

Hazard Analysis and Risk-Based Preventive Controls

Improving Food Safety in Human Food Manufacturing for Food Businesses



Hal King | Wendy Bedale



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Manufacturing for Food Businesses***

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Wendy Bedale



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Foreword

As an aspiring chef at a local restaurant in the late 80s, I had the good fortune of learning from and working alongside some of the best-known chefs in the small town I grew up in—Derby, Connecticut. Ron, Joe and Mark were guys who I knew I could ask anything about grill temperatures, flavor combinations, stockroom ordering/rotation of inventory, etc. I learned by watching, observing, and doing. While culinary school did not quite work out for me, I did learn a lot of life lessons there.

While my days as a chef taught me the importance of on-the-job training, my experience as a volunteer firefighter taught me the power of combining education with training. The volunteer firefighter, rescue personnel, or emergency medical technician (EMT) does not “learn” how to fight fire by being thrust into a live burning building. A minimum requisite classroom and lecture-based *education* is required before they participate in a controlled live burn or ride shotgun in an ambulance to the scene of an accident for the first time (which is where on-the-job *training* occurs). You have got to learn how to “breathe correctly,” at the right pace, before donning an airpak that could save your life in a smoke-filled room. You have got to understand how the jaws of life work, before applying what you have *learned* in the classroom to effectively and efficiently remove an entrapped victim from the tangled web of a motor vehicle accident.

In Derby, as many small towns across the United States, the first responders in the various emergency responder volunteers are part of the backbone of their communities. These volunteers choose to help others, not to become heroes, but because it is the right thing to do. At the end of the day, *doing the right thing*, for the right reasons—and having a solid educational foundation, being trained, maintaining relevant certifications or licenses, staying “on top” of evolving hazards in the community—could mean the difference between life and death.

What does any of this have to do with food safety? Nothing, on face value, but everything, if you think about it. We are all residents of the food safety community.

Education and training are elements of personal and professional development that are all too often considered to be interchangeable. You do not get “trained” by reading a book; you are educated. By completing an eLearning course or attending a seminar, you are educated in the subject matter. Training is complete when you are able to demonstrate what you have learned

by applying the principles to solve a problem or reach a stated objective. A firefighter must be educated before he or she can be trained in a live burn exercise. Food safety professionals, similarly, must build on their solid foundation of education and experience to demonstrate what they have learned in a food manufacturing environment or quick service restaurant. Education is a foundation. If you add training and “doing the right thing” to that educational foundation, good things can be accomplished.

Before I had the opportunity to read this book, I hoped that it would enable me to “see” what the intended outcomes were of adopting hazard analysis and preventive controls. I am happy to report that Hal and Wendy have done a great job in “illustrating” these new food safety requirements via diagrams and tables to make clear the points being made. Their book also provides an understanding of the various roles of the retailer, supplier, and buyer in the supply chain of a safe food being produced, sold to and enjoyed by consumers.

Within this work, the authors educate the reader by citing real-life and fictitious instances, factually relevant data and regulatory insights to develop this book into a resource compilation, to help you to learn how to choose to do the right thing and to encourage replicable, consistent behaviors in your colleagues, associates, direct reports, and among your peers. This book contributes to the mindset that food safety should not be a competitive advantage and that we all need to work together, collaborate, exchange, and share ideas to help stay “on top” of our game.

After an introductory chapter outlining what to expect, they provide an overview of the era of the Food Safety Modernization Act (FSMA)—think about it—30 years from now we will be talking about before FSMA and after FSMA. Near the end of [Chapter 3](#), the crux of the issue is presented, simply: “To ensure food safety in its supply chain, the retail food business must first know the potential hazards associated with its foods.” Food ingredient-related hazards are thoroughly summarized. And, just as the firefighter or EMT needs to stay up to date and on top of new trends in hazards in their communities or as vehicle construction changes (think autonomous vehicle controls), the authors encourage retailers to stay abreast of new hazards by monitoring CDC outbreak investigations, FDA recalls, and new FDA guidance documents to control foodborne disease risks.

In subsequent chapters, they cover the use of potential facilities/processing–hazard pairs as a final step in defining all “known” hazards. The synthesis of this information enables the hazard analysis of each product ([Chapter 5](#)) so that the preventive controls necessary to manage all potential hazards of each product can be defined ([Chapter 6](#)). Retailers should evaluate the following risk-based preventive controls contained within the Food Safety Plan of the manufacturers that they source from:

- Process preventive controls (which mirror the types of controls found in hazard analysis and critical control point plans)
- Food allergen preventive controls

- Sanitation preventive controls
- Supply-chain preventive controls
- Recall plans
- Other controls

In addition, retailers need to be sure their supplier is capable of providing documentation that satisfies the validation, verification, monitoring, corrective actions or corrections, and related documentation records are being met, to be able to ensure and demonstrate to others that the identified preventive controls are being properly performed, and that they are working appropriately ([Chapters 7 and 8](#)).

In [Chapter 10](#) “Beyond the Book: Interpretation” Wendy and Hal articulate some helpful hints intended to help guide the retailer in staying on top of their game. Recommendations such as pursuing additional education and training opportunities, attending food safety conferences and meetings, reading journals and magazines, leveraging governmental resources, and being sure to ask questions are explained and linked back to the source material provided within this resource.

Now, pardon me, while I seek out the source of satisfaction for my current craving for a double chocolate cookie dough milkshake.

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Preface

The goal of this book is to help demystify the FDA’s Preventive Controls for Human Foods (PCHF) regulations for the retail food sales and service business professional. Hazard analysis and risk-based preventive controls also represent invaluable tools to the retail food business to ensure food safety in their supply chain. Therefore, it is also our goal to help the retail food businesses, who purchase, prepare, and sell manufactured foods and ingredients to the consumer, use hazard analysis and risk-based preventive control processes as specifications for their suppliers to enhance the oversight of food safety in their supply chain.

