage ▪ High temperature during storage ▪ Physical damage during processing	▪ Effective insect control ▪ Adequate irrigation schedules ▪ Timely harvesting ▪ Minimize mechanical damage during harvesting ▪ Removal of extraneous material ▪ Dry products to under 10 percent moisture ▪ Storage on dry, clean surface ▪ Clean up and separation of product ▪ Thermal inactivation of mycotoxins ▪ Chemical inactivation of mycotoxins ▪ Ammoniation ▪ Activated carbons and clays
Suttajit, 1989	Peanuts and corn	▪ High temperature ▪ High humidity ▪ Insect damage	▪ Drying to less than 9 percent moisture for peanut and less than 13.5 percent moisture for corn ▪ Maintenance of warehouse at low temperature ▪ Effective insect control ▪ Chemical treatment ▪ Handpicking ▪ Organic solvents ▪ Heating and cooking ▪ Ionizing radiation
USDA/ARS, 2002	Wheat, barley, peanuts, corn, cottonseed, tree nuts, and figs	▪ Aflatoxin and deoxynivalenol production ▪ High humidity and rainfall	▪ Future: gallic acid ▪ Humidity control

Table A-5: Summary of Literature Findings on Physical Safety Issues and Preventive Controls

Source	Industry/Products	Problem/Risk	Preventive Controls Suggested
Folks and Burson, 2001	All foods	Any extraneous object or foreign matter in food, sources include: ▪ raw materials ▪ poorly maintained equipment ▪ improper production procedures ▪ poor employee practices	▪ Raw material inspection and specification ▪ Vendor certification and letters of guarantee ▪ Metal detectors ▪ X-ray technology ▪ Effective pest control ▪ Preventative equipment maintenance ▪ Proper sanitation procedures ▪ Proper maintenance and calibration of detection equipment ▪ Appropriate handling of packaging material ▪ Proper shipping, receiving, and storage practices ▪ Tamper-proof or tamper-evident packaging ▪ Employee education ▪ Protecting light fixtures ▪ Controlling contact between pieces of machinery
Olson, 2002	All foods	Hard or sharp objects are food safety hazards, further classified into metallic and non-metallic objects. Sources include: ▪ Processing equipment ▪ Glass containers	▪ Periodic checks of metal equipment ▪ Metal detectors ▪ Passing product through separation equipment ▪ Visual examination of empty glass containers or containing transparent product ▪ Cleaning with water or compressed air and inverting glass containers ▪ Monitoring lines for glass breakage ▪ Proper adjustment of capping equipment ▪ X-ray systems
Stier, 2001	All foods	▪ Mechanical harvesters that collect more than just the product ▪ Improperly maintained equipment and lines ▪ Packages infested by rodents or insects ▪ Not shielding lights ▪ Lack of policies about glass breakage ▪ Struvite	▪ Plant audits that evaluate systems ▪ Destoners ▪ Magnets ▪ Screens ▪ Washers ▪ Proper equipment maintenance ▪ Tamper-proof packaging ▪ Insect/rodent control ▪ Employee education ▪ Glass breakage policies ▪ Scanners for glass ▪ Metal detectors

American Meat Institute (AMI). 2003. Sanitary Equipment Design. *AMI Fact Sheet.* March.

The AMI Equipment Design Task Force (EDTF) is comprised of representatives from ten meat and poultry processing companies. The EDTF has developed operational and equipment guidelines to minimize the spread of *Listeria* in meat processing plants. The EDTF has identified the critical nature of equipment design in reducing the risk of contamination of food products by *Listeria monocytogenes*. The 10 principles of sanitary design published by the EDTF include; (1) cleanability to a microbiological level, (2) made of compatible materials, (3) accessibility for inspection, maintenance, cleaning, and sanitation, (4) self-draining that does not allow for product or liquid collection, (5) hermetically-sealed hollow areas, (6) niche-free parts, (7) sanitary operational performance, (8) hygienic design of maintenance enclosures, (9) hygienic compatibility with other plant systems, and (10) validated cleaning and sanitizing protocols.
Keywords: meat processing, poultry processing,* Listeria*, equipment, cleaning, sanitation

BBC News. 2002. Finger Nails Hide Nasty Food Bugs. *BBC News*. Newssearch.bbc.co.uk/ 1/hi/health/2148501.stm. July 24.

The study, conducted by Michael Doyle and colleagues at the University of Georgia, indicates that cooks and chefs with long finger nails are more likely to pass on food bugs, such as *E. Coli*, to consumers. Further, long and artificial nails are a breeding ground for potentially harmful bacteria. Even after thorough washing and brushing, pathogens, such as *E. Coli*, can remain under finger nails and can be passed on to consumers.
Keywords:* E. Coli*, risk assessment

Beauchat, Larry R. and Jee-Hoon Ryu. 1997. Produce Handling and Processing Practices. *Emerging Infectious Diseases.* Vol. 3, No. 4.

Contamination of fresh produce with pathogens is not rare. Contamination can occur through contact with soil, raw or improperly composted manure, irrigation water containing untreated sewage, or contaminated wash water. Contact with mammals, reptiles, fowl, insects, unpasteurized products of animal origin, and contaminated surfaces (including human hands) are other potential points of contamination. Treatment of produce with chlorinated water reduces pathogenic and other microorganisms on fresh produce but does not eliminate them. Potential points of contamination need to be controlled in the field, during harvesting, processing and distribution, in retail markets, at food-service facilities, and at home.
Keywords: fresh produce, pathogens, handling, processing, controls

Bell, Chris and Alec Kyriakides. 2002a. Pathogenic *Escherichia Coli*. *In Foodborne Pathogens: Hazards, Risk Analysis and Control* edited by Clive de W. Blackburn and Peter J. McClure. Woodhead Publishing Limited and CRC Press LLC. Boca Raton, FL.

Controls that can reduce introduction of fecal pathogens into raw milk include effective hygiene and routine monitoring for pathogens. Meat contamination can be minimized by effective animal husbandry and proper hygiene. The inability to eliminate the pathogen has resulted in the introduction of steam pasteurization that decontaminates the surface of the meat while retaining the raw meat quality and appearance. Good agricultural practices (GAPs), microbiological testing, and chlorine washing can minimize contamination of produce. *E. Coli* can survive fermentation and therefore products made with this process should be examined with challenge studies to determine the critical control points that require effective control to minimize contamination. Washing efficacy is dependent on good contact between the

contaminant and the microbial agent and agitation assists in this process. Sprouting processes (alfalfa seeds) have also been implicated in *E. Coli* contamination. Testing is essential to achieve some control over this form of contamination. Segregation, effective cleaning, and disinfection are key to preventing post-process contamination.
Keywords: **E. Coli*, good agricultural practices, risk analysis, pasteurization, controls, testing***

Bell, Chris and Alec Kyriakides. 2002b. *Salmonella*. In *Foodborne Pathogens: Hazards, Risk Analysis and Control* edited by Clive de W. Blackburn and Peter J. McClure. Woodhead Publishing Limited and CRC Press LLC. Boca Raton, FL.

Salmonella can be reduced by controlling the feed of food animals and poultry. Birds can also be vaccinated against infection. Animal husbandry practices also influence the spread of *Salmonella*. The same practices outlined for *E. Coli* can be used to prevent contamination of raw milk, raw meat and poultry, eggs, and produce.
Keywords: **Salmonella*, controls, risk analysis, animal husbandry***

Bell, Chris and Alec Kyriakides. 2002c. *Listeria Monocytogenes*. In *Foodborne Pathogens: Hazards, Risk Analysis and Control* edited by Clive de W. Blackburn and Peter J. McClure. Woodhead Publishing Limited and CRC Press LLC. Boca Raton, FL.

L. monocytogenes is widespread in the environment and occurs in all raw food materials from time to time. The factors that contribute include raw material or product exposed to contamination, product manufactured with no processing stage to kill the organism, product with few or no preservatives, and product exposed to post-process contamination. The pathogen can grow at very low temperatures in foods. Control of *Listeria* is dependent on preventing contamination of or growth in raw materials, destroying or reducing it if present in raw materials, preventing recontamination in the factory by the environment, equipment or personnel. Monitoring and testing the product can be appropriate in some products, such as raw milk or smoked fish. Washing produce with chlorine also reduces contamination with *Listeria*. With respect to post-process contamination, there is probably no bacterial pathogen that exploits the food processing environment better than *Listeria*. The organisms are transferred either from the environment to the product or via product contact surfaces from aerosols or poor personnel handling practices. The best way to control *Listeria* is to eliminate it from the post-processing environment by segregating raw materials and processed materials and by practicing effective cleaning and sanitation. In addition to food product contact surfaces, the environment should be checked and cleaned, including reservoirs where *Listeria* can quickly grow to high levels. Cleaning practices themselves can also spread the organism and should be controlled. Routine monitoring of cleaning efficacy by means of sampling is also essential.
Keywords: **Listeria*, risk analysis, controls, handling, post-processing, segregation, cleaning, sanitation***

Belluck, Pam and Christopher Drew. 1998. From a Farm in California to Outbreak of Food Poisoning in the East. *The New York Times*. January 5.

In July 1996, a small Californian lettuce company was identified as the source of an *E. Coli* O157:H7 bacteria outbreak. The organic farm did not use any chemicals to wash lettuce and operated in a barn next to a small cattle pen. The processing shed was completely open on one side, exposing the large stainless steel tub where the leaves of lettuce were washed before being mixed and shipped in three-pound boxes. Because the cattle were less than 100 feet away, cow feces could be blown into the shed by wind, washed in by rain, and tracked in on workers' boots, by animals or by the birds seen flying into the barn. Further,

dust from the trucks and cars driving in and out of the parking area and debris from the field were blown into the wash tank and wash area. In the wash tank, lettuce was swished around by employees, some of whom did not wear gloves, and who had no acceptable place to sanitize their hands. The company also had no quality control procedures in place. No chlorine, which can be used on organic foods to kill bacteria, was added to the wash water and no bacterial testing was done.
Keywords: fresh produce (lettuce), organic production,* E. Coli*, risk assessment

Berne, Steve. 1997. Simplifying Sanitation. *Prepared Foods*. March.

Sanitation and good employee hygiene practices are of high importance in ensuring food safety in a plant. Whether making sure employees keep good hygiene or checking the efficacy of sanitized equipment, keeping the procedure simple will more likely result in employees actually performing the required tasks. There are a number of systems on the market to ensure hygienic practices among employees and to check for the effectiveness of equipment sanitation. Meritech's CleanTech® system is a no-touch hand-washing system. The system provides a low-volume warm water wash followed by an antimicrobial solution spray. It also has a cycle counter so the frequency of hand and glove washing can be monitored. Color-coded cleaning materials are another way to simplify training and assure proper application. The colors and shapes ensure proper selection, ease identification and monitoring, simplify training and SSOP understanding. IDEXX has a new *Salmonella* detection system called Bind® which enables the manufacturer to test for the existence of *Salmonella* easily. There also are ATP bioluminescence cleaning validation systems for detection of food residue, yeast, mold, and bacteria on production surfaces.
Keywords: sanitation, employee hygiene, cleaning, equipment

Best, Daniel. 2000. Chicken or Egg – It's Safety First. *Food Processing*. April 2.

In-plant construction activities are a major culprit in food borne illness outbreaks in meat plants. Construction activity results in the dissipation of dust and, with it, microorganisms throughout a plant environment. Some of the control procedures include: avoidance of sample compositing during testing to detect contamination patterns, testing during operations to reflect true-life conditions in the plant, and nonrandomized testing. For egg producers, the control of *Salmonella* hinges on the adoption of multiple controls. Some of these controls include vaccination, competitive exclusion, and in-the-shell pasteurization. In the U.S., the United Egg Producers Association promotes the adoption of its Five Star program among its members that combines vaccination with sanitation, pest controls, washing and refrigeration controls.
***Keywords: meat processing, construction, risk assessment, controls, eggs, pasteurization,* Salmonella**

Bissessur, J., K. Permaul, and B. Odhav. 2001. Reduction of Patulin During Apple Juice Clarification. *Journal of Food Protection.* Vol. 64, No. 8.

Patulin is a mycotoxin produced by a number of molds involved in fruit spoilage. Various methods are currently used to reduce the levels of patulin in apple juice, including charcoal treatment, chemical preservation using sulfur dioxide, gamma irradiation, fermentation, and trimming of fungus-infected apples. Many of these processes are expensive and time-consuming. This study found that clarification methods, including pressing, centrifugation, fining, enzyme treatment, and filtration, were successful in reducing patulin levels in apple juice. However, the process resulted in high levels of patulin in the pressed pulp after filtration and centrifugation, and this could be harmful if used for animal feed.
Keywords: patulin, mycotoxin, juice, controls

Boutrif, Ezzeddine. 1999. Minimizing Mycotoxin Risks Using HACCP - The Cracker. *International Tree Nut Council.* September.

Pre-harvest drought, insect infestation and delayed harvesting are important external factors that contribute to mycotoxin formation. Some of these are difficult to control, but good agricultural practices (GAPs), such as timely harvesting and use of pesticides are controls that can reduce mycotoxin infestation. During harvest, mechanical damage should be minimized to prevent subsequent contamination. Crops should also be harvested in a timely manner to prevent mycotoxin formation due to high moisture levels. While prevention through pre-harvest management is best, should contamination persist or occur at a later time, processing and storage controls should be in place as well. Processing may involve removal of parts of the commodity, making it more susceptible to mold formation. Mycotoxins may be eliminated through physical separation or chemical/heat inactivation. Electronic sorting and handpicking can remove damaged, immature, or mold infested kernels and remove a significant amount of aflatoxins in shelled nuts. Proper storage is critical, as moisture, heat, and physical damage greatly increases the potential for mycotoxings to form. Stored products must be stored under dry and cool conditions that would prevent mold growth.
Keywords: mycotoxins, good agricultural practices, HACCP, risk assessment, controls, separation, storage

Brandt, Laura A. 1999. Hot Dog Days. *Prepared Foods*. August.

Listeria monocytogenes can grow at refrigerated temperatures if it gets on a product before packaging. Proper heating of hot dogs and meats can, however, reduce the risk of listeriosis, which affects mostly pregnant women, the elderly and the immunocompromised. Food manufacturers are trying to control such pathogens through revised plant procedures, packaging innovations, and by adding key ingredients. Some of the preservatives that are formulated into hot dogs and other processed meats to control the growth of pathogens include sodium nitrite, sodium lactate, sodium diacetate, polyphosphates, organic acids, smoke flavoring, and bacteriocins, such as nisin and pediocin.
Keywords: meat processing,* Listeria*, risk analysis, controls, preservatives

Bryan, Frank L., John J. Guzewich, and Ewen C.D. Todd. 1997. Surveillance of Foodborne Disease III. Summary and Presentation of Data on Vehicles and Contributory Factors; Their Value and Limitation. *Journal of Food Protection.* Vol. 60, No. 6: 701-714.

Factors that contribute to food borne illness outbreaks are identified in this paper, based on collection of food borne disease outbreak data from various sources. The contributory factors are situations or operations that allow contamination of foods and survival and/or proliferation of the etiologic agents in the foods. Contamination can occur with natural toxins, which are toxic elements found in animal or plant substances. Mushrooms are the most common example. Chemicals can enter foods through spillage or indiscriminate spraying. Misreading labels can also result in accidentally or incidentally adding poisonous substances to food. An approved ingredient can also be added in excessive quantities by accident, such as too much nitrite in cured meat or too much ginger powder in gingersnaps. Toxic substances in containers or pipelines can leach into food by contact with highly acidic foods. Raw ingredient can be contaminated or foods can be obtained from polluted sources. Foods that are not heated and are processed on or in equipment used previously with raw foods without proper cleaning can become cross-contaminated. Cross-contamination can also occur through workers who do not wash their hands, through cleaning aids, such as sponges that are not disinfected, or when raw foods touch or drip onto other foods. Inadequate hygiene on the part of food handlers and inadequate cleaning of equipment and utensils can also result in

contamination. Storage of dry foods in an environment where overhead drippage, back siphonage, airborne contamination, and access for insects and rodents are likely are also situations conducive to contamination. Other contributory factors are those that allow survival or fail to inactivate the contaminant, such as insufficient cooking time or temperature or inadequate acidification. Factors that allow proliferation of contaminants include inadequate refrigeration, insufficient acidification, inadequate fermentation, modified atmosphere packaging (MAP), and more. Data on these factors can suggest preventive measures to be adopted as practices.
Keywords: outbreaks, contributory factors, risk assessment, cleaning, cross-contamination

Calicioglu , Mehmet, Nancy G. Faith, Dennis R. Buege, and John B. Luchansky. 2002. Viability of *Escherichia coli* O157:H7 during Manufacturing and Storage of a Fermented, Semidry Soudjouk-Style Sausage. *Journal of Food Protection.* Vol. 65, No. 10: 1541-1544.