When we began research for this book, we identified a variety of resources that detailed how a food manufacturing business could perform a hazard analysis and develop risk-based preventive controls. These resources included the Food Safety Modernization Act (FSMA) regulations themselves, official industry comments (and FDA responses) to the proposed rules, other FDA information sources (FAQs, webinars, presentations), and guidance documents (some of which are still in draft form at the time of this publication). We both believed that another perspective on the prevention of foodborne disease outbreaks would be useful: that of retail food sales and service business professionals tasked with sourcing safe ingredients and food products from (and in collaboration with) manufacturers.

It is important to remember that this book is *not* a “how to” guide on complying with FSMA’s PCHF regulations nor is it a blueprint for following other rules established under FSMA. Indeed, during our research for this book, we found that the FDA and its collaborators have already done a tremendous job in preparing industry for PCHF through the Food Safety Preventive Controls Alliance (FSPCA). The FSPCA is a public–private alliance made up of industry, academic, and government stakeholders tasked with developing training programs and material to educate industry and others on PCHF (and other foundational rules of FSMA). The FSPCA’s mission is “to support safe food production by developing a nationwide core curriculum, training and outreach programs to help companies that produce human and animal food in complying with the preventive controls regulations that are part of the Food Safety Modernization Act (FSMA)” ([Food Safety Preventive Controls Alliance, 2016a](#)). The FSPCA training materials provide ample resources and tools, including easy-to-use templates to document the hazard analysis and risk-based preventive control requirements within a Food Safety Plan ([Food Safety Preventive Controls Alliance, 2016b](#)).

In preparation to write this book, we both attended the 2-day FSPCA training course on PCHF (Bedale, 2017) and made use of the excellent workbook available free to the industry at the FSPCA website (Food Safety Preventive Controls Alliance, 2016b). Working through a Food Safety Plan and performing mock hazard analyses and risk-based preventive control exercises for finished food products helped develop an appreciation for the use of preventive controls, which (like hazard analysis and critical control points did before in certain industries) represents a significant improvement in food safety management. The authors recommend that everyone involved in food safety management consider taking the FSPCA training course, which is offered by numerous organizations around the world.

Dr. Hal King began his career at the CDC working there as a commander, United States Public Health Service officer on infectious disease outbreaks caused by bacterial infections. The majority of those disease outbreaks were caused by pathogens that currently are not preventable by vaccines but must be prevented by avoidance of exposure to the pathogen. When he began his professional career in food safety management, leading the food safety program (retail operations and supply-chain safety) in a large quick service restaurant chain, many of the same tools used to manage risk of exposure to other pathogens (e.g., surveillance of product defects in the supply chain and root cause analysis for prevention, etc.) were applicable to the management of risk in a multiunit/multistate retail food business. Dr. King used many of the principles found in hazard analysis and risk-based preventive control processes as specifications and food safety management systems for suppliers in his former responsibility for food safety in a corporate retail food business. After writing about how valuable the principles of hazard analysis and risk-based preventive control can be in the food safety management of a retail food business's own suppliers (King and Ades, 2015) the need to expand this into a practical resource for the industry was established. These perspectives are brought forward into this book.

Wendy Bedale worked in a variety of scientific, clinical, regulatory, and project management roles in the pharmaceutical, medical device, and biotechnology industries before taking a position that fulfilled two of her passions (scientific writing and food) at the Food Research Institute (FRI) at the University of Wisconsin–Madison. Since then, she has written about many aspects of food safety for a variety of audiences. Being involved in FRI's investigation of the 2014 caramel apple listeriosis outbreak, in particular, gave her an appreciation of stealthy new risks that can arise in foods, an important consideration when considering preventive controls.

As indicated above, this book is not intended to be a comprehensive manual on how to comply with FDA regulations regarding preventive controls. However, we are hopeful it will serve as an additional resource for those seeking to understand hazard analysis and risk-based preventive controls and how they can prevent foodborne disease outbreaks. Focusing on all known hazards identified from biology, epidemiology, chemistry, food recall information, practical observations, and common sense should help reduce the numbers of foodborne

disease outbreaks that continue to plague our nation. Identifying food hazards and developing controls to prevent them based on the best academic and government research, science on pathogen elimination, and industry best practices is the best means to ensure food safety management within a supply chain.

Sometimes a different “set of eyes” on a problem such as foodborne disease prevention can be helpful to those tasked with doing the actual “preventing” (including both those representing the food manufacturer and the retail food buyer). If only one concept, process, recommendation, reference, or other nugget of information in this book helps a retail food safety professional prevent a single foodborne disease outbreak, it is well worth the investment that each of us makes in the business of food safety.

The authors would like to thank the many individuals who provided input and assistance as we wrote this book, especially Donna Schaffner for contributing the case study included in [Appendix C](#). John Zimmerman at First Watch Inc. and Dr. Steven Lyon at Chick-fil-A Inc. provided additional perspectives in corporate food safety management systems, while Glenda Lewis and Laurie Williams provided regulatory insights related to the retail food industry. Kathy Glass, Adam Borger, Chuck Czuprynski, Dennis Seman, and Lindsey Jahn at FRI at the University of Wisconsin–Madison contributed their expertise, insight, and support as we wrote this book, while Jackie Truesdell and Patricia Osborn at Elsevier guided development of this book from an idea to completion.

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Introduction

*Knowing is not enough; we must apply.
Willing is not enough; we must do.*

Johann Wolfgang von Goethe

1.1 Making the Case

A candy manufacturer was solicited by a quick service restaurant (QSR) chain to manufacture a new milk chocolate candy for the restaurants to blend into a frozen dairy dessert. The candy manufacturer could offer the restaurant chain a lower price for the candy if it could be manufactured in its current facility, which also produced milk chocolate–covered peanuts and used peanut flour in other products. The restaurant chain desired the lower cost candy supply to boost its margin on the frozen dessert but also wanted to ensure that the frozen dessert would be free from peanut allergen.

To further reduce costs, the restaurant chain planned to sell the frozen dairy dessert in single-use beverage cups that the chain currently used for other types of beverages. Since these cups were used for many different products, they were not labeled with any ingredient or product information, and the company did not want to include avoidance messaging, such as “may contain peanuts,” on the cups.

The restaurant chain’s quality department was responsible for ensuring the safety of the products manufactured by other companies for the chain. The quality department prescribed food safety specifications to the candy manufacturer that required undeclared allergen management controls and cleaning and sanitation cross-contact preventive control standard operating procedures (SOPs).

The candy manufacturer had a clean room with segregated production areas, detailed cleaning and sanitation schedules, and excellent production equipment maintenance, all of which should prevent allergen cross-contact between products. Verification that equipment was free of peanut allergen was performed following cleaning and sanitation by conducting on-site rapid peanut protein testing before the candy was run on a predetermined production line. The food safety specifications also required additional peanut protein testing on every lot of finished product. A hold and release protocol was in place so that product lots could not be released for distribution until a negative test result for peanut protein for that lot was obtained.

However, after numerous product test runs, product testing continued to show detectable peanut protein. The QSR chain food safety leader decided to do a walk-through of the candy manufacturing facility to try to identify the problem. All food safety specifications seemed to be in place. When asked for the source of the airflow that came into the candy production clean room, the QA manager reminded the food safety leader that the clean room used filtered air, the standard for such a production area. Because the facility was several years old, the food safety leader asked if changes had been made to the facility or the clean room since its original construction. The food safety leader and the QA manager followed the flow of air via the air ducts from the clean room back to its source. To their surprise, they found the air originated in the allergen storage room. During their investigation, they also found that key air filters were missing. Even more importantly, they actually observed an employee scooping peanut flour into a container in the allergen storage room, spreading peanut dust into the air.

The QA manager was a bit embarrassed that the positive peanut allergen test results were due to peanut flour from the allergen storage room flowing into the clean room. More concerning to the QA manager was the likelihood that his facility had been producing products for other buyers that likely also contained undeclared peanut protein.

After the clean room airflow had been corrected by rerouting from a nonfood and ingredient storage clean area (and a new small particle filtration system installed), no further positive peanut allergen test results occurred. The candy was produced and shipped to the QSR chain stores for the new frozen dairy dessert rollout.

Shortly after the rollout of the new product, a doctor called the QSR chain to inform them of terrible news. A mother had just lost her 3-year-old son after being rushed to the hospital due to an anaphylactic reaction. The local health department and doctors traced the reaction back to the QSR chain's milk chocolate candy frozen dairy dessert.

The product remaining in the restaurant was collected by the health department. Despite all the efforts to ensure the absence of undeclared peanuts in the product, testing confirmed the presence of peanut proteins in the milk-chocolate ingredient used by the candy manufacturer.

It was discovered that the candy manufacturer had switched to a new supplier for the regular wheat flour it used to make the milk chocolate to reduce cost of the ingredient. The candy company had switched (without any notice to the QSR buyer) to the same supplier they used for their peanut flour ingredients, and this supplier did not have an allergen management program in place to prevent peanut flour from contaminating the regular wheat flour.

When the food safety leader asked why the final product testing at hold and release did not identify peanut protein traces in the milk chocolate candy product, the QA manager stated that they thought they had *reduced the probability of the potential hazard* when they changed the source of airflow into the candy clean room. As a result, they decided to only test product

lots on a weekly basis to reduce the cost associated with testing every lot. This was obviously a poor decision that removed a necessary preventive control.

In this fictitious scenario that led to the death of a child, one important hazard existed: The cross-contact of peanut allergens in foods that, tragically, were served to the child. Preventive controls could have been implemented that would have significantly reduced the risk and stopped this outcome. Before the Food Safety Modernization Act (FSMA) and the Preventive Controls for Human Foods (PCHF) regulations, such controls might not have been considered. Most typically, the company would have relied on cleaning and sanitation together with allergen storage controls. However, in the era of FSMA, other preventive controls that could have prevented this type of tragedy likely would have been considered, such as the following:

- Allergen or process preventive controls, such as the separation of allergens from food-processing equipment and production lines
- Sanitation preventive controls beyond basic cleaning and sanitation that would have ensured the removal of all allergens from equipment used in previous production runs
- Process or allergen preventive controls such as mapping the source of airflow blowing into the clean room
- Supply chain preventive controls that could include obtaining assurances that supplier ingredients do not contain undeclared allergens

Customer avoidance of the product in the restaurant might have also been possible if the product had been labeled to indicate that it may have contained peanuts. However, as will be discussed in [Chapter 6](#), the use of precautionary allergen labeling such as “may contain peanuts” generally is not considered a preventive control.

1.2 Human Food Manufacturing Can Create Risk for a Retail Food Business

Before you begin reading this book, let us get on the same page on the difference between controlling food safety risk and preventing food safety hazards. A food safety hazard is something that can cause serious illness, injury, or death when found in foods. In the retail food business where consumers may be impacted, a foodborne illness can be a risk to a consumer based on the likelihood of a hazard occurring in a food, the probability of the hazard causing illness or injury to that individual, and the severity of the illness or injury to the individual. The risk of an illness is best avoided by focusing on and preventing the hazard. If a single hazard in a food could cause death (e.g., an undeclared allergen consumed by a severely allergic individual), but there is very little probability that the hazard can get into the food due to rigorous preventive controls, then the risk is very low ([Table 1.1](#)). However, if a preventive control that manages that hazard is removed, the risk may be high.

Table 1.1: Examples of how degrees of hazard and preventive controls define food safety risks.

The Risk = Hazard × Probability
Low risk = hazard high × low probability (e.g., due to multiple preventive controls)
High risk = hazard high × high probability (e.g., any failure in preventive controls)

The production of foods for human consumption is a complex system of relationships, supply chains, transportation, business partners, facility infrastructures, technologies, market forces, human behaviors, evolving equipment improvements, and politics, each of which can impact the safety of a manufactured ingredient and food for consumers. The risk of food adulteration is present throughout the food supply chain (Fig. 1.1).