This study evaluated the manufacturing process for soudjouk-style sausage on the viability of *E. coli* O157:H7. Natural fermentation and drying processes were found to be less effective than the use of a starter culture in reducing levels of *E. coli* O157:H7. These results indicate that naturally fermented old-country-type sausage may allow the survival of *E. coli* O157:H7 in the absence of controlled fermentation, post-fermentation cooking, and/or an ambient-storage processing step. These results provide a framework for small-scale producers of "old-world" sausage to modify their current manufacturing processes to enhance product safety with regard to *E. coli* O157:H7.
Keywords: meat processing,* E. Coli*, risk assessment

Chmielewski, R.A.N. and J.F. Frank. 2003. Biofilm Formation and Control in Food Processing Facilities. *Comprehensive Reviews in Food Science and Food Safety*. Vol. 2: 22-32.

Microorganisms within biofilms are protected from sanitizers increasing the likelihood of survival and subsequent contamination of food. The type of food contact surface and topography play a significant role in the inability to decontaminate a surface. Abraded surfaces accumulate soil and are more difficult to clean than smooth surfaces. In most food processing plants, food contact surfaces are cleaned and sanitized daily. However, many environmental surfaces, such as storage tank and pump exteriors, walls, and ceilings, are cleaned infrequently. This infrequent cleaning provides the opportunity for biofilm formation if moisture is present. Nutrient and water limitation, equipment design, and temperature control are important in biofilm control. Cleaning can be accomplished by using chemicals or combination of chemical and physical force (water turbulence or scrubbing). Sanitizer selection should be based on whether or not a biofilm is likely to be present and the organic load likely associated with the biofilm. Manufacturing equipment must be fabricated using appropriate materials. Plants should monitor the microbial load on surfaces with plating of swabbing solution, contact plates, and the dipstick technique.
Keywords: food processing, biofilms, cleaning, sanitation, controls

Cliver, Dean O. 1999. *Eating Safely: Avoiding Foodborne Illness*. Prepared for the American Council on Science and Health. June.

Most food borne disease hazards are caused, not by additives or pesticides, but by microbes. Poor sanitation and preparation practices are more common in food-service operations and in the home than they are in food processing. The scientific knowledge necessary to eliminate pathogens at the farm level does not yet exist. The main sources of food contamination include human errors in handling, pests and rodents, and temperature abuse during handling. Prevention or minimization of human error is possible via the enforcement of good sanitary practices, such as thorough hand washing and glove wear for various

cases. There are additional considerations for different categories of foods, such as fruits and vegetables, grains, milk and dairy products, meat, poultry, fish, egg products, and other food products, such as ethnic foods, spices, honey, mayonnaise and dressings. Some of these include cold storage and appropriate selection of packaging for fruits and vegetables, pasteurization for milk, irradiation and dipping in a trisodium phosphate solution for poultry, and proper handling and routine monitoring for toxins for fish.
Keywords: food service, handling, sanitation, risk analysis, controls

Cramer, Michael M. 2003. Building the Self-cleaning Food Plant: Six Steps to Effective Sanitary Design for the Food Plant. *Food Safety Magazine*. February/March.

Incorporation of sanitary design into your facility can prevent development of microbiological niches, facilitate cleaning and sanitation, maintain or increase product shelf life and improve product safety by reducing potential of food borne illness, injury or recall. Food safety hazards that must be controlled include microbiological (pathogens), physical (glass, metal shavings, wood) and chemical (allergen cross contamination), while preventing product exposure to sources of filth (dust, rodent excrement). For cooked, ready-to-eat (RTE) products, the study recommends adhering to the following six basic elements of sanitary design:

- Facility site selection,
- Grounds and dust control – grading grounds for drainage and paving driveway and parking areas,
- Pest control – landscaping design to prevent pest harborage, adequate door seals, use of insect electrocuters,
- Basic facility flow – separate entrance for employees, isolation of lunchrooms, lockers, and restrooms, and use of captive shoes,
- Plant materials – use of easily cleanable materials for floors, walls, and ceilings, caulk-sealed seams, flush doorjambs, no sewage lines running over production or storage areas, and positive airflow in RTE areas, and
- Equipment – sanitary equipment design and third-party review of equipment design.

The study also recommends cross-functional training of staff in sanitary facility and equipment design to evaluate existing structure and plant equipment or to facilitate expansion and improvements. This can be accomplished through the use of available literature, or more effectively, through training courses offered by experts in the field.
Keywords: facility design, equipment, cleaning, sanitation, ready-to-eat, pest control, employee training

CSPI. 2001. *FDA Inspections Find Undisclosed Allergens in Processed Food*. April 3.

An unpublished government report found that many processed foods are contaminated with peanut or egg allergens but labeling does not disclose these substances. In an FDA survey of 85 small, medium, and large food plants, FDA and state inspectors found that only half of the firms were cross-checking ingredients on the labels with ingredients used in manufacturing the product. Some companies modified the product recipe without changing the label. Others were using contaminated equipment. In another study of cross-contamination issues, companies did not separate production runs or clean their machinery

properly. HACCP has been recommended by CSPI to ensure food does not become contaminated with allergens.
Keywords: allergens, labeling, risk analysis, cross-contamination, HACCP

Curiel, Roy. 2003. Building the Self-cleaning Food Plant: Hygienic Design of Equipment in Food Processing. *Food Safety Magazine*. February/March.

As a result of the development and application of increasingly mild preservation technologies, processed foods become more sensitive to microbial contamination, requiring greater control of the manufacturing process. One way to achieve this added control is to "build in" hygiene into the equipment used in the food manufacturing facility from the start. Selected criteria and basic requirements for a variety of hygienic equipment characteristics provide a fundamental overview of areas that can be addressed by food manufacturers. These include:

- *Materials of construction*. Product-contact materials must be inert to the product under operating conditions, as well as to detergents and antimicrobial chemicals (sanitizers) under conditions of use.
- *Surface roughness*. Product contact surfaces should be smooth enough to be easily cleanable. To achieve this quality of surface, polishing or other surface treatment may be required.
- *Crevices.* Crevices cannot be cleaned, and as such, will retain product residues that may effectively protect microorganisms against inactivation. The presence of slide bearings should be considered when writing procedures for cleaning and disinfection. These procedures may require instructions for both partial or total dismantling of equipment, or for increased cleaning times.
- *Screw threads*. The use of screw threads and bolts in the product area should be avoided. Where unavoidable, the crevices created should be sealed, at minimum.
- *Sharp corners*. Sharp corners in the product area should be avoided. Exceptions are constructions where the sharp corner is continually swept, such as in lobe pumps. Welds should not be made in corners, but on the flat surfaces, and must be smooth.
- *Dead areas.* There is a significantly reduced transfer of energy to the food residues (soil) in dead areas in process equipment that is placed outside of the main flow of cleaning liquids than there is to the soil in the main flow.
- *Drainability of equipment and process lines.* To make it possible to remove all chemicals from process equipment, the equipment must be designed to be self-drainable.
- *Top rims of equipment*. The design of the top rims of product-containing equipment must avoid ledges, where product can lodge and that are difficult to clean.
- *Mandoor covers*. Mandoor covers intended to protect the food products may accumulate dirt, which will enter the product in the vessel when the lid is opened. Policy should specify that no tank is opened during production unless absolutely necessary.

- *Shaft passages and seals*. Shaft passages and seals may leak product to the outside of the line. Microorganisms may then multiply in the product and grow back to the product side. Reciprocating shafts should be sealed by means of flexible diaphragms or bellows. To prevent the ingress of microorganisms in rotating shafts, double seals with microbiocidal barrier liquids should be used.

Keywords: equipment, facility design, cleaning, sanitation, controls

Deibel, Virginia. 2001. Biofilms. *Brain Wave Technologies: Thought for Food.* Vol. I. No. 1. May.

Chlorine, iodophors, and most quaternary ammonium compounds are ineffective against removing biofilms. The best method of controlling biofilms is to prevent their development in the manufacturing environment. Effective cleaning and sanitation, which combines physical and chemical methods within the program, will often prevent the accumulation of food product residues and bacterial cells on equipment surfaces. Cleaning by brushing, scrubbing, and scraping surfaces is often necessary because once a bacterial cell is released from the protection of a biofilm, it is much less resistant to subsequent sanitizers. Acid cleaners can be used to remove inorganic soil or material, such as rust, and using soft water for cleaning aids in the effectiveness of cleaning chemicals. Further, peroxide and peroxide containing sanitizers have been found to be highly effective in removal of biofilms.
Keywords: biofilms, cleaning, sanitation

Deibel, Kurt, Tom Trautman, Tom DeBoom, William H. Sveum, George Dunaif, Virginia N. Scott, and Dane T. Bernard. 1997. A Comprehensive Approach to Reducing the Risk of Allergens in Food. *Journal of Food Protection.* Vol. 60, No. 4: 436-441.

The control of food allergens in a food processing plant requires an allergen prevention plan that determines the potential sources of contaminating allergens and appropriate controls to prevent their introduction into products. A close working relationship with suppliers is important. The ingredient specification should warrant that the product is free of foreign material, including allergens. An on-site audit is recommended. The supplier should also provide a list of other products with allergens used on the processing line on which the manufacturer's ingredient is produced. It may be necessary to raise awareness of suppliers through a training program. Longer run times that minimize changing products and scheduling the allergen-containing product at the end of a run reduce the chance of allergen contamination. Belts that run materials from one place to another should be covered to prevent ingredients from falling onto other belts and airflow should be considered. Rework must be clearly identified and documented. Maintenance tools should be color coded for specific areas or proper cleaning procedures should be specified. A process control check to verify that known allergens are listed on the ingredient label is essential. It is also important to verify that the food product is placed in the appropriately labeled package and that the appropriate label is placed on the product. Bar code scanners are sometimes used for this. The design of new lines or equipment must minimize the potential for human error. It is necessary to use physical detachments or lockouts of high-risk equipment if lines are used for both allergen and nonallergen containing foods. Crossover points should be enclosed. Verification of cleaning between allergen and non-allergen containing product runs is essential. Some equipment may need to be disassembled and manually cleaned. ELISA tests are being developed for allergens that could help verify the cleaning procedures, which is currently limited to visual inspection. A major problem is that older equipment may not be designed to verify visual cleaning. Employee training programs have proven to be one of the most effective tools for preventing inadvertent contamination with allergens.
Keywords: allergens, controls, prevention, suppliers, equipment, labeling, cleaning, employee training

Donnelly, Catherine W. 2002/2003. Inside Microbiology: Getting a Handle on Listeria. *Food Safety Magazine*. December 2002/January 2003.

Listeria is a very common pathogen that can be found almost anywhere in the environment. Some of the high risk foods for *Listeria* contamination include smoked seafood, ready-to-eat (RTE) meat and poultry products, soft cheeses, raw milk and Mexican-style cheeses, especially products not commercially prepared. The main control mechanism that the food industry has in place for protecting products like RTE meat and poultry from *Listeria* contamination is to clean and sanitize to eliminate the pathogen and then to conduct environmental testing and monitoring to verify that sanitation efforts have been successful. *Listeria* establishes niches in food processing plant environments and unless there is absolutely rigorously focused sanitation, it can persist for months or years within food plant environments. Further, most food processing plants in the U.S. were not designed with control of this pathogen in mind. For example, drains may have been placed in undesirable high-traffic floor areas where cross-contamination can easily occur. One of the responses to the *Listeria* crisis in the mid-1980s in the dairy industry was major plant redesign activities, including redesign of floors and drains so they could be effectively cleaned and sanitized and increased protection of the filling equipment from air contamination. There are many interventions used as part of the sanitation program in food companies, including the use of advanced chemical sanitizers to clean and sanitize surfaces and the rotation of those chemical sanitizers so that organisms do not have a chance to develop resistance over time, employee gowning protocols, easily cleanable boots, segregation of raw materials and food production areas, use of foot baths, foaming sanitizers and handwashing systems. Another intervention strategy involves making changes within the products themselves. Kraft Foods, for instance, has developed a potassium lactate and sodium diacetate preservative system that, when used in the formulation of products like hot dogs, creates a good chemical barrier to the growth of *Listeria.* Additional control technologies include electronic pasteurization, especially when done in the package, irradiation, other non-thermal processing intervention technologies, such as high pressure processing (HPP). Because the greatest risk of *Listeria* growth is through process contamination, however, it is very important that the intervention is applied in final package with any of these technologies.
Keywords:* Listeria*, cleaning, sanitation, facility design, intervention, controls

Doyle, Ellin M. 1999. Literature Survey of the Various Techniques Used in *Listeria* Intervention. *FRI Briefings*. Food Research Institute, University of Wisconsin. November.

Recalls, illnesses, and deaths associated with *Listeria* in food products have been reported over the past years. These incidences indicate that additional techniques may be needed for controlling *Listeria* in food processing plants and especially in those processing ready-to-eat (RTE) products. In response to the *Listeria* issue, on March 8, 1999, the Food Safety and Inspection Service (FSIS) of the USDA amended the Federal meat and poultry inspection regulations of certain RTE meat and poultry products. The new performance standards indicate the objective level of food safety performance that establishments must meet. The amended regulations, however, allow establishments to develop and implement processing procedures customized to the nature and volume of their production. The techniques covered in the literature survey include the use of organic acids, other preservatives, and bacteriocins in product formulations, application of additional process steps, such as thermal processes, irradiation, high pressure, pulsed electric field pasteurization, electrolyzed oxidizing water, ultraviolet light, and ultrasound, and use of modified atmosphere packaging (MAP) to suppress growth of food borne pathogens.
Keywords: ready-to-eat,* Listeria*, intervention, regulation

Doyle, Michael P. 2000. Food Safety Issues Arising at Food Production in a Global Market. *Journal of Agribusiness.* Vol. 18, No. 1: 129-133.

Food borne illness is a major public health concern in the United States, with an estimated 76 million cases occurring annually. More than 90 percent of food borne illnesses of known cause are of microbial origin. Animals used for foods and their manure are leading sources of food borne pathogens. Recent advances in the investigation of food borne outbreaks using genetic fingerprinting techniques enable epidemiologists to identify outbreaks and sources of implicated foods that heretofore were undetected. Tracebacks of outbreaks to the point of production place greater liability and responsibility on food producers. Implementation of Hazard Analysis Critical Control Point (HACCP) systems at the point of production is essential to increasing the safety of foods of animal and plant origin.
Keywords: outbreaks, tracking, HACCP

Drew, Christopher and Pam Belluck. 1998. Deadly Bacteria a New Threat to Fruit and Produce in U.S. *The New York Times*. January 4.

Several outbreaks of deadly bacteria in juice and produce have occurred in recent years. Lettuce from a small producer caused an outbreak of *E. Coli* O175:H7 in three states and sickened at least 61 people. The producer operated under unsanitary conditions, with the lettuce being washed and packaged less than a hundred feet from a cattle pen.

In mid-1995, orange juice served at Walt Disney World was contaminated with Salmonella. The contamination was believed to be caused by a toad that crawled onto the juice processing equipment. In response, the state of Florida drafted rules that required a two-step cleaning process of fruit, including an acid-based detergent and chlorine and that prevented the use of split or decayed fruit.

In late 1996, 70 people became sick after consuming Odwalla's fresh-squeezed apple juice. Odwalla's juice was not pasteurized at the time and thus required additional controls, like sorting out damaged fruit and washing the remaining fruit with sanitizers. Documents show, however, that in the weeks before the outbreak, Odwalla began relaxing its standards on accepting blemished fruit. Apples with defect rates of 25 to 30 percent were used, compared to the 5 percent that was normally acceptable to Odwalla in the past. Furthermore, a QA manager's recommendation to add a chlorine rinse to the acid rinse already being used was not implemented because another executive feared it would affect the taste of the juice (the brand of acid wash Odwalla was using was only able to kill all the *E. Coli* O175:H7 in 8 percent of lab tests and should not have been used without chlorine). Another quality assurance manager suggested testing for *Listeria monocytogenes* again, which had been found in orange and apple juice in 1995, but dropped the plan after resistance from upper management. In the outbreak case, the company was accused of using a batch of rotten apples, some with worms in them. Odwalla denied that the company took any such risks, but recognized that their safety systems failed. As a result of the outbreak, Odwalla hired safety consultants and voluntarily implemented a Hazard Analysis Critical Control Point (HACCP) plan. Odwalla also started using pasteurization to kill all pathogenic bacteria in its apple juice given that the skin gets mashed into the juice. Odwalla decided not to pasteurize orange juice given that the juice can be extracted without touching the rind.
Keywords: outbreaks, juice, fresh produce (apples),* E. Coli*, HACCP, pasteurization

Economic Research Service (ERS). 2001a. *Industry Food Safety Actions: Conventional Practices and Technologies*. U.S. Department of Agriculture, Economic Research Service. February 12. www.ers.usda.gov/briefing/IndustryFood Safety/convenprac/.

In meat and poultry processing, the primary means of preventing the spread of pathogens is with conventional work practices, such as effective sanitation programs and the use of work programs that minimize opportunities for product contamination. Some of the most effective work practices as identified by food safety experts and plant managers include:

- Animal or meat testing for pathogens,
- Knife sterilization and temperature, airflow, and other process controls,
- Improved evisceration and hide, hair, and feather removal techniques,
- Employee work methods and empowerment for food safety decisions,
- Production line layouts that minimize cross-contamination,
- Pathogen testing of equipment and plant environment,
- Use of labor-saving equipment that reduces cross-contamination,
- Rate at which workers' hands, tools, and equipment are sterilized, and
- Management strategies, like the Hazard Analysis and Critical Control Points (HACCP) system.

These methods may be particularly important for small plants that may not have the resources to buy expensive technologies, such as automated carcass steam pasteurizers or irradiation equipment. Some of the conventional technologies available to meat and poultry processors include (1) steam pasteurization and/or vacuuming systems, (2) hot water sprays, (3) use of chlorinated water and other sanitizers to sanitize the product, work surfaces, and equipment, (4) competitive exclusion (applicable to poultry), and (5) automation of manual processes.
Keywords: meat processing, poultry processing, controls, sanitation, testing, work practices, HACCP

Economic Research Service (ERS). 2001b. *Industry Food Safety Actions: Unconventional Technologies/Irradiation*. U.S. Department of Agriculture, Economic Research Service. February 22. www.ers.usda.gov/briefing/IndustryFood Safety/unconventech/.

Food processing firms, universities, and the USDA are conducting research on many new technologies to control pathogens. One of these technologies commonly accepted as a tool to kill all pathogens is irradiation. Depending on the type of food and radiation dosage, irradiation can be used to sterilize packaged food for storage at room temperature, eliminate or reduce pathogens, delay spoilage, control insect infestations, delay ripening, and inhibit sprouting. The capital costs of food irradiation equipment depend primarily on the irradiation source, food product, plant volume, and facility design. Further, there are substantial economies of scale involved in food irradiation with the cost per pound of irradiated meat decreasing by increases in annual volume.
Keywords: pathogens, irradiation, costs

Ennen, Steve. 2003. Safety Tops Concerns for Coming Year. *Food Processing*. January 1.

According to Food Processing's 2003 Manufacturing Survey, food safety is one of the most important issues facing the food industry today. The majority (64 percent) of respondents indicated that their companies have either implemented new food safety and sanitation initiatives or intend to do so. Among these respondents, 84 percent noted that their companies will address food safety with employee training. Another 73 percent indicated that their companies have plans to tweak or implement HACCP plans. Meanwhile, 60 percent of respondents said that their companies plan to improve pest control, while 55 percent said that plans to augment sanitation equipment are underway or completed. Among the many scientific safety initiatives cited were improved *E. Coli* testing, stronger biosecurity measures, audits, access restrictions, implementation of date/lot/batch coding, metal detection, and x-ray machines. Overall, 22 percent of respondents indicated that their companies had no plans to improve safety this year but no reasons were given for their decision.
Keywords: food safety initiatives, sanitation, employee training, HACCP, pest control

Erickson, J.P. 1995. An Assessment of Escherichia coli O157:H7 Contamination Risks in Commercial Mayonnaise From Pasteurized Eggs and Environmental Sources, and Behavior in Low-pH Dressings. *Journal of Food Protection*. Vol. 58, No. 10: 1059-1064. [only have abstract]

This study evaluated *E. Coli* contamination risk during commercial mayonnaise and mayonnaise dressing production, and *E. Coli* behavior in low-pH dressings. Two potential contamination sources, pasteurized liquid eggs and wet environmental areas were observed for 4 months in 3 processing plants. The study concluded that if plants use pasteurized eggs and GMPs, plants are unlikely to harbor *E. Coli*. Further, stringent hygienic practices by consumers and food-service workers can prevent microbial pathogen contamination during preparation, handling, and storage of mayonnaise-ingredient recipes, such as chilled perishable salads and salad-bar dressings.
Keywords: risk assessment,* E. Coli*, dressing (mayonnaise), eggs, employee hygiene

FDA/CFSAN. 2001a. *Draft Assessment of the Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods*. January.

This risk assessment includes analysis of available scientific information and data in the development of exposure assessment and dose-response models to predict the public health impact of *Listeria monocytogenes* from 20 RTE food categories. Outbreaks often are due to a breakdown in food safety controls that have been put in place to prevent such occurrences. Outbreaks of listeriosis have been linked to plant renovations, use of defective processing equipment, and inadequate pasteurization. Maintenance of food safety controls and strengthening of existing controls is therefore paramount.
Keywords: ready-to-eat, risk assessment,* Listeria*, outbreaks, controls

FDA/CFSAN. 2001b. *Seafood HACCP Alliance HACCP Training Curriculum Manual: Hazards – Biological, Chemical, and Physical (Chapter 2)*. November.

Food safety hazards are typically categorized into three classes: biological, chemical, and physical. Biological hazards include harmful bacteria, viruses or parasites, such as *Salmonella*, Hepatitis A, and Trichinella. Chemical hazards include compounds that can cause illness or injury due to immediate or long-term exposure. Chemical hazards can be subdivided into naturally occurring chemicals (mycotoxins, allergens, marine toxins), intentionally added chemicals (preservatives, nutritional additives, color

additives), and unintentionally added chemicals (pesticides, veterinary drugs, toxic elements, food processing plant chemicals such as cleaners). Risks increase when chemicals are not controlled or the recommended treatment rates are exceeded. Physical hazards, on the other hand, include foreign objects in food that can cause harm when ingested, such as metal or glass fragments.
Keywords: seafood processing, HACCP, biological hazards, chemical hazards, physical hazards

FDA/CFSAN. 2001c. ***Analysis and Evaluation of Preventive Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-cut Produce*****. September 30.**

The extensive study identifies the various production practices that may influence the risk of contamination and exposure to pathogens in fresh and fresh-cut produce. Key areas of concern are practices related to prior land use, adjacent land use, field slope and drainage, soil properties, crop inputs and soil fertility management, water quality and use practices, equipment and container sanitation, worker hygiene and sanitary facilities, harvest implement and surface sanitation, pest and vermin control, effects of domesticated animal and wildlife on the crop itself or packing area, post-harvest water quality and use practices, post-harvest handling, transportation and distribution, and documentation and recordkeeping. Some of the control measures recommended include temperature control, physical removal of microorganisms, use of cleaning agents, such as chlorine, chlorine dioxide, bromine, iodine, quaternary ammonium compounds, acidic compounds with or without fatty acid surfactants, alkaline compounds, peracetic acid, hydrogen peroxide, and additional/new processing technologies, such as ozone, irradiation, and biocontrol.
Keywords: fresh produce, risk analysis, controls

FDA/CFSAN. 2001d. ***Food Allergen Partnership*****. January.**

In October of 1998, FDA formed a partnership with the Minnesota Department of Agriculture (MDA) and the Wisconsin Department of Agriculture, Trade, and Consumer Protection (WDATCP). One of the goals of the partnership was to obtain current information on allergen awareness and to provide training and information to the industry about effective control measures. Three ice cream, 31 bakery, and six candy manufacturers were inspected in Minnesota and 10 ice cream, 23 bakery, and 12 candy manufacturers were inspected in Wisconsin. A questionnaire was used to assess industry practices. Routine regular inspections were conducted. Six establishments in Minnesota and ten establishments in Wisconsin had written recall procedures addressing allergens. In 25 percent of establishments inspected, raw ingredients, such as nuts or artificial colors were omitted from the label. Of firms that felt they had adequate label review policies, 15 percent were found to have discrepancies. Further, 38 percent of the Minnesota and 64 percent of Wisconsin firms without label verification procedures were found to have undeclared allergen residues in their products. Most firms discarded labels after formulation changes. Further, of the 37 of 85 firms that utilized rework, roughly half had product that tested positive for allergens. Only four percent of establishments inspected used analytical testing to verify the effectiveness of cleaning and sanitation procedures. In Minnesota, 10 of the 40 firms had SSOPs that were proven effective and followed. In many establishments, common utensils were used in the production of allergen and nonallergen-containing products. Cross-contamination also occurred when baking sheets were reused without cleaning. Production was frequently not scheduled or sequenced for allergen control. Many firms also did not have dedicated equipment for allergen and nonallergen production. Cleaning of these lines was found to be inadequate, rinsing with water only or cleaning only at the end of the day. Further, only three of the 85 Minnesota and Wisconsin firms utilized personnel that were trained and dedicated to allergen control. When product was tested, a number of samples were positive for allergen residue. Many establishments changed operating procedures as a result of the findings from these inspections, including many sanitation changes. A number of establishments also did not make changes, however. In sum, industry awareness is

essential in the control of potential allergen residue risk. Possible controls include scheduling production of allergen-containing products at the end of manufacturing runs, appropriate labeling, proper use of rework, equipment and system design considerations, thorough cleaning of lines after running allergen-containing products, effective management of label inventories, control of ingredients from suppliers and training of employees.
Keywords: allergens, industry practices, labeling, testing, sanitation, cross-contamination, cleaning, employee training, controls

FDA/CFSAN. 2001e. *Food Allergen Monitoring*. January.

Food allergens can become part of food unintentionally by means of misformulation, improper scheduling, use of rework, improper sanitation, and cross-contamination. Controls include good manufacturing practices (GMPs), minimizing equipment exposure to the allergen, designating and labeling equipment for use with specific products, enclosing equipment and avoiding crossovers, adding allergens near the end of a process, scheduling longer run times, running non-allergen products before products with allergens, producing allergen products on a separate day from non-allergen products, color coding tools for allergen and non-allergen products, adequate controls on rework, discarding old labels and packaging materials, conducting label audits, appropriate sanitation, and training on allergens and proper sanitation.
Keywords: allergens, risk assessment, controls

FDA/CFSAN. 2001f. Chapter 19: Allergens, Food Intolerance Substances and Prohibited Food and Color Additives. *Fish and Fisheries Products Hazards and Controls Guidance.* June.

Some food and color additives can cause an allergic-type reaction in consumers. Sulfiting agents and FD&C Yellow #5 are additives used on fish and fisheries products that can cause such reactions. A number of foods also contain allergenic proteins. Possible preventive measures include declaring the presence of the allergen, testing for residue, requiring supplier certification that the product is allergen free, and reviewing labeling of raw materials.
Keywords: allergens, prevention, testing, labeling

FDA/CFSAN. 1999a. *Potential for Infiltration, Survival, and Growth of Human Pathogens within Fruits and Vegetables*. November.

Water, insects, and birds may serve as vectors resulting in contamination of damaged or decayed sites on the rind of fruits and vegetables. Under certain conditions, pathogens can infiltrate and become internalized in the fruit or vegetable. Fruit can also become contaminated if immersed in cold, contaminated water or if vulnerable external points of fruit are immersed in contaminated water. Equipment may also cross contaminate both fresh apple and orange juice during processing. Despite their natural acidity, pathogens are able to survive in these fruit juices. Thus, sanitation is extremely important in juice processing.
Keywords: fresh produce, risk analysis, juice, sanitation

FDA/CFSAN. 1999b. *Preliminary Studies on the Potential for Infiltration, Growth, and Survival of Salmonella enterica Hartford and Escherichia coli O157:H7 Within Oranges*. November.

Study indicated that infiltration of pathogens into oranges can occur. This study found that oranges can internalize pathogen at an uptake frequency of 3 percent. Observed infiltration levels may be conservative because intact fruit was used as well as a decontamination step. Cold storage reduced survivability of *E. Coli* but not of *S. Hartford*. These findings indicate that refrigeration cannot be used to ensure reduction of microbial pathogens. Further study is required to determine factors that lead to contamination and infiltration, with respect to cultivation, harvesting, transport, storage, and processing.
Keywords: fresh produce (oranges),* E. Coli, Salmonella*, cold storage

FDA/CFSAN. 1999c. *Report of 1997 Inspections of Fresh, Unpasteurized Apple Cider Manufacturers*. January.

Contamination of apple cider likely occurs during the growing and harvesting phase, through direct or indirect contact with animal feces. Washing apples may reduce surface contamination, but studies also report pathogens can migrate into the tissue of the apple through the flower end or breaks in the skin of the apple. Best practices include culling; initial washing; prompt processing or refrigerated holding; final culling, washing, and brushing; a closed processing system; equipment sanitation; environmental sanitation; and employee hygiene. Applying these best practices does not guarantee pathogen-free cider, but when applied along with HACCP, will substantially reduce the likelihood of contamination. Other possible control methods include pasteurization, UV treatment, high pressure sterilization, electric resistance heating, aseptic packaging, ultrafiltration, pulsed electric field, electromagnetic fields, pulsed light, ozone treatment, hot water rinses, irradiation, and freezing and thawing. Studies are needed to assess the effectiveness of some of these treatments and others (such as pasteurization) have been proven effective. Redundant processing controls, such as duplicating culling and washing/brushing steps at several points during the chain and use of sanitizer dips and sprays and preservatives, have also proven effective in other segments of the food industry. However, the inspection indicated that these practices are largely absent in the cider industry. Microbiological testing of products and the environment would also be helpful in assessing effectiveness of the controls in place.
Keywords: cider, fresh produce (apples), best practices, HACCP, controls, pasteurization, testing

Floyd, Bruce M. 2000. Battling Allergen Contamination. *Food Product Design.* December.

Companies must review their products to determine whether it contains any of the known 160 allergens. The people reviewing the products must receive training to recognize problematic families of foods. Other controls include scheduling, separation of products, staging areas, line clearance, and verification. Nonallergenic products should be scheduled first, preceded by a thorough cleaning of the line. Allergenic materials and nonallergenic materials should be stored separately, with dedicated bins, scoops and weighing buckets. Dust control is also essential and required by GMPs. Staging (putting all of the ingredients for a specific batch on a pallet prior to taking them to the processing area) will also eliminate errors before they occur. Removing all the ingredients from the weighing and production areas of a line and checking for cleanliness are also helpful in avoiding contamination. Test kits are also available that can detect the presence of peanut, egg, and milk at very low levels. These kits have to be applied by a technically experienced person who will need additional training. However, random, inadvertent contamination will be difficult to detect with testing. A good system builds preventative efforts into earlier components of the production process. Unavoidable contamination can occur if it is impossible to verify that all allergen residue has been removed from equipment or if plant design prevents separation of lines, increasing the likelihood of dust carryover. Furthermore, contamination of raw materials may be

beyond a manufacturer's control. In these cases, companies may need to redesign the plant or add warnings to the label, although these should be a last resort since they eliminate potential customers. Allergen contamination prevention boils down to improved equipment design, plant layout, material handling within the plant, supplier control and verification, and employee training. If allergen contamination still cannot be avoided, warnings should be put on the label.
Keywords: allergens, product review, prevention, controls, separation, facility design, equipment, employee training, handling, labeling

Floyd, Bruce M. 1999. Testing for Foodborne Pathogens. *Food Product Design.* July.

The article addresses pathogen-testing procedures for products that are minimally cooked by the consumer, including all RTE products, as well as microwaveable products that may not receive sufficient heating to kill the bacteria in question. Pathogen testing involves environmental testing, equipment swabbing and product testing of raw materials and finished product. If the product is not cooked in its packaging material, packaging should be tested as well. The quantity and type of testing depends on the product. GMPs must be in place and have been validated before designing a testing program. Traffic patterns need to be examined and environmental testing should occur in areas that have the potential to contaminate processing and packaging areas and their surrounding space. The particular organisms tested for will be those that are a problem in the given industry. Processes without a cook step and products that the consumer minimally processes, have a much greater need for testing on the raw material side. Under such a testing program, breaches will be detected before they reach crisis proportions.
Keywords: pathogens, testing, packaging, good manufacturing practices

Folks, Heather and Dennis Burson. 2001a. *Food Safety: Chemical Hazards*. University of Nebraska Cooperative Extension.

Raw materials can be contaminated with pesticides, antibiotics, hormones, toxins, fertilizers, fungicides, heavy metals, and PCBs. During processing, contamination can occur with food additives, preservatives like nitrite, flavor enhancers, color additives, peeling aids, and defoaming agents. Lubricants, paints, and coatings from buildings and equipment can also contaminate food. Further, pesticides, cleaners, and sanitizers can contaminate products. Chemical hazards can be controlled by storing them separately from food and packaging materials. Cleaning agents and sanitizers should be thoroughly rinsed from equipment during cleanup. Only USDA-approved chemicals should be used. Pest control should be performed by professionals and chemical residues in incoming food products should be controlled. An inventory should be kept of all chemicals, colorings, and additives. Audits should be conducted of chemicals used, employees should be trained adequately, and in-house testing of product should be conducted.
Keywords: chemical hazards, risk assessment, controls, separation, cleaning, pest control

Folks, Heather and Dennis Burson. 2001b. *Food Safety: Physical Hazards*. University of Nebraska Cooperative Extension.