Food manufacturing companies often obtain raw food ingredients with some inherent hazards and turn them into value-added packaged food ingredients and products, which are then distributed to retail food service or sales establishments around the world with little to no risk of foodborne illness, injury, or death. Preventive controls are an important way that such hazards are managed to reduce risk. On the other hand, the complex nature of human food manufacturing logistics, distribution, and sales/service leads to numerous opportunities where hazards can be introduced into foods leading to foodborne illnesses, injuries, and deaths, many of which could have been avoided if preventive controls had been used.

The importance of prevention in managing hazards and reducing risk is a key component of FSMA with its significant focus on hazards and the methods to prevent them during human food manufacturing.

1.3 A Focus on High-Risk Food Manufacturing to Reduce Risk to Retail Food Businesses

Section 204(d)(2) of FSMA requires that the FDA designates high-risk foods (HRFs) to enable a focus on the manufacturing of these human foods due to their higher associated hazards and probabilities of adulteration. The FDA plans to use historical data and risk scoring (including both qualitative and quantitative methods) to designate HRFs based on the public health significance of the food with respect to outbreaks and cases of foodborne disease as well as a number of food- and processing-related factors (U.S. Food and Drug Administration, 2014).

Many of the factors that the FDA will use to designate HRF are related to food manufacturing (Table 1.2). Most interestingly, many of these factors relate directly to how often the food manufacturing industry fails to prevent hazards that have led to human foodborne disease illness, injury, and death.

Although the FDA has not yet made any designations for HRFs, there are data that hint at the types of foods that might receive such designations. The US government collects a large amount

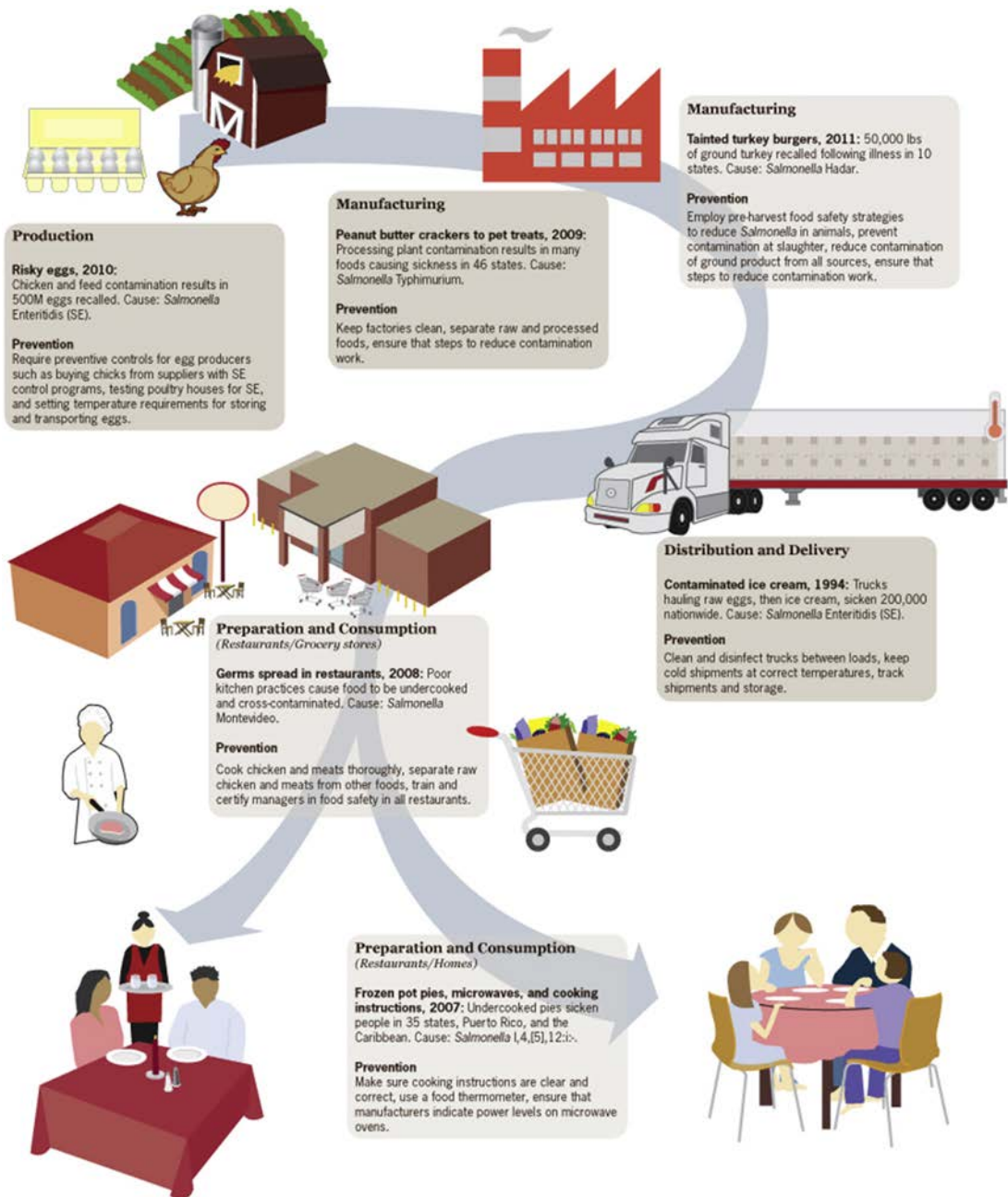


Figure 1.1

Example of food production and distribution in the typical food supply chain with examples of a single hazard, *Salmonella*, and its risk at each stage. From Centers for Disease Control and Prevention, 2011. *Vital Signs: Making Foods Safer to Eat*. Available at: http://www.cdc.gov/vitalsigns/FoodSafety/?s_cid=vitalsigns_070.

Table 1.2: Factors that the FDA uses to measure risk of foods for human consumption.