A physical hazard is any extraneous object or foreign matter in a food item, which can cause illness or injury to a person consuming the product. Sources for such contaminants include raw materials, badly maintained equipment, improper production procedures, and poor employee practices. Controls include raw material inspection and specification, vendor certification and letters of guarantee, metal detectors, x-ray technology, effective pest control, preventative equipment maintenance, proper sanitation procedures, proper maintenance and calibration of detection equipment, appropriate handling of packaging material, proper shipping, receiving and storage practices, tamper-proof or tamper-evident packaging, and

employee education. Less obvious measures, such as protected lighting fixtures and controlling contact between pieces of machinery, should also be considered.
Keywords: physical hazards, risk assessment, controls

Food Quality Magazine. 1997. Did You Wash Your Hands? *Food Quality Magazine*. March.

Good sanitation is one of the most important aspect of working in a food processing plant. To ensure good sanitation, Haagen-Dazs has installed automatic washing systems at various locations in its processing area. The system is claimed to be 60 percent more effective in removing pathogenic bacteria from hands than manual hand washing. New versions of the automatic handwashing system also incorporate a boot dip for washing boots and an air curtain for drying hands.
Keywords: sanitation, cleaning, employee hygiene

Gagliardi, J.V., P.D. Millner, G. Lester, and D. Ingram. 2003. On-Farm and Postharvest Processing Sources of Bacterial Contamination to Melon Rinds. *Journal of Food Protection.* Vol. 66, No. 1: 82-87.

This study assessed the sources and extent of melon rind contamination in production fields and at processing and packing facilities. In the spring of 1999, cantaloupe sampled from two sites in the Rio Grande River Valley showed that postharvest-processed melon rinds often had greater plate counts of bacterial contaminants than field-fresh melons. Sources of coliforms and enterococci were at high levels in melon production soils, especially in furrows that were flood irrigated, in standing water at one field, and in irrigation water at both sites. At one processing facility, wash water pumped from the Rio Grande River may not have been sufficiently disinfected prior to use. Because soil, irrigation water, and process water were potential sources of bacterial contamination, monitoring and management on-farm and at processing and packing facilities should focus on water quality as an important control point for growers and packers to reduce bacterial contamination on melon rinds.
Keywords: fresh produce (melons), production, processing, risk analysis, water quality

GASGA/CTA. 1997. Mycotoxins in Grains. *Technical Leaflet.* No. 3. June.

There are five types of mycotoxins that occur often in food: deoxynivalenol, zearalenone, ochratoxin, fumonism, and aflatotoxin. There are those that invade before harvest, called field fungi, and those that occur after harvest, called storage fungi. The primary factors influencing the growth of field fungi are insect damage and temperature stress. For storage fungi, these are moisture content and temperature. To prevent growth in stored grain, the grain should be dried as soon as feasible. Storage under modified atmosphere conditions is desirable. The grain should be protected from damage and insects. Under storage, the grain can be sampled for fungi. [Note: Article is written in an international tone and thus, may be less applicable to U.S. operations.]
Keywords: mycotoxins, fungi, prevention, grains, storage

Gregerson, John. 2003. Plain Talk About Allergen Management. *Food Processing.* January 29.

Manufacturers are sometimes using a “may contain” statement on labeling that critics argue is regarded as a substitute for GMPs. Problems have been uncovered by FDA inspections that include conveyors handling both allergen and non-allergen containing products which were only washed once a year, use of common utensils with both types of products and reusage of baking parchments. Another case included an

ideal operation in terms of best practices, with the exception that a table contained surface knicks that caused cross-contamination. Many processors have begun to include allergens as part of their HACCP plan. Manufacturers should obtain full ingredient lists from their suppliers as well as investigate whether any allergenic processing aids or rework have been incorporated into the product, or whether product carryover from common equipment might have occurred. During product development, manufacturers should consider whether any non-functional or non-characterizing allergens can be replaced. Allergenic and non-allergenic runs should be done on dedicated lines, or otherwise scheduled at the end of the day and followed by a complete clean up. Allergens should be made in successive batches and runs should be longer to further minimize potential carryover. Rework areas, equipment and containers should be clearly identified, as well as the rework itself, through use of color tags, containers, plastic liners or bar coding. Equipment should be made of sanitation-friendly material, like stainless steel. ELISA tests can also be conducted.
Keywords: allergens, labeling, equipment, sanitation, HACCP

Gregerson, John. 2002. Third Annual Best Manufacturing Practices Survey. *Food Engineering.* February.

Food Engineering conducts an annual survey of best manufacturing practices in the food industry by interviewing a panel consisting of more than 400 food manufacturing professionals in top management, production management, engineering, quality control, packaging, and purchasing across every segment of the food industry. More than 80 percent of survey respondents work at plants with 249 employees or less. When asked about maintenance, 25 percent of respondents said they will run equipment until it breaks, while nearly 56 percent indicated that their plant maintains routine preventive maintenance schedules. Only 2.6 percent are employed in plants where condition monitoring tools are used and 8.5 percent have a predictive maintenance program. Employee training and HACCP programs continue to dominate efforts to improve food safety. Anti-microbial and rapid microbial detection systems are not as prevalent but 53 percent of respondents who use them rate them as very useful, compared to 40 percent of plants that use HACCP (either voluntarily or as mandated). Only 2 percent of respondents involved in voluntary HACCP programs rated them as not useful, compared to 14 percent involved in government-mandated HACCP programs. Employee training rated lowest among all food safety measures implemented. About one-third of those whose plants emphasized employee training in food safety rated it as "very useful." Half of the plants that added sanitary equipment rated their results as very useful, compared to 41 percent whose plants improved employee training to improve sanitation.
Keywords: best practices, HACCP, employee training, equipment, maintenance, sanitation

The Hartford. 1999. Food Processing: *Salmonella. The Hartford Loss Control Department Technical Information Paper Series.*

A number of states, along with the United Egg Producers, have established voluntary quality assurance programs for egg producers. Participants agree to follow certain practices, including cleaning and disinfecting hen houses between flocks, adopting strict rodent control measures, washing eggs properly, refrigerating eggs between transport and storage, putting in place biosecurity measures, monitoring mortality of chickens, using salmonella-free chicks and pullets. Newer technologies are currently being explored, including in-shell pasteurization, irradiation, spraying newly hatched chickens with Preempt (a biotechnology product, approved by FDA, that contain bacteria that reduce Salmonella colonization of chicks' intestines). The risk management control that can have the greatest effect in controlling *Salmonella* is the implementation of HACCP at all levels of food processing.
Keywords: eggs,* Salmonella*, animal husbandry, controls, HACCP

Hegenbart, Scott. 1996. Reinforcing the Links in the Food Safety Chain. *Food Product Design*. March.

In 1989, the Council for Agricultural Science and Technology (CAST), Ames, IA, created a task force to determine the state of knowledge about U.S. food borne disease risks. The task force's findings were released in a 1994 report entitled "Food Borne Pathogens: Risks and Consequences." Among the report findings are that the application of Hazard Analysis Critical Control Point (HACCP) systems can reduce the likelihood of foodborne illness. By designing hurdles along the entire length of this chain, the reduction of incidence and prevention of contamination would contribute to the overall safety. Pathogenic bacteria are usually the first targets of any food safety discussion because they are behind 90 percent of all food safety outbreaks. In dairy farming, the sanitation of the milking facility, cleaning of the cows' udders prior to milking, and careful thermostatic control of milk holding tanks are among the contributors to microbial control. Keeping *Salmonella* in check in poultry involves controls, such as more frequent changing of the bedding materials in holding pens, testing of feed, and competitive exclusion. Fruits and vegetables contain naturally occurring toxins most of which are destroyed or inactivated by processing and cooking. Because consumers are eating more fresh vegetables raw, however, it becomes important to control/minimize naturally occurring toxins. Eliminating the stress through the use of herbicides, pesticides, etc., can help reduce the natural toxins a plant produces. Controlling weeds is also critical because they may contain toxins and they could be harvested along with the crop. Mycotoxins that are produced by certain types of mold also pose a public health risk. Thus, controlling mold growth early in the food chain is critical since many mycotoxins are stable to the heat of subsequent processing. Fields must be given adequate moisture (through irrigation) and pest protection because drought and blight leave plants more susceptible to mold. Preliminary research is further revealing that specific soil conditions may reduce the plant's tendency toward mold growth. Fish and seafood commonly contain parasites. Because these foods are still primarily harvested rather than farmed, less control over the source is possible. Instead, more attention is given to post-harvest seafood handling because most parasites can be destroyed by processing/cooking heat and by freezing. Viruses also are readily destroyed by heat. The ones of greatest concern are Hepatitis A and Norwalk virus, which do not enter the food chain at this early stage and are usually the result of contamination by handlers. In the early links of the food chain, most viral food safety risks come from seafood.
Keywords: food chain, pathogens, risk analysis, HACCP, controls, good agricultural practices

Higgins, Kevin T. 2003. Food Safety: Say Goodbye to the Burn. *Food Engineering.* January.

Food and beverage processors have to determine which food safety initiatives give them the greatest return on investment. In-package sterilization is the solution to post-processing contamination associated with *Listeria* and is slowly gaining more acceptance in terms of irradiation of meat. Brawley Beef in California employs multiple food safety interventions, including steam vacuuming, organic acid sprays, washes and rinses, thermal pasteurization, and irradiation. Ultra high pressure pasteurization can also be applied in package, as is done by Avomex, Inc. Coating drains or equipment parts with antimicrobials are other applications that help keep facilities clean and safe, although they do not eliminate the need for cleaning and sanitizing surfaces. Given that the economic payoff of these investments is not clear, processors have to do a qualitative assessment of the technologies available to help them meet their food-safety objectives.
Keywords: food processing, post-processing, packaging, pasteurization, cleaning, sanitation, costs

Higgins, Kevin T. 2002. The Culture of Clean. *Dairy Foods.* November.

The key to keeping food plants safe is to develop the right strategies to make sure that sanitation standards are met. Effective training is essential and language may be a barrier. Bilingual signage manuals and instructional manuals can fall short when multiple languages are spoken. A picture and symbol based approach can be an affordable and effective solution. Experts can be helpful in motivating employees to comply with fundamental sanitation principles. Various aids, like keypad controls on hand sanitizers and sensor-equipped paper towels are also available. Contour mapping and spatial analysis can be used to proactively manage pest control. Overall, numerous technologies are available to sanitize a plant, but they are only effective if supported by plant employees.
Keywords: sanitation, employee hygiene, employee training

Higgins, Kevin T. 2001. Are Maintenance Needs Predictable? *Food Engineering*. May.

Predictive maintenance is scarce among food processors. Further, firms, who have reportedly adopted predictive maintenance, typically monitor some critical equipment while continuing preventive schedules and reactive maintenance on less important assets. A survey by Entek IRD suggests that only 5 percent of plant maintenance is predictive in nature. Another 25 percent is preventive and at least half of that work is unnecessary. Most of the rest is corrective despite the fact that it costs more than three times as much as predictive steps would have cost. In a food processing facility, the key to a workable maintenance plan is to prioritize the assets and to apply predictive maintenance to the most critical units. It is also important to integrate the control systems at a plant for predictive maintenance to work.
Keywords: food processing, maintenance, equipment, costs

Higgins, Kevin T. 2000. A Practical Approach to Allergen Control. *Food Engineering.* July.

Food processors have made a lot of progress on the issue of allergens, but a lot of work remains to be done. Good manufacturing practices (GMPs), HACCP, and sanitation are at the heart of any allergen control program. Wash-down techniques may need adjustment to ensure that sanitarians are removing allergen proteins as well as pathogens from equipment surfaces. Longer production runs to minimize changeovers and scheduling allergen-containing products on a line at the end of the day are also good control strategies. Thermal treatment is ineffective in ridding equipment of proteins that are the basis of food allergens. Sanitary equipment design is also very helpful to minimize the presence of allergens. UPC scanners can minimize the chance that allergen-containing products get shipped in the wrong package. Separation of lines will prevent cross-contamination. Adding allergens at the end of the line also simplifies cleanup. One of the problems is that any food that has a protein has the potential to be allergenic, but a manufacturer cannot control for all. Currently, the focus is on the eight most common allergens. There is also a lack of consensus on the acceptable trace levels of an allergen. Testing kits of in-process and finished foods and of equipment will help manufacturers validate their allergen-control programs.
Keywords: food processing, allergens, good manufacturing practices, separation, HACCP, sanitation, controls

Hoffman, Adam D. , Kenneth L. Gall, Dawn M. Norton, Martin Wiedmann. 2002. *Listeria monocytogenes* Contamination Patterns for the Smoked Fish Processing Environment and for Raw Fish. *Journal of Food Protection.* Vol. 66, No. 11: 52-60.

Environmental samples and raw fish from two smoked fish processing facilities were screened for *L. monocytogenes*, and all isolates were subtyped by automated ribotyping to examine the relationship between *L. monocytogenes* contamination from raw materials and that from environmental sites. Results indicate a disparity between the subtypes found on raw fish and those found in the processing environment. This study indicates that environmental contamination is separate from that of incoming raw materials and includes strains persisting, possibly for years, within the plant. Operational and sanitation procedures appear to have a significant impact on environmental contamination, with both plants having similar prevalence values for raw materials but different contamination prevalence values for the environmental sites. Plant A, which had a higher environmental contamination prevalence value, may have more potential reservoirs for *L. monocytogenes*, as it has a larger production volume, is housed in an older facility, and used continuous running water as part of processing. This study concludes that regular *L. monocytogenes* testing of drains, combined with molecular subtyping of the isolates obtained, allows for efficient monitoring of persistent *L. monocytogenes* contamination in a processing plant.
Keywords: seafood processing,* Listeria*, controls, environmental sampling

Holah, John and Richard Thorpe. 2002. Hygienic Plant Design and Sanitation. In *Foodborne Pathogens: Hazards, Risk Analysis and Control* edited by Clive de W. Blackburn and Peter J. McClure. Woodhead Publishing Limited and CRC Press LLC. Boca Raton, FL.

The primary objective of a hygienic plant design is to set up effective barriers to microbial and other contamination. Level 1 is the factory site. Issues at Level 1 include rodent control (bait), bird control (clean up spillage), insect control (screens, lighting), and avoidance of dust (good landscaping). Level 2 is the factory building. Issues at Level 2 include external environment protection and internal microbiological, chemical, and physical protection. In some factories, drainage and subsequent contamination has occurred through leakage from floors above due to floor defects and badly maintained drains. Level 3 is the internal barriers separating manufacturing processes. Processing areas should be separated from non-processing areas and high-risk areas should be separated from low-risk areas. Some ovens have been designed to drain into high-risk areas, which presents a contamination risk. Problems have also occurred with leakage of sumps under ovens, into the high-risk area. Boot baths and washes have been shown to inadequately disinfect low-risk footwear, so different boots should be worn in high-risk areas. Providing an environment in which the formation of biofilms is limited, undertaking cleaning and disinfection programs as required, and monitoring and controlling these programs to ensure their success can control the formation of biofilms. Routine cleaning operations are never 100 percent and intensive periodic cleans are required to remove the soil accumulation over time. These can include increased cleaning time, higher temperatures, alternative chemicals, and manual scrubbing. For the majority of food operations, it is necessary to use multiple cleaning products for specific operations. The efficacy of disinfectants is controlled by interfering substances, pH, temperature, concentration, and contact time. Of the acceptable chemicals, the ones most often used are chlorine-releasing components, quaternary ammonium compounds (QAC), amphoterics, and quaternary ammonium/amphoteric mixtures. Efficacy tests can be conducted to test cleaning and disinfecting agents. Cleaning equipment is prone to contamination with *Listeria* and should be specific to high-risk area and disinfected after use. Microbiological sampling can be used to assess the effectiveness of a sanitation program.
Keywords: facility design, food processing, separation, equipment, risk assessment, controls, cleaning, sanitation

Horne, C.W., L.L. Boleman, C.G. Coffman, J.H. Denton, and D.B. Lawhorn. 1989. Mycotoxins in Feed and Food Producing Crops. *U.S. National Dairy Database.* http://www.mda.state.mn.us/dairyfood/mfgallergens.htm on April 23, 2003.