1. The known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention (CDC)
2. The likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food
3. The point in the manufacturing process of the food where contamination is most likely to occur
4. The likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination
5. The likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food
6. The likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food

From U.S. Food and Drug Administration, 2014. FDA's Draft Approach for Designating High-Risk Foods as Required by Section 204 of FSMA. FDA Center for Food Safety and Applied Nutrition. College Park, Maryland. Available at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm380210.htm>.

of data about food safety hazards that have led to outbreaks of foodborne diseases. One source of industry-related data on food safety hazards involves the discovery and reporting of product defects by food (and animal feed) manufacturers to the FDA in the form of the Reportable Food Registry (RFR). The RFR was established by Section 1005 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), which requires all food manufacturers to report when a food (or animal feed) has a reasonable probability that the use of, or exposure to, that food/feed could cause serious adverse health consequences or death to humans or animals.

The FDA publishes annual RFR reports summarizing the types of foods and hazards reported. The data collected by the FDA between September 8, 2013 and September 7, 2014 tabulates foods (categorized into 22 commodities) that were adulterated by eight different hazards, including drug contamination (1.0%), pathogenic *Escherichia coli* (1.0%), *Listeria monocytogenes* (18.9%), nutrient imbalances (4.0%), lead (0.5%), *Salmonella* (24.9%), undeclared allergens (47.3%), and sulfites (2.5%) (Table 1.3). Thirteen of the human foods were reported to be adulterated by more than one hazard. Approximately 88% of the reports of adulterated foods over a 5-year period were caused by *Salmonella*, *L. monocytogenes*, and/or undeclared allergens. Undeclared allergens were the most significant hazard reported (5-year average 43.4%), compared with *Salmonella* (36.1%) and *L. monocytogenes* (20.4%). Interestingly, although we do not know the number of illnesses, injuries, and deaths that occur from undeclared allergens in foods (a short-sighted and consistent omission of public health surveillance, *author's personal observation*), the types of foods contaminated with *Salmonella* (dairy, fruits and vegetables, nuts and seeds, produce, spices), and *L. monocytogenes* (sauces/dressing/gravies, prepared foods, produce, and seafood) generally correlate to the attributed foods from US foodborne disease outbreaks caused by these two pathogens.

**Table 1.3: Commodity type and hazards reported to the FDA via the reportable food registry
(September 8, 2013–September 7, 2014).**

Commodity	Drug Contamination	<i>Escherichia coli</i>	<i>Listeria monocytogenes</i>	Nutrient Imbalance	Lead	<i>Salmonella</i>	Undeclared Allergens	Undeclared Sulfites	Total No. (%)
Animal food/feed	2	0	2	8	0	6	0	0	18 (9.0%)
Bakery	0	0	0	0	0	0	23	0	23 (11.4%)
Beverages	0	0	0	0	0	1	3	0	4 (2.0%)
Breakfast cereals	0	0	0	0	0	0	2	0	2 (1.0%)
Chocolate/ confections/ candy	0	0	0	0	0	1	14	1	16 (8.0%)
Dairy	0	1	5	0	0	5	12	1	24 (11.9%)
Dressing/ sauces/ gravies	0	0	0	0	0	0	6	0	6 (3.0%)
Frozen foods	0	0	1	0	0	1	10	0	12 (6.0%)
Fruit and vegetable products	0	0	0	0	0	2	1	2	5 (2.5%)
Meal replacement/ nutritional food and beverages	0	0	0	0	0	0	2	0	2 (1.0%)
Multiple products	0	0	1	0	0	0	1	0	2 (1.0%)

Continued

**Table 1.3: Commodity type and hazards reported to the FDA via the reportable food registry
(September 8, 2013–September 7, 2014).—cont'd**

Commodity	Drug Contamination	<i>Escherichia coli</i>	<i>Listeria monocytogenes</i>	Nutrient Imbalance	Lead	<i>Salmonella</i>	Undeclared Allergens	Undeclared Sulfites	Total No. (%)
Nuts/nut products/ seed products	0	0	2	0	0	5	2	1	1 (5.0%)
Pasta	0	0	1	0	0	0	1	0	2 (1.0%)
Prepared foods	0	1	7	0	0	0	9	0	17 (8.5%)
Produce— fresh cut	0	0	5	0	0	5	1	0	11 (5.5%)
Produce— raw agricultural commodity	0	0	8	0	0	6	0	0	14 (7.0%)
Seafood	0	0	6	0	0	0	1	0	7 (3.5%)
Snack foods	0	0	0	0	0	0	4	0	4 (2.0%)
Soup	0	0	0	0	0	0	2	0	2 (1.0%)
Spices and seasonings	0	0	0	0	1	11	0	0	12 (6.0%)
Stabilizers/ emulsifiers/ flavors/ colors/ texture enhancers	0	0	0	0	0	6	0	0	6 (3.0%)

**Table 1.3: Commodity type and hazards reported to the FDA via the reportable food registry
(September 8, 2013–September 7, 2014).—cont’d**

Commodity	Drug Contamination	<i>Escherichia coli</i>	<i>Listeria monocytogenes</i>	Nutrient Imbalance	Lead	<i>Salmonella</i>	Undeclared Allergens	Undeclared Sulfites	Total No. (%)
Sweeteners	0	0	0	0	0	1	0	0	1 (0.5%)
Whole and milled grains and flours	0	0	0	0	0	0	1	0	1 (0.5%)
Total	2	2	38	8	1	50	95	5	201
Percentage	1.0	1.0	18.9	4.0	0.5	24.9	47.3	2.5	100%

Note: Due to rounding, the combined sum may not total 100%. There were zero entries in year 5 for acidified/low-acid canned foods. Egg, game meats, oil/margarine, and other commodity types. For years 1–4 “Distribution of primary RFR entries by commodity and hazard” values, see *The Reportable Food Registry: Targeting Inspection Resources and Identifying Patterns of Adulteration Fourth Annual Report: September 8, 2010–September 7, 2013*. From U.S. Food and Drug Administration, 2016. *The Reportable Food Registry: A Five Year Overview of Targeting Inspection Resources and Identifying Patterns of Adulteration. September 8, 2009–September 7, 2014*. FDA Center for Food Safety and Applied Nutrition, College Park, Maryland. Available at: <http://www.fda.gov/Food/ComplianceEnforcement/RFR/ucm200958.htm>.