Methods for detecting mycotoxin range from visual inspection made with black light to ELISA tests to complex laboratory analysis using high-pressure liquid chromatography. Aflatoxin is a major toxin group. Properly designed and operated storage facilities can prevent aflatotoxin development but field conditions, such as droughts, often cannot be altered. Grains should be removed from temporary storage as soon as possible. The major influences on growth and reproduction of mycotoxins in grains are moisture content, temperature, oxygen supply, pH, and condition of the grain. Grains should not be stored under high moisture conditions. The long-term safe storage moisture content is generally accepted to be 13 percent. Many U.S. processors have established vigorous screening programs for aflatoxins and other mycotoxins in their raw materials. Treatment with anhydrous ammonia, which breaks the bond of the aflatotoxin molecule and reduces its destructive potential, has not received full approval of the FDA but has been used in several states to treat contaminated commodities. It also has a number of disadvantages, including discoloration of the grain. Shaking out immature or broken kernels is also done.
Keywords: mycotoxin, storage, grains

Ilyukhin, Sasha V., Timothy A. Haley, and Rakesh K. Singh. 2001. A Survey of Control System Validation Practices in the Food Industry. *Food Control*. Vol. 12. No. 5: 297-304. [only have abstract]

Over the last decade, there has been a significant increase in the use of digital control systems in the food manufacturing industry. The additional tasks with which digital controllers are burdened make their function much more complex than the electro-pneumatic-mechanical systems they replace. Potential control system failures can affect operator and process safety. Proper control system validation measures can prevent such potentially tragic failures. A nationwide scientific survey of US food manufacturers was conducted to generate information regarding the validation practices within the food manufacturing industry. This survey also included system integrators and equipment suppliers that sell goods and services to the US food manufacturers. It has been determined that the majority of food manufacturers delegate the responsibility for control system validation to a third-party, such as equipment supplier, system integrator or a consulting firm, with little understanding of the validation process and its importance. Only a few food manufacturing companies utilize validation resources available from equipment suppliers and system integrators. Equipment suppliers and system integrators should combine their efforts to provide the food industry with formal and comprehensive training and maintenance programs for the equipment as well as the system that controls it.
Keywords: validation, equipment, suppliers

Jackson, Lauren S.,, Tina Beacham-Bowden, Susanne E. Keller, Chaitali Adhikari, Kirk T. Taylor, Stewart J. Chirtel, and Robert I. Merker. 2003. Apple Quality, Storage, and Washing Treatments Affect Patulin Levels in Apple Cider. *Journal of Food Protection.* Vol. 66, No. 4.

Patulin is a mycotoxin produced primarily by *Penicillin expansum*, a mold responsible for rot in apples and other fruits. The growth of this fungus and the production of patulin are common in fruit that has been damaged. However, patulin can also be detected in sound fruit. This study found that dropped apples contained patulin, while tree-picked apples did not. Patulin was also discovered in unculled tree-picked apples stored at 0 to 2 degrees Celsius for 4 to 6 weeks, whereas none was found in culled tree-picked apples. Further, washing apples reduced patulin levels by 10 to 100 percent, depending on the initial patulin levels and the type of wash solution used. This study indicates that the avoidance of using dropped

apples and the careful culling of apples are good methods for reducing patulin levels in apples. Washing is also useful, however, when apples are highly contaminated with patulin, washing treatments are not able to reduce patulin levels to less than 50 micrograms per liter, the FDA action level for the toxin.
Keywords: patulin, mycotoxin, fresh produce (apples), risk assessment, controls

Jahncke, Michael L. and Daniel Herman. 2001. Control of Food Safety Hazards During Cold-smoked Fish Processing. *Journal of Food Science*. Vol. 66 No. 7: 1104-1112.

Waters where finfish are harvested may contain bacteria or spores that may be pathogenic to humans, such as *Clostridium botulinum* and *Listeria monocytogenes*. Fish may also come in contact with pathogenic microorganisms during harvesting, handling on board, and off-loading and transportation to a smoking facility. In general, good sanitation procedures should be applied throughout harvest, transportation, storage, and postharvest handling. In the U.S., direct treatment of finfish to reduce microbial load is permitted after harvest and before processing. Chlorine solution dips, which require intense management to avoid recontamination, have been replaced by chlorine solution rinses or sprays that are followed by a rinse with potable water. The following constitute some of the potential hazards and the applicable controls for cold-smoked finfish processing:

- Incoming fish may harbor parasites and contain unsafe levels of biogenic amines. All lots of fish directly received from the harvest vessel should be accompanied by documentation certifying proper time and temperature handling of the fish.
- Contamination of the raw material or outgrowth of pathogenic microorganisms may occur if the fish is not maintained in a sanitary facility with proper refrigeration controls. Thus, fish should be stored so that their internal temperature is less than 40 degrees Fahrenheit.
- Frozen raw fish should be thawed under sanitary conditions.
- *Listeria monocytogenes* and *C. botulinum* spores present on a single fish could contaminate an entire batch within the brine solution. Thus, to minimize microbial growth and cross-contamination, temperature control of the brine solution during brining is recommended.
- Presence of sufficient salt in the fish is essential to inhibit the outgrowth of *Clostridia* species and to prevent the formation of toxins. Portions that are too thick or too large should be removed and cut to the proper size.
- Cross-contamination with *L. monocytogenes* can occur during slicing and cutting. Strict adherence to SSOPs and GMPs is essential. In particular, effective SSOPs can be used to minimize or prevent cross contamination with *L. monocytogenes*.

Keywords: seafood processing, sanitation, risk assessment, controls, cross-contamination

Keller, Susanne E., Robert I. Merker, Kirk T. Taylor, Hsu Ling Tan, Cathy D. Melvin, Stuart J. Chirtel, and Arthur J. Miller. 2002. Efficacy of Sanitation and Cleaning Methods in a Small Apple Cider Mill. *Journal of Food Protection.* Vol. 65, No. 6: 911-917.

The efficacy of cleaning and sanitation in a small apple cider processing plant was evaluated by surface swab methods as well as microbiological examination of incoming raw ingredients and of the final product. Surface swabs revealed that hard-to-clean areas, such as apple mills or tubing for pomace and

juice transfer may continue to harbor contaminants even after cleaning and sanitation. Use of poor quality ingredients and poor sanitation led to an increase of approximately 2 logs in aerobic plate counts of the final product. Reuse of uncleaned press cloths contributed to increased microbiological counts in the finished juice. Finally, using apples inoculated with *Escherichia coli* K-12 in the plant resulted in an established population within the plant that was not removed during normal cleaning and sanitation. The data presented in this study suggest that current sanitary practices within a typical small cider facility are insufficient to remove potential pathogens.
Keywords: cleaning, sanitation, cider, testing,, risk analysis, fresh produce (apples)

Kindle, Lauryn. 2001. Opening Doors to Food Safety and Sanitation. *Food Processing*. May 22.

In a recent study, it was found that doors have a significant effect on room air distribution. Food processing doors should be of corrosion-resistant materials and remain shut as much as possible to minimize the transfer of food pathogens. Most door frames are wood covered and are vulnerable to microbial contamination over time as the wood corrodes with repeated cleaning. One control developed by The Rytec Corp. of Jackson, WI is a stainless steel high-speed roll door.
Keywords: sanitation, food processing, facility design, control

Krysinki, E.P. 1992. Effect of Cleaners and Sanitizers on *Listeria monocytogenes* Attached to Product Contact Surfaces. *Journal of Food Protection.* Vol. 55, No. 4: 246-251. [only have abstract]

A variety of chemical cleaning and sanitizing compounds were evaluated for their ability to remove and/or inactivate surface adherent *Listeria monocytogenes*. Resistance of adherent cells to sanitizers was dependent upon the surface studied, being greatest on polyester/polyurethane, followed by polyester, and stainless steel. Biofilm removal with cleaners followed the same pattern, with polyester/polyurethane the most difficult to clean. Complete biofilm removal/inactivation was obtained in many cases where a surface was cleaned prior to sanitization. Listeria biofilms should be controllable by combining GMPs with HACCP.
Keywords: cleaning, sanitation,* Listeria*, biofilms, HACCP, good manufacturing practices

Kuhn, Mary Ellen. 1995. Getting Lathered up About Plant Sanitation. *Food Processing*. June.

Elimination of bacterial contamination not only improves food safety but also aids in increasing product shelf life. Thus, food processors have started giving serious consideration to how equipment should be cleaned and sanitized during the design stage. National Sanitation Foundation (NSF) has developed standards to assure that equipment can be quickly disassembled for cleaning and does not have difficult-to-clean features, such as screws or rough surfaces. Further, an increasing number of food manufacturers are looking to standardize their cleaning operations so that they can better control the end results. Some of the technologies food plants are adopting for this purpose include automated hand-washing systems, ATP bioluminescence monitoring for detection of soil or bacteria on plant surfaces, and portable sanitation equipment.
Keywords: food processing, sanitation, equipment, facility design, cleaning

Kuntz, Lynn A. 1992. Keeping Microorganisms in Control. *Food Product Design*. August.

Molds, yeast, viruses, and bacteria can cause food spoilage and more importantly food borne illness when ingested. Controlling these constitutes the most important challenge to food manufacturers. Some of the

basic preventative controls that should be in place in food processing plants to control for these food safety hazards include:

- Prevention of contamination by proper cleaning of manufacturing equipment,
- Removal of microorganisms by washing, trimming, centrifuging, and filtration,
- Removal of oxygen by applying a vacuum, or the replacement of oxygen by gases, such as nitrogen or carbon dioxide,
- High or low temperature treatments depending on the type of food product,
- pH control,
- Control of water activity levels via cooking, baking, or dehydration,
- Use of preservatives or inhibitory substances that have Generally Recognized as Safe (GRAS) status, and
- Irradiation.

Keywords: food processing, cleaning, sanitation, irradiation, controls

Minnesota Department of Agriculture. 2003. Managing Food Allergen Risks. http://www.mda.state.mn.us/dairyfood/mfgallergens.htm.

Food manufacturers need to evaluate their operations and develop plans to control unidentified allergens. Evaluation of allergen hazards should be part of a HACCP plan. Non-allergenic ingredients should be considered as substitutes. Allergenic ingredients should be added at the end of a process. Equipment should be easy to clean, inspect, and maintain. Production lines should be designed to isolate allergen addition point, dedicate re-feed systems, ensure product containment, and eliminate crossover of conveyor lines. Manufacturers should ensure that suppliers have implemented and documented an allergen plan. Reconditioned ingredients and oils should not be purchased. Proper sanitation or dedicated use should be ensured regarding transportation of bulk ingredients/shipping containers that are reused. Specifications/ingredient statements should be reviewed before substituting raw materials. Production systems should be dedicated or products with allergens should be run at one time or at the end of a production run. Adequate clean up should be performed between runs. A documented rework plan should be available. All rework should be clearly labeled. Labels on incoming ingredients should be checked. Label accuracy should be verified. The use of "may contain" labeling in lieu of GMPs should be limited. Outdated packaging materials should be removed from plants. Product traceability systems should be in place and verified. Sanitation practices should be validated using sight, bioluminescence testing, and ELISA testing. Maintenance tools should be checked to make sure that they are not potential vectors for cross-contamination. Employee practices for sanitation should be specified and employees should receive good training and education about allergens.

Keywords: allergens, HACCP, controls, equipment, facility design, suppliers, sanitation, labeling, packaging, maintenance

Morris, Charles E. 2002. Best Practices for Allergen Control. *Food Engineering.* March.

The basic allergen control strategy is similar at many companies. The big eight allergens include peanuts, tree nuts, milk, eggs, soybeans, finfish, shellfish, and wheat. The first step in formulating a product is to eliminate allergens if possible or add them in towards the end of the process. Dedicated production lines are also a preferred strategy while a portion of a given line can also be dedicated. Many food plants were not designed with allergen control in mind, such as where a product on an upper conveyor can drop on a product on the conveyor below. Covering the conveyors can solve this problem. "Hang-ups", where product residues can collect to be swept up in a later production run, can be contained by cleaning, isolating, or sealing off allergen-addition points on the line. Color coding maintenance tools can prevent cross-contamination. Full ingredient lists should be obtained from raw material suppliers and audits should be conducted to help assure that allergens are properly identified in raw materials and ingredients. Best practices can also include longer production runs with minimal changeovers for high-volume products. Where changeovers are necessary, products containing allergens can be scheduled last in the production cycle to minimize cross-contamination and cleanup. To prevent packaging mix-ups, old packaging should be discarded and a tracking system should be used. ELISA (enzyme-linked immunoabsorbent assays) tests, developed by FARRP and Neogen, can validate the effectiveness of an allergen cleaning program. A HACCP-like approach and employee training are also important. Allergens should be evaluated with a HACCP-like approach, with process areas identified as high-risk considered as critical control points. Employee training is also very important to the success of allergen control.
Keywords: allergens, best practices, facility design, equipment, packaging, cleaning, testing, HACCP, employee training

Morris, Charles E. 2000a. Best Manufacturing Practices. *Food Engineering.* February.

Food Engineering conducted a survey of an Executive Advisory Panel, consisting of more than 400 food-manufacturing professionals in various roles in the industry, to share manufacturing improvements implemented in the past five years and how they achieved these improvements. HACCP programs were established by 75 percent of panelists and 79 percent have improved employee training in plant sanitation and food safety. More than 65 percent of panelists regularly review and document GMPs, SOPs, and SSOPs, while 62 percent conduct independent audits or inspections, to better assure plant sanitation and food safety. Forty-five percent added equipment of sanitary design and 39 percent replaced equipment with new equipment with a more sanitary design. Thirty-eight percent increased lab testing and 32 increased QA staff. One-third of panelists implemented or increased use of microbial detection systems. Only 9 percent of the panelists reported that their plants had appointed a HACCP coordinator with no other responsibilities and of those, half were meat processors. When asked about maintenance, 71 percent of panelists apply preventive maintenance, but 28 percent practice reactive maintenance.
Keywords: best practices, HACCP, sanitation, good manufacturing practices, facility design, equipment, maintenance

Morris, Charles E. 2000b. HACCP Under the Microscope. *Food Engineering.* October.

According to the 2000 Food Engineering's Best Manufacturing Practices Survey, 75 percent of respondents have established HACCP programs in their plants. More than two-thirds of respondents in every industry outside of meat, poultry, and seafood, have voluntarily implemented HACCP. HACCP has gained acceptance in industries where it is not required, but compliance and enforcement problems have arisen in industries that do require it. Compliance failures include weak prerequisite programs (SSOPs, GMPs, QA programs, consumer complaint monitoring, environmental monitoring, vendor certification, and allergen management), "half-way" HACCP programs due to lack of upper-management commitment,

product releases despite CCP violations, inclusions of quality components in HACCP that dilute its effectiveness, weak CCP validations and hazard analyses, inadequate/inefficient documentation, inadequate training, and a lack of continuous improvement.
Keywords: best practices, HACCP, compliance

Mortimore, Sara. 2003. Problems Encountered Applying the HACCP Approach to Food Safety: If HACCP can Work so Well, Then Why do so Many Businesses Have Problems With It? *FoodInfo Online Features*. IFIS Publishing. January 27. www.foodsciencecentral.com.

HACCP can be seen as an unnecessarily burdensome and bureaucratic activity among food manufacturers. Implementation of an effective HACCP plan requires education on (1) food borne illness and trends, (2) why HACCP is a minimalist system that ensures maximum control, and (3) how it can help reduce sanitation costs and down time, and lengthen shelf life, improve efficiency, and reduce waste. The cause of many of the problems of implementation can be traced back to the decision to adopt HACCP and the reasons why it was chosen. While it seems that the best HACCP systems are developed by businesses that are driven to self-improvement, the prompt may also come from regulators and customers. The lack of understanding of the HACCP concept or methods, as well as a lack of appropriate microbiological and toxicological knowledge, often leads to over-reliance on advice from many quarters, and can result in over-complex HACCP systems. This is further confounded by reliance on "off-the-shelf" HACCP packages, inadequate or improperly deployed generic plans and consultant plans that do not fit the business. This is particularly relevant for small and medium-sized enterprises (SMEs) but also for many larger companies. In the industry, there is a shift towards second generation HACCP models that allow greater flexibility and that emphasize prior development of effective prerequisite hygiene programs. Another prime requirement for effective implementation of HACCP programs is having an understanding of the people that will be responsible for operating the system and providing adequate training. [Note: Article is based on the U.K experience of HACCP implementation. Thus, the findings may not be fully applicable to the U.S.]
Keywords: HACCP, implementation, sanitation, employee training

Moss, Maurice. 2002. Toxigenic Fungi. In *Foodborne Pathogens: Hazards, Risk Analysis and Control* edited by Clive de W. Blackburn and Peter J. McClure. Woodhead Publishing Limited and CRC Press LLC. Boca Raton, FL.

Toxigenic fungi are found primarily in foods of plant origin, such as cereals, legumes, oilseeds, and treenuts. They may also pass through food in chain in milk and meat. Controls for aflatotoxin (occurring in corn and treenuts) include preventing insect damage, alleviating drought stress, and reducing water activity in the product. Controls for ochratoxin A (occurring in coffee, cocoa, vine fruits, spices, cereals) include prevention of mold growth at every stage of the production process. Removing moldy apples, conversion to cider, treatment with activated charcoal or sulfur dioxide can control Patulin (occurring in apple juice). Fumosin (occurring in corn) elimination is difficult. Ear rot and insect damage are associated with high levels of infection. The breeding of cultivars resistant to such damage is a possible control strategy. The possibility of biological control in the field is also being investigated.
Keywords: fungi, risk analysis, controls

Moulton, Curtis J. 1992. Reducing Pesticide Residues in Food. *Food Safety and Quality.* June.