Another clue as to which food commodities might receive a “high-risk” designation comes from CDC and FDA reports on foodborne disease outbreak investigations. The CDC reports annually on the actual number of foodborne illnesses, injuries, and deaths by food commodity based on local, state, and federal outbreak investigations (Centers for Disease Control and Prevention, 2016a), with about 1 in 6 (or 48 million) people sickened each year from contaminated food (Centers for Disease Control and Prevention, 2011).

As reported for 2014 (Centers for Disease Control and Prevention, 2016a,b), restaurants were again the most commonly reported food preparation location associated with foodborne disease outbreaks in the United States, accounting for 65% of foodborne disease outbreaks. However, multistate outbreaks (often arising from a common source of manufactured foods, for example) caused 52% of deaths in all reported foodborne outbreaks. During 2010–14, an average of 24 multistate foodborne disease outbreaks was reported each year, each involving between 2 and 37 states (Crowe et al., 2015). Approximately half (46%) of multistate foodborne outbreaks resulted in product recalls (Crowe et al., 2015).

Although some HRFs can be predicted from historical data, such data are not available for all foods. Although the FDA has not published the results of its planned risk assessments that define HRFs at the time of this writing, the published data being analyzed in the risk models (including the ranked criteria shown in Table 1.4) can be used by the manufacturing industry to predict foods that will be classified as HRFs. Equally important will be new data collected from outbreaks occurring each year, including newly identified hazards (such as those arising from novel food-pathogen combinations). Current definitions for HRFs will

Table 1.4: Ranked criteria and data needs for risk models to define high-risk foods.

Criteria	Data Needs
C1	Frequency of outbreaks, the number of cases per year (outbreak and sporadic cases, disease multiplier)
C2	Severity of illness (including hospitalization rate, mortality rate, and other indicators)
C3	Likelihood of contamination
C4	Growth potential/shelf life
C5	Manufacturing process contamination/intervention
C6	Consumption
C7	Economic impact

From U.S. Food and Drug Administration, 2014. FDA's Draft Approach for Designating High-Risk Foods as Required by Section 204 of FSMA. FDA Center for Food Safety and Applied Nutrition, College Park, Maryland. Available at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm380210.htm>, which also includes example data sources for the identified data needs.

therefore evolve, and the food industry must continue to monitor this information as it update its Food Safety Plans.

1.4 Retail Food Businesses Have a Role in the Prevention of Foodborne Injury, Illness, and Disease

It can be argued that no single entity, including the FDA, CDC, USDA, or any other agency, can do more to ensure the safety of a food than the company that manufactures or sells that food.

Children should not die after eating caramel apples or ice cream, no matter that such events are rare. There continues to be too many (and one is too many) food-related deaths that can and must be prevented through controls in every production run in every food processing facility. Preventing foodborne disease is not only the right thing to do as a public health responsibility but also is a good business practice for the company. Preventing an outbreak protects the national economy when whole commodities (such as spinach or cantaloupes) are communicated as dangerous to consumers because the CDC or FDA are not always able to immediately determine the specific source (e.g., a grower or processor) of the dangerous adulterated commodity.

Now, as a result of FSMA, there are very specific and available resources (including training, guidance documents, and other tools; discussed further in [Chapter 10](#)) to assist in preventing foodborne illnesses and injuries known to arise as a consequence of human food manufacturing. Although guided by scientific principles, prevention of foodborne illnesses through manufacturing controls is not rocket science, and by taking advantage of these resources, the food industry should be able to enhance the food safety and quality of its products significantly. As retail operators or buyers (e.g., at a large retail store or restaurant chain), we can ask for documentation of compliance with the new FSMA requirements, such as the prevention of the hazards in products produced for our brand using preventive controls. This is an important opportunity for retail food businesses to ensure food safety for customers and not just to meet minimum regulatory requirements.

1.5 Retail Food Businesses Need to Know and Leverage the Government's Role in the Prevention of Foodborne Injury, Illness, and Disease

Most of us eat foods without normally thinking about the possible risk until it may be too late, and this is often similar to how we take prescription medicine purchased from a pharmacy without a second thought to its safety; because of the regulatory oversight and enforcement provided by the FDA. Foods can neither be manufactured nor regulated to the same level of prescription drugs, but they can be made safer. Retail food businesses can play an important part in preventing foodborne illness and injury by knowing what their suppliers

need to do and ensuring that they are doing those things. This requires the retail food industry to have basic knowledge of the latest government regulations, especially preventive controls, and how it can manage hazards in manufactured foods. It also requires retail food businesses to know how to gather information about hazards and the best methods to prevent them.

In addition, the government needs to put more resources in the timely release of important information about food hazards to continue to help the industry focus resources toward preventive controls. For example, the following resources are needed:

- FDA needs to continue to study, publish, and update the food industry on HRFs so that industry can develop preventive controls appropriate to these foods.
- We do not know how many consumers actually have allergic reactions to recalled foods. Better surveillance data is needed specific to exposure to undeclared allergens in foods.
- Foodborne outbreak tools such as CDC's FOOD Tool ([Centers for Disease Control and Prevention, 2016b](#)) do not specify how many children (a more vulnerable population, and thus at higher risk) versus adults are impacted by foodborne illnesses, injuries, and deaths annually and do not identify which foods are more likely associated with illnesses in this and other vulnerable populations.
- We do not know how many foodborne illnesses occur from packaged foods versus ingredients purchased and used to make meals at home or in restaurants.

1.6 How to Use This Book for Supply Chain Food Safety Management

This book is written from the perspective of a retail operator/buyer of manufactured ingredients and foods for human food consumption. The retail food business is the final “gate” for the safety of a food product before it is purchased and consumed. This perspective is relevant to both the buyer and food manufacturer as it relates to the rigor necessary to find and prevent hazards during food manufacturing. We will discuss in detail known hazards and how they may adulterate a food during processing. More importantly, we will explain how to look for hazards in a food facility and how to prevent them. To get started, consider the following:

1. Have you considered the hazards (and their likelihood) of the ingredients and foods you source, specify, and approve for your retail food service and sales establishments? Do you consider possible hazards each time a new ingredient or new product is sourced?
2. Have you considered how to minimize hazards associated with the environment where your ingredients or products are manufactured, perhaps by using suppliers certified by organizations such as the Global Food Safety Institute (GFSI)?
3. Have you considered whether the processing procedures and equipment your suppliers use can increase the probability of a hazard in an ingredient or food?
4. Have you assessed whether preventive controls can be implemented to prevent a hazard in general processes performed at your suppliers' facilities?

5. Have you determined if preventive controls could prevent a hazard in undeclared allergen exposure to the ingredients and foods you source?
6. Have you considered whether sanitation controls could be used as preventive controls by your suppliers?
7. Have you determined if preventive controls could be implemented in the supply chain before the ingredients and products are brought into your suppliers' manufacturing facilities?
8. Do you monitor and document each control measure (process, allergen, sanitation, and supply chain) via a food safety management system reported to you after each product run by your suppliers (perhaps with documentation based on risk)?

It is not the purpose of this book to serve as the comprehensive end-point reference for hazard identification and preventive controls in human food manufacturing, as the FDA is the key source for this information. There are and will continue to be well-known references for these materials (many cited in this book), and the knowledge of hazards in the food industry will continue to evolve. However, this book can serve as a foundation for methods to continue to identify hazards and enable effective preventive controls of ingredients and products you source for your business, i.e., your approved supply. This must be done to ensure food safety and prevent avoidable foodborne illnesses, injuries, and deaths for your consumers. The outcome of this is economic growth for all of the food industry (manufacturers, distributors, and retailers) as consumers will experience higher and more consistent quality food, thereby improving overall trust in manufactured foods for human consumption.

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The Era of the Food Safety Modernization Act and Hazard Analysis and Risk-Based Preventive Controls

2.1 Overview of Food Safety Modernization Act

The United States experienced several devastating and high-profile foodborne disease outbreaks at the beginning of the 21st century, including illnesses attributed to *Salmonella* in peanuts and peanut products (Centers for Disease Control and Prevention, 2007; Johnson, 2015), *Escherichia coli* O157:H7 in ground beef and spinach (Maki, 2006), and *Listeria monocytogenes* in turkey deli meat (Gottlieb et al., 2006). Newly problematic pathogens, or familiar pathogens in unexpected foods such as produce, were widely reported in the media (Moss, 2009; The New York Times, 2007) and the newly influential social media, attracting considerable public and political attention.

During this same time period, outbreak surveillance improved, facilitated in part by new technology, such as whole genome sequencing. More outbreaks were reported to and linked together by the Centers for Disease Control and Prevention (CDC), evidenced by a doubling in the number of outbreak reports received annually by the agency between 1998 and 2008 compared with previous decades (Gould et al., 2013). Foodborne diseases were becoming identified more frequently and were perceived as a significant and growing concern.

Food safety hazards were not limited to microbial pathogens, and concern extended beyond human foods. Another event receiving tremendous publicity in the early 21st century was China's melamine scandal (Everstine et al., 2013). Melamine-tainted infant formula sickened nearly 300,000 and killed at least six children in China, leading to a US ban on imports of Chinese milk products (Ingelfinger, 2008). More directly impacting the United States were the deaths of many dogs and cats due to melamine adulteration of pet food (Brown et al., 2007) and the nationwide recalls of human food products containing melamine (Ingelfinger, 2008).

These events occurred in the same time period of the devastating terrorist attacks of September 11, 2001. In the aftermath of 9/11, national security became a major priority.

The nation's infrastructure and protection systems were scrutinized heavily. Vulnerabilities in the nation's food supply, which increasingly had involved international supply chains, were revealed ([Takhistov and Bryant, 2006](#)).

These events contributed to a realization that the US food safety systems needed major updates, ultimately leading to the development of the Food Safety Modernization Act (FSMA). FSMA (Public Law 111-353) was passed by the US Congress and signed into law by President Obama on January 4, 2011. The new law received bipartisan support and was also largely supported by industry ([Higgins, 2012](#)).

FSMA brought about the most extensive changes ever made to the Federal Food, Drug, and Cosmetic Act of 1936 (see also [Chapter 10](#) for detailed information about the regulatory rulemaking process). At its core, FSMA shifts the emphasis for food safety and security from a reactive to a preventative approach, requiring preventive controls for identified hazards that present a risk to humans and animals. It goes so far as to change the definition of a farm and will also expand the definition of "retail food establishment" to include more direct-to-consumer food businesses such as farm stands, farmers markets, etc. FSMA revised current Good Manufacturing Practice (cGMP) for food products and gives FDA new enforcement powers, including the authority to issue a mandatory recall of food products. Transport of food is now under FDA's authority. FDA will continue to rely upon state and local organizations to help manage food safety. Finally, FSMA acknowledges the increasingly significant role that imported foods play in the US food chain. FSMA puts more emphasis on prevention of hazards before importing a food into the United States rather than relying on testing a small fraction of imports for hazards when the food reaches the border. Imported foods must now meet the same high standards for food produced and manufactured within the United States. FSMA's impact will be felt worldwide: Not only will it require foreign food suppliers to meet US standards, but it is also prompting other countries to assess their own food safety standards. For example, Canada's 2012 Safe Food for Canadians Act ([Gould, 2012](#)) is intended to help align that country's food safety system with the FSMA-related changes occurring in the United States.

The key changes that FSMA is bringing are specified in the seven foundational rules that FDA has published to implement FSMA (shown as the output of FSMA in [Fig. 2.1](#)).