While FDA reports that 96 percent of all foods have safe levels of pesticide residue or none, consumers remain concerned. Pesticide residues can be controlled by reducing dependence on them through organic

production systems, integrated pest management, and low input sustainable agriculture (LISA). Other farm industry efforts include development of safer chemicals and genetically engineered, pest-resistant plants.
Keywords: pest control, organic production, chemical hazard, risk assessment

Murphy, R.Y., L.K. Duncan, K.H. Driscoll, B.L. Beard, M.B. Berang, and J.A. Marcy. 2003. Determination of Thermal Lethality of *Listeria monocytogenes* in Fully Cooked Chicken Breast Fillets and Strips during Postcook In-package Pasteurization. *Journal of Food Protection.* Vol. 66, No. 4: 578-583.

The presence of *Listeria monocytogenes* in processing environments renders meat or poultry products at risk for contamination after cooking and before packaging. This study evaluates the post-cook in-package pasteurization on eliminating *Listeria monocytogenes* from three types of vacuum-packaged fully cooked chicken breast meat products that were treated with continuous pilot scale steam or hot water cooker. Results indicate that both steam and hot water pasteurization are effective for the inactivation of *Listeria monocytogenes* in fully cooked and vacuum-packaged chicken breast meat products.
Keywords: meat processing, poultry processing,* Listeria*, packaging, pasteurization, controls

National Food Processors Association (NFPA). Undated. *Industry Position on Control of Listeria Monocytogenes, With Emphasis on Meat and Poultry Products*. National Food Processors Association. www.nfpa-food.org.

Listeriosis is a serious disease that is primarily transmitted through a limited number of foods. Specifically, it appears that foods that support the growth of pathogenic *Listeria monocytogenes* over the shelf life of the product, especially foods given a listericidal process which have become recontaminated, pose the greatest risk to consumers. Control of *L. monocytogenes* has proven to be a difficult challenge in food processing establishments that manufacture RTE products that are not treated in their final package to eliminate this organism. In 1999, the food industry reviewed and revised suggested programs designed to minimize the presence, survival, and multiplication of *L. monocytogenes* in foods. These programs include:

- Applying a validated listericidal process where appropriate,
- Purchasing from suppliers with a *Listeria* control program,
- Minimizing the potential for recontamination,
- Adopting new technologies as soon as they are available, and
- Implementing an environmental monitoring program for *Listeria* spp. to verify that the control program is effective.

In addition to modifying in-plant practices and upgrading verification programs, many in industry are also seeking long term and more dependable solutions to this problem, such as in-package pasteurization with heat or ionizing radiation, use of ionizing radiation, and product reformulation to retard or preclude growth of *L. monocytogenes*.
Keywords: food processing,* Listeria*, ready-to-eat, controls, suppliers, packaging, pasteurization

Neff, Jack. 1999. Beyond Chlorine. *Food Processing*. January 1.

Chlorine has been the disinfectant of choice for the food and beverage manufacturing industry for years. Despite its widespread use, chlorine usage is not problem free. In water with high levels of organic residue, chlorine dissipates quickly. Using too much chlorine to compensate, however, can lead to the formation of excessive hypochlorous acid that causes chlorine to volatize more rapidly creating fumes that can pose hazards to plant workers. Further, one food processor found chlorine to be ineffective in sunlight or if it has warmed up significantly above room temperature. Thus, it is difficult to find the right level of chlorine needed to kill all the microorganisms without leaving too much chlorine or volatile fumes behind. An alternative to chlorine is peroxyacetic acid that one frozen vegetable processing facility is currently using. Although it costs 50 to 100 percent more than chlorine, the agent reportedly provides improved microbial control and safety. Other emerging disinfecting technologies include ozone and ultraviolet radiation.
Keywords: food processing, disinfectant

Olson, Alan R. 2002. Hard or Sharp Objects. *Compendium of Fish, Fishery Product Processes, Hazards, and Controls.* October.

Foreign objects can be broadly classified as food safety hazards (e.g., glass) and food non-safety hazards (e.g., filth). Foreign objects that are physical hazards are referred to as hard or sharp objects. Hard or sharp objects are further divided into metallic objects, which are divided into ferrous and non-ferrous metals, and non-metallic objects. Controls for metal inclusion can include periodic checks of metal equipment and passing the product through metal detectors or separation equipment. Glass can be controlled by visual examination of empty glass containers containing transparent product, cleaning with water or compressed air and inverting empty glass containers, periodically monitoring lines for glass breakage, proper adjustment of capping equipment, and passing the product through an x-ray system. Non-metallic objects can also be detected by an x-ray system.
Keywords: seafood processing, physical hazards, risk analysis, controls

Park, Douglas L., Henry Njapau, and E. Boutrif. 1999. Minimizing Risks Posed by Mycotoxins Utilizing the HACCP Concept. *Food, Nutrition, and Agriculture.* No. 23.

Prevention through pre-harvest management, such as enforcing effective insect control programs and maintaining adequate irrigation schedules, is the best way to control mycotoxin formation. Field crops should be harvested in a timely manner and damage kept to a minimum during harvesting to prevent infestation of mycotoxins. Extraneous material should be removed and products should be dried rapidly to under 10 percent moisture. In the post-harvest phase, storage and processing are the major areas where contamination can be prevented. An accumulation of moisture and heat and/or physical damage can increase the likelihood of mycotoxins. Appropriate packaging or general hygiene are generally useful in minimizing damage from insect infestation. Product should be stored on a dry, clean surface. During processing, mycotoxins can be intentionally eliminated or introduced. Control procedures that can be employed include clean up and separation, thermal inactivation, and chemical inactivation. For example, electronic sorting and hand-picking can remove a significant proportion of aflatoxins in shelled peanuts. Complete separation of all contaminated particles may not be achieved, however, and other procedures have to be used to manage contamination in the final product. Thermal inactivation is a good alternative, although aflatoxins and deoxynivalenol are resistant to heat. Other potential control processes include ammoniation and activated carbons and clays.
Keywords: mycotoxins, HACCP, prevention, risk assessment, separation, controls

Paulson, Daryl S. 1996. To Glove or to Wash: A Current Controversy. *Food Quality*. June/July.

Both hand washing and using gloves have their adherents and detractors. The article argues that using these in tandem may be the most effective solution, combined with vigorous enforcement and employee training, and an environmental sanitation program. An intact glove provides adequate protection from microbial transmission of hand-contaminating microorganisms. However, some food-grade gloves may have existing pinhole punctures and/or can be easily ripped, torn, or punctured during use. While hand washing, on the other hand, can be very effective in removing microorganisms, ensuring that food workers perform effective hand washes is difficult. Thus, the study recommends (1) donning of gloves to be preceded by an effective hand wash, (2) ongoing employee training and education, (3) high personal hygiene requirements, and (4) institution of a quality control program to monitor and enforce hand washing and gloving sanitation practices. Further, to reduce disease transmission by contaminated objects, the study suggests an effective environmental and sanitation program and restriction of tasks among workers to prevent contamination in addition to the previously noted four controls.
Keywords: employee training, employee hygiene, sanitation, controls

Raloff, Janet. 1998. Staging Germ Warfare in Foods. *Science News*. Vol. 153. No. 6. February 7.

Many bacteria generate small proteins known as bacteriocins. Bacteriocins function as unusual, narrow-spectrum antibiotics. They tend to harm only microbes that closely resemble the bacteria that manufactured them. In many cases, bacteriocins attack potentially fatal food-poisoning germs, such as *Listeria monocytogenes* or the *Clostridium* responsible for botulism. A number of studies on foods ranging from pasteurized egg products, hot dogs, poultry summer sausage to meat products, have shown promising results where the bacteriocins added were effective in killing certain types of pathogens.
Keywords: pathogens, control, bacteriocins

Riordan, D. C. R., G. M. Sapers, T. R. Hankinson, M. Magee, A. M. Mattrazzo, and B. A. Annous. 2001. A Study of U.S. Orchards To Identify Potential Sources of *Escherichia coli* O157:H7. *Journal of Food Protection.* Vol. 64, No. 9: 1320-1327.

Fourteen U.S. orchards were surveyed in autumn 1999 to determine the incidence and prevalence of *E. Coli* O157:H7, *E. Coli*, total aerobic microflora, and yeasts and molds. Fruit was also tested for internalization of microflora by aseptically removing the core, stem, and calyx areas, and the individual sections were assessed for the categories of microflora listed above. Findings suggest that dropped or damaged fruit should not be included in fruit designated for the production of unpasteurized juice or for the fresh or fresh-cut market. In addition, orchards should be located away from potential sources of contamination, such as pastures.
Keywords: fresh produce,* E. Coli*, risk analysis

Rushing, J.E. and H.P. Fleming. 1999. Scheduled Processes. Department of Food Science, Food Processing. FSE 99-21.

A scheduled process is a process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food product that will not permit the growth of microorganisms having public health significance. A scheduled process must be established by a qualified person or a competent process authority, with expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods. The key to safe preservation of acidified

foods is the maintenance of an adequately low pH in the finished product to prevent growth and toxin production by the *Clostridium botulinum* bacterium. Acidified foods must have a finished equilibrium pH of 4.6 or lower. While a pH of 4.6 or lower is adequate to prevent growth and toxin production by *Clostridium botulinum*, it may not be adequate to prevent growth of other microbiological pathogens. Thus, acidified foods must be thermally processed to an extent that is sufficient to destroy the vegetative cells of microbes of public health significance and those of non-health significance that can grow in the product under the conditions in which it is stored, distributed, and held by the consumer.
Keywords: scheduled process, acidified foods

Senkel, I. Arthur, Robin A. Henderson, Beverly Jolbitado, and Jianghong Meng. 1999. Use of Hazard Analysis Critical Control Point and Alternative Treatments in the Production of Apple Cider. *Journal of Food Protection.* Vol. 62, No. 7: 778-785.

The purpose of this study was to evaluate the practices of Maryland cider producers and determine whether implementing hazard analysis control point (HACCP) would reduce the microbial contamination of cider. Cider producers were surveyed to determine existing manufacturing practices and sanitation. A training program was then conducted to inform operators of safety issues, including contamination with *Escherichia coli* O157:H7, and teach HACCP concepts and principles, sanitation procedures, and good manufacturing practice (GMP). Although all operators used a control strategy from one of the model HACCP plans provided, only one developed a written HACCP plan. None developed specific GMP, sanitation standard operating procedures, or sanitation monitoring records. Six operators changed or added production controls, including the exclusion of windfall apples, sanitizing apples chemically and by hot dip, and cider treatment with UV light or pasteurization. Facility inspections indicated improved sanitation and hazard control but identified ongoing problems. Microbiological evaluations of bottled cider before and after training, in-line apples, pomace, cider, and inoculated apples was conducted. *E. Coli* O157:H7, *Salmonella, or Staphylococcus aureus* were not found in samples of in-line apple, pomace, and cider, or bottled cider. Generic *E. Coli* was not isolated on incoming apples but was found in 4 of 32 (13%) in-line samples and 3 of 17 (18%) bottled fresh cider samples, suggesting that *E. Coli* was introduced during in-plant processing. To produce pathogen-free cider, operators must strictly conform to GMPs and sanitation procedures in addition to HACCP controls. Controls aimed at preventing or eliminating pathogens on source apples are critical but alone may not be sufficient for product safety.
Keywords: cider,* E. Coli, *HACCP, sanitation, fresh produce (apples), risk assessment, controls

Siddiqi, Zia. 2001. New Technologies in Pest Management Prevent Pathogen Spread. *Food Processing*. February 21.

Because of their behavior, biology, and morphology, insect and rodent pests serve as exceptional disease vehicles for harboring and rapidly transporting diseases. In the food handling environment, the three main pests that have been known to transmit pathogens are rodents, roaches, and flies. An integrated pest management program (IPM) is necessary to eliminate insect and rodent pests and hence the spread of pathogens from these sources. IPM relies on inspection, monitoring, establishing action threshold levels, and implementing first non-chemical and then chemical measures. IPM also involves communication and education. Some of the newer technologies, such as computer-aided monitoring and nonvolatile nonrepellant insecticide formulations, enable the placement of control agents in precise locations thereby eliminating the possibility of pathogen spread.
Keywords: pest control, handling, pathogens

Snowdon, J.A. and D.O. Cliver. 1996. Microorganisms in Honey. *International Journal of Food Microbiology*. Vol. 31. No. 1-3: 1-26. [only have abstract]

Microbes of concern in post-harvest handling are those that are commonly found in honey (i.e., yeasts and sporeforming bacteria), those that indicate the sanitary or commercial quality of honey (i.e., coliforms and yeasts), and those that under certain conditions could cause human illness. Primary sources of microbial contamination are likely to include pollen, the digestive tracts of honey bees, dust, air, earth, and nectar, which are very difficult to control sources. The same secondary (after-harvest) sources that influence any food product are also sources of contamination for honey. These include air, food handlers, cross-contamination, equipment, and buildings. Secondary sources of contamination are controlled by good manufacturing practices (GMPs). Routine microbiological testing of honey is necessary to control for microorganisms. The testing might include standard plate counts for general information, specialized tests (such as yeast counts and an assay for bacterial spore formers), and coliform counts for checking sanitary quality.
Keywords: honey, risk assessment, controls, handling, testing

Sommers, Christopher, Michael Kozempel, Xuetong Fan, and E. Richard Radewonuk. 2002. Use of Vacuum-Steam-Vacuum and Ionizing Radiation To Eliminate *Listeria innocua* from Ham. *Journal of Food Protection.* Vol. 65, No. 12: 1981-1983.

Vacuum-steam-vacuum (VSV) technology is known to successfully to eliminate *Listeria innocua* from hot dogs and ionizing radiation has been used to eliminate *Listeria* spp. from RTE meats. The application of these technologies can cause changes in product quality. This study investigated the ability of VSV and ionizing radiation, together, to eliminate *Listeria innocua* from ham meat and skin. The use of both treatments resulted in an additive reduction of *L. innocua* on ham. The combination treatment did not cause statistically significant changes in product quality.
Keywords: meat processing,* Listeria*, controls

Stier, Richard F. 2002. Validating Safety in Your Plant. *Food Engineering*. September.

The root cause of most food borne illness is often a breakdown in plant sanitation. Changes in operations can have profound and often devastating effects on the plant sanitation system. Construction projects and increases in production volume have the potential to adversely affect safety. For example, *Listeria* contamination resulting from construction operations has been cited as a cause of one of the largest recalls of processed meats in recent history. Plants need to ensure that changes are undertaken in an orderly and controlled fashion to ensure food safety.
Keywords: sanitation, validation, construction, risk analysis

Stier, Richard F. 2001. Foreign Materials in Foods: Are They Really Dangerous? *Market Pulse.*

Sources of foreign materials include inadvertent materials from the field (e.g., stones, metal, insects, undesirable vegetable matter, dirt, or small animals), inadvertent results from processing and handling (e.g., bone, glass, metal, wood, nuts, bolts, screening, cloth, grease, paint chips), materials entered during distribution (e.g., insects, metal, dirt, stones), materials intentionally placed in food (employee sabotage), and miscellaneous sources (e.g., struvite). Mechanical harvesters often collect more than just the product and so processors include destoners, air cleaners, magnets, screens and washers as part of their lines. Grain processors and manufacturers used four screens to remove foreign materials. Preventive maintenance is important in preventing foreign materials from entering the processing operation and is

considered a HACCP prerequisite. Properly maintained equipment and lines usually do not cause problems. All packages should be designed to prevent tampering after the container is sealed. Packages should be examined for insect or rodent infestation that came from the exterior. The greatest concern with contamination during distribution and storage is bulk products. Employee sabotage is difficult to monitor. Controls include good management and proper employee education. A good QA system and good line workers are essential. Struvite, a hard crystalline material that can be formed in canned proteinaceous seafoods, is also hard to control. It resembles glass and can break a tooth, but will not cut like glass. Stone and wood, based on the author's experience, are usually foreign materials that are controlled by HACCP and are not common. Glass can be controlled by policies that require throwing away all containers within 10 feet of the breakage and shielding lights. Scanning for glass on-line is possible too, although expensive. Metal is a common industry concern and best addressed by preventive maintenance. Ferrous materials can be removed by magnets. Metal detectors are also becoming more common, especially in the meat sector. In sum, the following practices should be followed: plant audits that evaluate systems for pest control, foreign object removal, plant condition, shipping and receiving practices, and plant maintenance procedures; a review of packaging materials and container/package handling procedures; a review of agricultural practices; a review of personnel practices; package evaluation to ensure it is tamper proof; a review of consumer complaints to see whether foreign materials are an issue. These steps should be part of a HACCP program.
Keywords: physical hazards, HACCP, maintenance, equipment, packaging, controls

Stopforth, J.D., J. Samelis, J. N. Sofos, P. A. Kendall , and G. C. Smith.. 2002. Biofilm Formation by Acid-Adapted and Nonadapted *Listeria monocytogenes* in Fresh Beef Decontamination Washings and Its Subsequent Inactivation with Sanitizers. *Journal of Food Protection.* Vol. 65, No. 11: 1717-1727.

Despite conventional cleaning methods, such as washing and sanitizing, pathogenic bacteria can remain on equipment surfaces and contaminate food. This study investigated the effect of various sanitizers on *Listeria monocytogenes* cells in suspension and those attached to a surface by means of a biofilm (slime layer to which pathogenic bacteria can attach and grow). The study results indicate that attached cells are more resistant than cells in suspension to the effects of sanitizers. Further, the study indicates that each sanitizer has an optimal working environment in which it is most effective.
***Keywords: sanitation, biofilms,* Listeria**

Suttajit, Maitree. 1989. Prevention and Control of Mycotoxins. *Mycotoxin Prevention and Control in Foodgrains.*

The inhibition of fungal growth can be achieved by physical, chemical, and biological treatment. This includes drying (less than 9 percent moisture for peanut and less than 13.5 percent moisture for corn) and proper storage after harvest, such as maintenance of the container/warehouse at low temperature and humidity and keeping insects out. Various chemical treatments have been used and are the most effective means to remove mycotoxins from contaminated commodities as compared to hand picking, organic solvents, heating and cooking, or ionizing radiation.
Keywords: mycotoxins, prevention, controls

Thimothe, Joanne, Jonathan Walker, Voranuch Suvanich, Ken L. Gall, Michael W. Moody, Martin Wiedmann. 2002. Detection of Listeria in Crawfish Processing Plants and in Raw, Whole Crawfish and Processed Crawfish (*Procambarus spp.*). *Journal of Food Protection.* Vol. 65, No. 11: 1735-1739.

This study monitored the presence of *L. monocytogenes* and other *Listeria* spp. in the processing environment, in raw, whole crawfish, and in cooked crawfish meat from two processing plants. Although *Listeria innocua* was the predominant *Listeria* spp. found (20 samples), four samples were positive for *L. monocytogenes. L. monocytogenes* was detected in three raw material samples and in one environmental sample. *Listeria* spp. were found in 29.5% of raw, whole crawfish (n = 78) and in 4.4% of environmental samples (n = 181) but in none of the finished product samples. Among the environmental samples, *Listeria* spp. were found in 15.4% of the drains (n = 39) and in 5.1% of the employee contact surfaces (gloves and aprons) (n = 39) but in none of the samples from food contact surfaces. Even though a high prevalence of *Listeria* spp. was detected on raw materials, it appears that the heat treatment during the processing of crawfish and the practices preventing post-processing recontamination can significantly reduce *Listeria* contamination of RTE crawfish meat.
Keywords: seafood processing,* Listeria*, risk assessment

Thomas, Ingram, Bevis, Davies, Milne, and DelvesBroughton. 2002. Effective Use of Nisin to Control Bacillus and Clostridium Spoilage of a Pasteurized Mashed Potato Product. *Journal of Food Protection*. Vol. 65. No. 10: 1580-1585. [only have abstract]

Heat-resistant spore-forming bacteria, such as Bacillus and Clostridium, can survive and grow in cooked potato products. The natural food preservative nisin is used in heat-treated foods to prevent the growth of such bacteria. The study shows that nisin remains at effective levels after pasteurization and extends shelf life of the product by at least 30 days. The ingredients and the preservatives, however, must be well mixed to ensure nisin efficacy.
Keywords: bacteria, pasteurization, cooked product (potatoes), controls

Tilden, John Jr., Wallace Young, Ann-Marie McNamara, Carl Custer, Barbara Boesel, Mary Ann Lambert-Fair, Jesse Majkowski, Dur Vaga, S. B. Werner, Jill Hollingsworth, and J. Glenn Morris. 2002. A New Route of Transmission for *Escherichia coli*: Infection from Dry Fermented Salami. *American Journal of Public Health.* Vol. 85, No. 8: 1142-1145.

This study evaluated the production of dry fermented salami associated with an outbreak of *Escherichia coli* O157:H7 infection in Washington State and California. Facility inspections, review of plant monitoring data, food handler interviews, and microbiological testing of salami products were conducted. Production methods complied with or exceeded federal requirements and industry-developed good manufacturing practices. No evidence suggested that post-processing contamination occurred. This study suggests that *E. Coli* O157:H7 may have been present on raw meat and subsequently survived the currently accepted processing methods.
Keywords: meat processing,* E. Coli*, risk analysis, post-processing

Tompkin, R.B. 2002. Control of *Listeria monocytogenes* in the Food Processing Environment. *Journal of Food Protection.* Vol. 65, No. 4: 709-725.

Recontamination is the primary source of *Listeria monocytogenes* in many commercially prepared ready-to-eat processed foods. Product testing will not indicate the mode of contamination or how to prevent

further occurrences. Environmental testing is better and more cost-effective in detecting the mode of contamination and enabling timely corrections. Listeriosis can occur in isolated cases or as a cluster of cases due to a contaminated lot of food, both of which are generally due to errors in food handling. Outbreaks of a few to several hundred cases that are scattered with regards to time and location are typically due to the establishment of the pathogen in a niche, which is a site within the manufacturing environment in which *Listeria monocytogenes* becomes established and multiplies. These niches may be impossible to reach and clean with normal cleaning and sanitizing procedures and continue to contaminate food during processing operations. Environmental and equipment testing is necessary to detect niches. The sampling sites should include areas that are good indicators of control, like food contact surfaces. The food processing environment should be sampled at least weekly. It should be noted that while *Listeria monocytogenes* can be reduced, it cannot be eliminated from the environment. Continued improvements in equipment design are necessary to make cleaning more effective and to minimize breakdowns and repairs. There will be increased use of post-packaging pasteurization with irradiation, hot water, steam, and high pressure in the future.
Keywords: food processing,* Listeria*, ready-to-eat, testing, risk analysis, controls

Tybor, Phillip T., William C. Hurst, A. Estes Reynolds, and George A. Schuler. 1990. Preventing Chemical Foodborne Illness. *The University of Georgia College of Agricultural and Environmental Sciences Cooperative Extension Service.* November. http://www.ces.uga.edu/pubcd/b1042-w.html.

Chemical hazards include metals, pesticides, intentional food additives, and other chemical residues. The residues, if consumed in large enough quantities, can be harmful to humans. Some agents implicated in chemical foodborne illness are beneficial and essential in the diet as nutrients, others preserve food and others are part of food plant sanitation. Chemical foodborne illness is usually the result of human error. With regards to metal poisoning outbreaks, the source is primarily food handling equipment and utensils made of inappropriate materials. When high-acid foods come into contact with the equipment or utensil, corrosion occurs and is leached into the food. This can occur with citrus fruits, fruit drinks, fruit pie fillings, tomato products, sauerkraut, and carbonated beverages. Pesticide contamination can occur due to spills, indiscriminate spraying of food-handling facilities or equipment, improper storage of pesticides or mistaken identity, and incomplete washing of fruits and vegetables. Possible controls include storing and securing pesticides away from food products, maintaining the chemical in its original container, reading and following instructions on the label, handling pesticides like poisons, avoiding indiscriminate application of pesticides, and using trained and certified personnel for pesticide application. Some food additives can cause health problems in sensitive individuals. FDA requires declaration on labels of sulfites at 10 ppm or higher. Sodium nitrite, a controlled additive, must be stored in a locked cabinet and weighed and bagged separately before addition to any product. Unintentional food additives, such as detergents, cleaning compounds, drain cleaners, polishers, and sanitizers can best be controlled by properly training personnel about cleaning and sanitizing, reading and following label instructions, storing chemicals away from food, maintaining chemicals in their original containers, avoiding use of empty cleaning chemical containers for food storage, using only approved food grade lubricants and greases, and keeping an inventory of these chemicals in a secure, supervised area.
Keywords: chemical hazards, equipment, risk assessment, controls, storage, employee training

USDA/ARS. 2002. Food Safety: National Program Annual Report FY 2002.

Aflatoxin is found in peanuts, corn, cottonseed, tree nuts and figs. Fumosins are found in corn and deoxynivalenol is found in wheat and barley. Scientists have demonstrated that gallic acid is an inhibitor of aflatotoxin in some tree nuts. High humidity and rainfall were found to stimulate aflatotoxin

production in cottonseed. Providing improved management recommendations may prevent the occurrence of aflatotoxin in cottonseed.
Keywords: mycotoxins, control, prevention

USDA/FSIS. 2002. Guidance for Minimizing the Risk of *Escherichia coli* O157:H7 and *Salmonella* in Beef Slaughter Operations. September.

Despite good slaughter practices, which are also detailed in this guidance, contamination of carcasses can still occur. Post-slaughter antimicrobial decontamination methods can be used to address this issue, including spray-washing, steam-vacuuming, steam pasteurization, warm water wash, trimming, lactic acid decontamination. Chilling and finished product storage at temperatures that preclude pathogen growth are also post-slaughter processes that aid in minimizing contamination risks.
Keywords: meat processing,* E. Coli*, risk analysis, controls

USDA/FSIS. 2001. Controlling *Listeria monocytogenes* in Small and Very Small Meat and Poultry Plants. September.

Contamination of foods with *Listeria monocytogenes* most frequently occurs when a product or food contact surface is contaminated between the cooking and packaging steps. Control methods include the following sanitation steps: dry cleaning, pre-rinsing equipment, foaming and scrubbing, rinsing, visual inspection of equipment, cleaning walls and floors, sanitizing, and drying. Also, environmental and contact surface testing should be done to determine the effectiveness of cleaning and identify potential sources of contamination. Sanitizers that have proven most effective include quaternary ammonia compounds, chlorine solutions and products containing peracetic acid. Rotating sanitizers periodically is a good practice as it is more effective against *Listeria monocytogenes* and other bacteria. Alternating between alkaline and acid based detergents also helps to avoid soapstone or hard water buildups and the formation of biofilms and to alter the pH of the environment to prevent adaptation of the bacteria. Plants must be designed to eliminate traffic flow between RTE and raw product areas. RTE areas should have dehumidifiers and drip pans that are sanitized regularly. Ceilings, floors, and walls should be smooth, sealed, and moisture free. Air supply should be filtered. Light fixtures should be designed so that they do not harbor dirt or moisture. Environmental testing of non-food contact surface, food contact surface testing, and product testing can be conducted in-house by an establishment. Results, however, should be validated on a regular basis by a third party.
Keywords: meat processing, poultry processing,* Listeria*, controls, sanitation, testing, facility design, ready-to-eat

Walker, Elizabeth, Catherine Pritchard, and Stephen Forsythe. 2003. Food Handlers' Hygiene Knowledge in Small Food Businesses. *Food Control*. Vol. 14. No. 5: 339-343. [only have abstract]

Personal interviews were conducted with 444 food handlers in 104 small food businesses regarding their knowledge of food hygiene. The study reports that 57 percent of food handlers thought that they could tell if food was contaminated with food poisoning bacteria by sight, smell, and taste. Roughly, 25 percent of the interviewees thought that bacteria readily multiplied at –10, 75, or 120 degrees Celsius. Around 16 percent thought that the correct temperature of a refrigerator was –18 degrees Celsius or below. The study demonstrated that the basic lack of hygiene knowledge and understanding could prove to be a major barrier to the effective implementation of HACCP in small food businesses in the U.K.
Keywords: employee hygiene, handling, HACCP, implementation

Young, Renee. 2003. Rethinking Sanitation. *Food Engineering*. March 29.

Manufacturers must adopt a holistic view of plant sanitation from how ingredients are delivered to the shipment of finished goods. This includes not only rethinking the sanitation of processing systems but of all the building systems, including electrical fixtures and duct work. With the advent of PLC, PC and CIP systems that measure the temperature, cleaning fluid mix, and pressure used in a cleaning session, operators can correct the problem immediately. In the majority of smaller plants, equipment is not designed to be cleaned with the help of automation. Plants have different types of equipment that range in age and design, making it virtually impossible to set up a spray pattern that will automatically and effectively clean each or provide accurate measurements. In such plants, manufacturers are placing more emphasis on the employees. Many companies are transferring sanitation from the third shift to the first or second and staffing those shifts with better-trained employees. Other plants are working to fully automate their sanitation systems, eliminating the possibility of human error. Further, concern over the use of toxic chemicals in sanitation procedures and the cost associated with their handling and disposal has many manufacturers looking for safer alternatives. Ozone is making strides as a safe alternative and a powerful oxidant that destroys microbes. For example, salad maker, Sandridge Food Corp., uses aqueous ozone to disinfect celery and its associated equipment. Plumrose USA Inc., a processor of ham, turkey, chicken, and deli meats, uses ozonated water to sanitize work areas and processing equipment used for slicing and packaging and to rinse its stainless steel transportation racks.
Keywords: sanitation, facility design, equipment, employee training

APPENDIX B

DEFINITIONS OF FOOD SAFETY PROBLEMS

Biofilms. A slime layer formed by bacteria on a surface, which provides an environment for pathogens to proliferate. Food contamination can result when biofilms detach from their substrate and enter food products/ingredients.

Condensate on pipes and other equipment. When cold pipes come in contact with humid air in a food processing plant, condensate will form, which can drip and contaminate food.

Contamination by reworked product. When food contamination results from using reworked product originating from one product line in another product line.

Contamination during processing. The adulteration of a product during processing (with pathogens, chemicals, allergens, or foreign objects) so that it is no longer wholesome and safe, therefore potentially rendering the finished product unsafe to eat. While contamination during processing can be caused by other problems listed in the questionnaire (e.g., inadequate glass cleanup policy), contamination during processing, as defined here, is meant to capture those problems not listed in the questionnaire that result in contamination during processing.

Contamination of raw materials. The adulteration of a product ingredient (with pathogens, chemicals, allergens, or foreign objects) so that it is no longer wholesome and safe, therefore potentially rendering the finished product unsafe to eat. The problem encompasses those instances where the incoming raw materials arrive contaminated as well as those where raw material contamination occurs at the plant. While the contamination of raw materials can be caused by other problems listed in the questionnaire (e.g., use of unpotable water to wash food ingredients), contamination of raw materials, as defined here, is meant to capture those problems not listed in the questionnaire that result in the contamination of raw materials.

Deficient employee training. Training that does not meet the following minimum requirements is considered deficient. Training, at a minimum, must include a written policy covering GMPs, personal hygiene, plant sanitation policies and procedures, food safety and quality control policies, and product tampering awareness and consequences. Training must be presented in a language that can be understood by all employees. Training programs should be updated annually and records should be kept of training sessions. All new employees must be provided with initial training that covers the minimum requirements and refresher courses should be provided quarterly. Operational deficiencies should result in additional training.

Difficult-to-clean equipment. When food production and packaging equipment is not designed and installed in such a way as to produce a wholesome product (e.g., the equipment is difficult to access for cleaning or the equipment is not operating properly).

Inadequate cooling. Not using the proper temperature during storage or processing of food ingredients or food products, especially refrigerated or frozen foods.

Inadequate glass cleanup policy. If a glass cleanup policy, which should include properly cleaning glass containers, providing shielding in the event of glass breakage during productions, and the proper cleanup

of glass in nonproduction areas (glass should not be used in or near processing or storage areas), does not exist or is not comprehensive.

Incorrect labeling or packaging. Products can be packaged from old or other products or placed in the wrong packaging. In other cases, allergens might not be declared on the label when they should be.

Lack of allergen control programs. Not available. Added by one expert.

Lack of chemical control programs. Not available. Added by one expert.

Lack of crisis management protocol. No written procedures or training on how to manage crises at the facility.

Lack of equipment knowledge. Poor understanding by employees who operate equipment on how to keep equipment clean and prevent equipment maintenance tasks, such as lubrication of machinery, from contaminating food.

Lack of equipment parts reconciliation after repairs. No written procedures or training to ensure that all equipment parts are accounted for after a repair.

Lack of knowledge of welding standards. No written standards or training on how to properly conduct welding in a food-processing environment.

Lack of product recovery protocol. No coding, traceability, or recall systems.

No preventive maintenance. When no documented plan of regularly scheduled inspections exists that identifies and corrects facility and equipment problems before they become a food safety hazard.

Poor employee hygiene. Employee hygiene is considered poor if it could result in unsafe food or increases the likelihood of unsafe food manufactured at the plant. This could be attributable to inadequate employee hygiene policies and procedures, lack of monitoring and compliance verification, and other causes.

Poor pest control. Absence of a detailed pest management policy and program that is documented and conducted under the supervision of a licensed pest control contractor.

Poor plant and equipment sanitation. Plant and equipment sanitation is considered poor if it could result in unsafe food or increase the likelihood of unsafe food manufactured at the plant. This could be attributable to lack of adequate sanitation procedures, ineffective application of sanitation policies, inadequate or lack of monitoring and verification of cleanliness, and/or other causes.

Poor plant design and construction. When the construction and design of the facility increase the likelihood of food contamination (e.g., cross-over of flow paths of raw and finished products, contacts between walls or floors and food ingredient or finished food product, and poorly drained floors).

Post-process contamination at manufacturing plant. The adulteration of a finished food product after processing (with pathogens, chemicals, allergens, or foreign objects) at the manufacturing facility so that it is no longer wholesome and safe, therefore rendering the finished product unsafe to eat. The post-processing contamination might occur between the lethality treatment and packaging or post packaging at the manufacturing plant. While post-processing contamination can be caused by other problems listed in

the questionnaire (e.g., inadequate pest control), post-processing contamination, as defined here, is meant to capture those problems not listed in the questionnaire that result in post-processing contamination.

Stagnant water due to dead-ends in plumbing. When plumbing connections do not have a drain into other areas and thus result in sitting water that can contaminate food.

Use of unpotable water. Use of water that does not meet local health requirements, at a minimum.

APPENDIX C

EXAMPLES OF PREVENTIVE CONTROLS AND/OR CORRECTIVE ACTIONS FOR THE TOP TEN FOOD SAFETY PROBLEMS

Contamination during processing. Separation of production lines, use of physical detachments and lockouts, use of staging areas, routine maintenance of manufacturing equipment, and properly conducted, unbiased, third party audit of GMPs.

Contamination of raw materials. Supplier audits, raw material testing and verification, supplier training, pre-processing treatments (i.e., pasteurization, irradiation, washing, culling, etc.), documentation from suppliers certifying safety of materials, and properly conducted, unbiased, third-party audit of GMPs.

Deficient employee training. Provision of training specific to the employees' duties, bilingual training, provision of learning aids, such as newsletters, posters, and videos, seminars and employee reviews, evaluation of the effectiveness of training, training refresher courses, in-house training (versus consultants), and properly conducted, unbiased, third-party audit of GMPs.

Difficult-to-clean equipment. Environmental sampling, cleaning areas prone to niches, SSOPs, taking equipment apart to clean, addition of a kill-step at the end of processing (i.e., pasteurization, irradiation, etc.), and properly conducted, unbiased, third-party audit of GMPs.

Incorrect labeling or packaging. Institution of label review policies, removal of old label and packaging inventories from the manufacturing site, verification of labels by scanning barcodes, label audits, training and properly conducted, unbiased, third-party audit of GMPs.

No preventive maintenance. Preventive maintenance plan, documentation of repairs and servicing, and properly conducted, unbiased, third party audit of GMPs.

Poor employee hygiene. Use of sensor-equipped towel dispensers, keypad controls for hand washing, automated hand washing stations, and properly conducted, unbiased, third party audit of GMPs.

Poor plant and equipment sanitation. Keypad controls that keep track of hand washing, sensor-equipped hand towels, pay incentives, beeping dispenser to ensure adequate hand-washing time, documentation of hygiene activities (i.e., logs), SSOPs, and properly conducted, unbiased, third-party audit of GMPs.

Poor plant design and construction. Properly conducted, unbiased, third party audit of GMPs.

Post-process contamination at manufacturing plant. Environmental sampling, inclusion of a kill-step at the end of processing (i.e., pasteurization, irradiation, etc.), use of preservatives, SSOPs, and properly conducted, unbiased, third-party audit of GMPs.

APPENDIX D

EXPLORATORY FACTOR ANALYSIS

Factor analysis is 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. The factor analysis conducted for this report reduced the number of variables from ten to four factors. The underlying theory behind factor analysis is that a set of multivariate observations stem from a lesser number of underlying factors. For example, data on students' test scores in math, science, art, and literature might reflect two underlying factors: one for "technical ability" and one for "creativeness." A student's "technical ability" will probably be better reflected in math and science test scores, while a student's "creativity" should be reflected in art and literature test scores. The factors are meant to reflect some underlying abstract dimension or concept. The measured variables are imperfect measures of those dimensions or concepts.

A factor analysis looks for trends in correlations among the variables. Given that the factors are unmeasured, it is necessary to use numerical algorithms to solve a factor analysis. The first step in a factor analysis is to determine the number of relevant factors. Many algorithms used to solve factor analyses have methods of determining an appropriate number of factors, but it is also possible to specify (fix) a number of factors. For the analysis in this report, we allowed the algorithm to determine the number of factors.

The output from the factor analysis will generate a table that relates each variable to each factor and assigns a numerical value between -1 and 1 to each relationship. The numerical values are referred to as factor loadings and reflect the strength of relationship between the factors and the variables. Variables that are closely related to one another should all load highly on the same factor. This is the essence of factor analysis: combining redundant variation in the data.

The factors generated in a factor analysis do not have a straightforward interpretation. In fact, it is up to the researcher to determine how a factor should be named. For the most part, theoretical considerations can guide in naming a factor. Nevertheless, developing appropriate names for factors is an important aspect of factor analysis.

Once a factor analysis has been performed, a mathematical operation called *rotation* is performed. The purpose of rotation is to make each factor distinct (in terms of factor loadings) from the other factors. Most raw factor loadings require rotation. The term rotation stems from the technique involved: the axes are literally rotated around the score to generate new axes and thus new factor scores. From a mathematical perspective, this transformation is justified since the factor loadings are only unique up to a multiplicative constant. Thus, rotation need only preserve the order of the loadings to be consistent.

Scoring is the process of generating values for the factors for each observation in the data. For example, a factor analysis that reduces a set of 20 variables to six factors might be based on 1,000 observations on those 20 variables. The factor analysis only generates 120 factor loadings (20 variables × six factors). Although each observation has a value for each variable, none of the observations has a value for the six factors (at this point). Scoring assigns a value to each observation for each factor. Once again, because the factors are unobserved, it is necessary to use numerical algorithms to solve the equations used to score the factors.

APPENDIX E

COMPARISON OF FOOD GMPS TO QUALITY SYSTEMS AND OTHER GMPS

Table E-1: Comparison of Pharmaceutical GMPs, Medical Device GMPs, ISO 9001:2000, and ASQ Quality System to Food GMPs

Food GMPs	ISO 9001:2000	ASQ Quality System	Medical Device GMPs	Pharmaceutical GMPs
Key Provisions				
▪ Personnel - Disease control - Cleanliness - Education and training, supervision ▪ Plants and grounds - Grounds - Plant design and construction ▪ Sanitary operations - General maintenance - Substances used for cleaning - Pest control - Sanitation of food-contact surfaces - Storage and handling. ▪ Sanitary facilities and controls - Water supply - Plumbing - Sewage disposal - Toilet facilities - Hand-washing facilities - Rubbish and offal disposal ▪ Equipment and utensils ▪ Processes and controls - Raw materials - Manufacturing operations ▪ Warehousing & distribution	▪ Management responsibility - Management commitment - Customer focus - Quality policy - Planning - Responsibility, authority, and communication - Management review ▪ Resource management - Provision of resources - Human resources - Infrastructure - Work environment ▪ Product realization - Planning of product realization - Customer-related processes - Design and development - Purchasing - Production and service provision - Control of monitoring and measuring devices ▪ Measurement, analysis, and improvement - Monitoring and measurement - Control of nonconforming product - Analysis of data - Improvement ▪ Quality management system - Documentation requirements	▪ Management responsibility ▪ Marketing ▪ Specification and design ▪ Procurement ▪ Production and production control ▪ Product verification ▪ Measuring and test equipment ▪ Nonconformity ▪ Corrective action ▪ Handling and post-production ▪ Documentation and records ▪ Personnel ▪ Product safety and liability ▪ Quality methods	▪ QS Requirements - Management responsibility - Quality audit - Personnel ▪ Design Control ▪ Document Controls ▪ Purchasing Controls ▪ Identification and Traceability ▪ Production and process Controls ▪ Acceptance Activities ▪ Nonconforming Product ▪ Corrective and Preventative Action ▪ Labeling and Packaging ▪ Handling, Storage, Distribution, and Installation ▪ Records ▪ Servicing ▪ Statistical Techniques	▪ Organization and Personnel - Responsibilities of quality control unit - Personnel qualifications and responsibilities ▪ Buildings and facilities - Design & construction - Sanitation & maintenance ▪ Equipment - Design, size, & location - Construction, cleaning, & maintenance ▪ Control of components and drug product containers and closures ▪ Production & process controls - Written procedures, deviations - Change in components - Equipment identification - Sampling and testing of in-process materials and drug products - Control of microbiological contamination - Reprocessing ▪ Packaging and labeling control ▪ Holding & distribution ▪ Laboratory controls - Testing and release for distribution - Stability testing ▪ Records and reports

Table E-1: Comparison of Pharmaceutical GMPs, Medical Device GMPs, ISO 9001:2000, and ASQ Quality System to Food GMPs

Food GMPs	ISO 9001:2000	ASQ Quality System	Medical Device GMPs	Pharmaceutical GMPs
				▪ Returned & salvaged drug products
Training				
▪ Appropriate training for food handlers and supervisors in proper food handling techniques and food protection principles. ▪ Training should ensure awareness of the dangers of poor personal hygiene and insanitary practices.	▪ Personnel training necessary to meet organization needs; identification of training needs through a gap analysis ▪ Appropriate level of training in hygiene practices by job function (basic-level and advanced-level training) ▪ Training in sensory evaluation and identification of hazards and associated controls ▪ Training of personnel in appropriate hygienic practices ▪ Training and reevaluation of testing personnel	▪ Training all levels of personnel within the organization: Selection & training of recruited personnel & personnel transferred to new assignments ▪ Training of executive management in quality system operation and criteria for evaluating the effectiveness of the system ▪ Training of technical personnel (including marketing, procurement, and product & process engineering personnel) in statistical techniques, process capability studies, statistical sampling, data collection & analysis, problem identification, problem analysis, and corrective action ▪ Training of supervisors and workers in their respective tasks, such as equipment operation, reading & understanding of documentation provided ▪ Formal qualification of personnel performing specialized operations ▪ Motivation and quality awareness ▪ Measuring quality achievements and	▪ Management responsibility to define training needs for personnel ▪ Training in current GMP regulation and how individual job functions relate to the overall quality system ▪ Training for temporary work under special environmental conditions	▪ Training in the regulations applicable to each employee ▪ Additional training for supervisory personnel to ensure the safety, identity, strength, quality, and purity of the product ▪ Personnel who provides training must be qualified to do so

Table E-1: Comparison of Pharmaceutical GMPs, Medical Device GMPs, ISO 9001:2000, and ASQ Quality System to Food GMPs

Food GMPs	ISO 9001:2000	ASQ Quality System	Medical Device GMPs	Pharmaceutical GMPs
		recognition of good performance		
Audits				
Audits are not explicitly specified	▪ Internal audits at planned intervals to determine whether the quality management system (1) conforms to the planned arrangements and (2) is effectively implemented and maintained ▪ Selection of auditors should ensure objectivity and impartiality (auditors should not audit their own work) ▪ Internal audits of management system records, hygiene, housekeeping, and other functions ▪ Management review of internal audit results	▪ Internal audits of the quality system at regular intervals to evaluate the effectiveness of the various quality system elements ▪ Audit needs to have a plan with a clearly defined scope and reason (i.e., routine verification, organizational change, consumer complaints, etc.) ▪ To avoid conflict of interest, auditors should not audit their own work ▪ Audit results should be documented with specific examples of deficiencies and noncompliance and suggestions of corrective/preventive actions ▪ Review and evaluation of the quality system by company management members, customers, or qualified independent auditors ▪ Quality system audits should consist of (1) specific findings, (2) overall effectiveness of the quality system in achieving quality objectives, and (3) considerations for updating the quality system with changes brought about by new technologies, quality	▪ Management needs to establish procedures for quality audits of its documented quality system and ensure that they are performed ▪ Only those records that demonstrate the quality auditing system are to be made available to an FDA inspector. FDA does not have access to the actual audit reports	▪ Audits are not explicitly specified but are embodied within the required record review process. ▪ Annual record review to evaluate the applicability of quality standards, need for changes in specifications, manufacturing processes, or control procedures.

Table E-1: Comparison of Pharmaceutical GMPs, Medical Device GMPs, ISO 9001:2000, and ASQ Quality System to Food GMPs

Food GMPs	ISO 9001:2000	ASQ Quality System	Medical Device GMPs	Pharmaceutical GMPs
		concepts, market strategies, customer requirements, etc.		
Documentation				
No documentation requirements explicitly specified, except for supplier certification for cleaning compounds and raw materials.	▪ Records of quality management system reviews ▪ Personnel records ▪ Product realization process records ▪ Records of customer-related product requirement reviews ▪ Records of design and development inputs, outputs, reviews, verification, and validation ▪ Design and development changes and reviews including control process changes ▪ Supplier selection evaluation records ▪ Production process validation records where verification is not possible ▪ Monitoring and measuring device calibration and verification records ▪ Internal audit records ▪ Records of production inspection and tests ▪ Records of nonconforming products ▪ Corrective and preventive action records.	▪ Sufficient documentation of achievement of required product quality and food safety ▪ A method for removing and disposing of documents that are out of date ▪ Documents include: specifications, test procedures, inspection instructions, work instructions, operational procedures, quality manuals, laboratory procedures, and quality assurance procedures ▪ Records should be for verification of operation of quality system ▪ Examples of records include: inspection reports, test data, qualification reports, validation reports, audit reports, calibration data, and regulatory inspection reports.	Explicitly requires that all of the following records be readily available to FDA inspectors ▪ Device master record: device, production process, quality assurance, packaging and labeling, and installation specifications. ▪ Device history record: date of manufacture, quantity manufactured, quantity distributed, acceptance records (of DMR), identification label and control numbers. ▪ Quality system record: procedures and documentation of activities ▪ Complaint files: compliant files to determine if investigation needed. If so, record of investigation	Explicitly requires that all of the following records be readily available to FDA inspectors ▪ Equipment cleaning & use log: Must contain dates, times, products, lot numbers, and signatures ▪ Component, drug product container, closure, and labeling records: Supplier names, lot numbers, receiving codes, test results, individual inventory records, documentation of labeling examination, and records of rejected materials ▪ Master production & control records: Prepared, dated and signed by one individual and checked by another ▪ Batch production and control records: documentation of completion of each significant step in manufacturing ▪ Laboratory records: All data, test method modification records, stability testing results ▪ Distribution records: Date

Table E-1: Comparison of Pharmaceutical GMPs, Medical Device GMPs, ISO 9001:2000, and ASQ Quality System to Food GMPs

Food GMPs	ISO 9001:2000	ASQ Quality System	Medical Device GMPs	Pharmaceutical GMPs
				and quantity shipped ▪ Complaint files
Evaluation/Validation				
There are no evaluation/validation requirements to determine whether a performed activity is achieving its goal. Only for raw materials, the facility is to "verify" compliance using supplier certification or some other method.	▪ Evaluation of information relating to customer perceptions of whether the organization has met its customer requirements ▪ Evaluation of the effectiveness of the actions taken, such as training and education ▪ Evaluation of the ability of results of design and development to meet requirements ▪ Physical, chemical, microbiological, shelf-life, and sensory evaluations ▪ Evaluation of design and development changes on constituent parts and product already delivered ▪ Reevaluation of testing personnel ▪ Quality system effectiveness evaluation ▪ Evaluation of the need for action to prevent occurrence of nonconformities ▪ Validation of product shelf-life through market research and transit tests	▪ Process and product design qualification and validation involving periodic evaluation of the design at significant stages ▪ Validation of the process and product design through small-scale trial and sample tests ▪ Periodic reevaluation and requalification of the product to ensure that it meets all specified requirements ▪ Product verification ▪ Evaluation of training effectiveness	▪ Verification of product design, i.e., testing to determine whether the design output meets the functional and operational requirements of design inputs ▪ Design validation with lab testing of prototypes ▪ Process validation and revalidation in case of changes or process deviations ▪ Validation of computer software when it is used as part of production or the quality system ▪ Evaluation of the need for an investigation of a nonconforming product ▪ Retesting and reevaluation of the nonconforming product after it has been reworked	▪ Process validation ▪ Evaluation of product and process deviations ▪ Verification of yield calculations and component charge-ins by different people

Table E-1: Comparison of Pharmaceutical GMPs, Medical Device GMPs, ISO 9001:2000, and ASQ Quality System to Food GMPs

Food GMPs	ISO 9001:2000	ASQ Quality System	Medical Device GMPs	Pharmaceutical GMPs
	▪ Ensuring that the product meets customer requirements through specific target user groups or test marketing ▪ Design and development validation, revalidation upon design and development changes ▪ Process validation ▪ Test method validation			