Importantly, the FDA will also now require that facilities producing food for humans or animals develop safety plans that both identify and minimize potential hazards. The human food component of these requirements, the Preventive Controls for Human Food (PCHF) regulations, is anticipated to be the most challenging and labor-intensive component of FSMA for food companies to address. Food establishments that are not required to follow PCHF, such as restaurants and institutions that sell food directly to customers, still need a

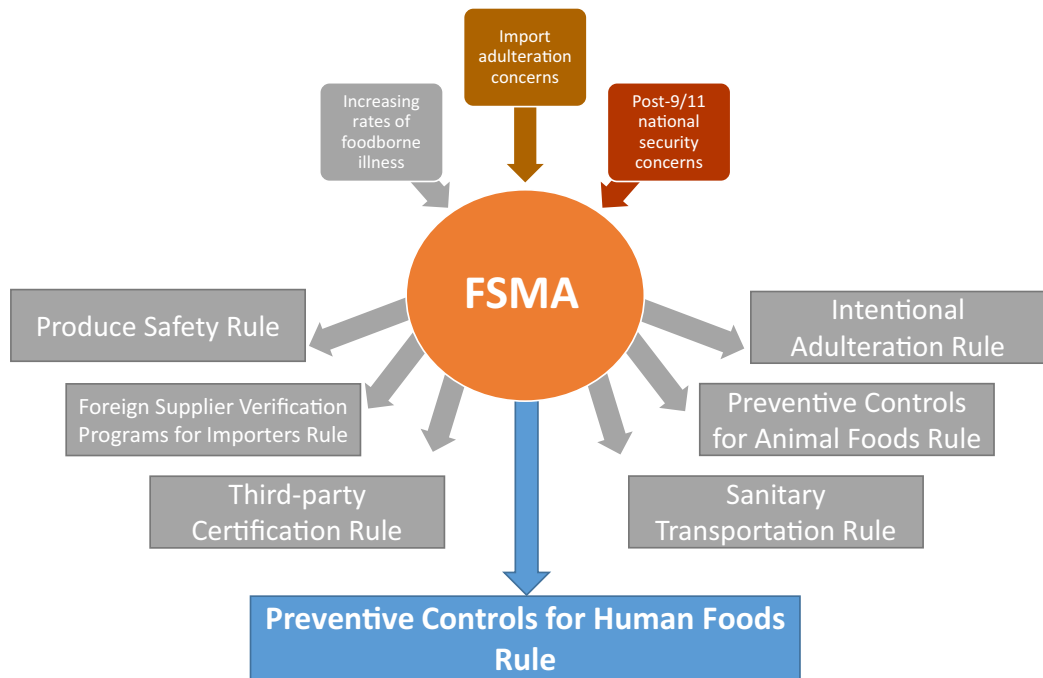


Figure 2.1

Seven foundational rules emerging from Food Safety Modernization Act.

working knowledge of how FSMA affects the food they purchase for their establishments. A primary goal of this chapter is to frame FSMA's PCHF regulations in ways that will help the retail food industry understand what will be changing and how these changes may affect their own organizations.

2.2 Preventive Controls Rule for Human Food

Preventive controls are defined in 21 CFR Part 117.3 as “risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of analysis.” Essentially, nearly all food manufacturers now will be required to follow hazard analysis and critical control point (HACCP)–like principles. A discussion of HACCP and its similarities to the new preventive control requirements is found in [Section 2.3](#).

FSMA AND HUMAN PREVENTIVE CONTROLS: BY THE NUMBERS

\$381 million: Estimated total annual cost for food industry to comply with human preventive controls

157,000: Number of illnesses that would need to be prevented by the human preventive controls to break even in terms of domestic costs

46,685: FDA-estimated number of facilities subject to human preventive controls that will need to create a Food Safety Plan

110 hours: Average number of hours the FDA estimates it will take to create a Food Safety Plan

>50: Number of regulations, guidelines and studies for which FDA is responsible for under FSMA

Sources: Johnson, R., 2015. Implementation of the FDA Food Safety Modernization Act (FSMA, P.L. 111-353). U.S. Food and Drug Administration, 2015c. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods; Final Rule. 80 Fed. Reg. 55908 (September 17, 2015).

In addition to being the most comprehensive change for food companies to address, the new PCHF is the part of FSMA that arguably will have the most labor-intensive impact on the food industry. Even after a Food Safety Plan for a food product is developed, it will require continual monitoring (with associated documentation). The Food Safety Plan will need to be updated when any food process or product ingredient is changed, new risks are realized, and as new products are added to a company's product line. For example, the continual request by retail buyers of their suppliers to source new ingredients and products to grow sales in their business will require suppliers to consider updates to their Food Safety Plans. The impact of PCHF's changes was quickly recognized: as shown in [Table 2.1](#), the number of public comments received on the proposed PCHF regulation is by far greater than for any other FSMA regulation. Unusually, foreign governments and businesses both weighed in on the proposed regulations, highlighting their far-reaching scope and impact ([U.S. Food and Drug Administration, 2015c](#)). The final publication of the Final Rule in the Federal Register, including the comments and FDA responses, encompasses a massive 260 pages.

The rulemaking process for the PCHF regulations took more than 4 years to complete. Implementation (publishing of the final regulations) in fact took longer than specified by law, at least partly because of the extensive and appropriate input FDA sought and received on the proposed regulations. FDA held approximately 600 engagements (public meetings, webinars, presentations, etc.) to communicate with stakeholders about FSMA during the rulemaking process ([U.S. Food and Drug Administration, 2015c](#)).

The Center for Food Safety filed suit against the FDA because of delays in implementing the key FSMA regulations, and the FDA finished the Final Rules under court-order deadlines (which also were extended) ([Johnson, 2015](#)).

Fig. 2.2 outlines the key steps, dates, and notices leading to the Final Rule for Human Preventive Controls on September 17, 2015.

The Final Rule is entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods." Putting the Final Rule into the Code

Table 2.1: Major Food Safety Modernization Act (FSMA) regulations (foundational rules).

FSMA Regulation	Final Rule	Comments Received Through May 6, 2016
Preventive Controls for Human Food	Final Rule published September 17, 2015	71,386
Preventive Controls for Food for Animals	Final Rule published September 17, 2015	2,269
Standards for Produce Safety Final Rule	Final Rule published November 27, 2015	39,856
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals Final Rule	Final Rule published November 27, 2015	450
Accredited Third-Party Certification Final Rule	Final Rule published November 27, 2015	212
Sanitary Transportation of Human and Animal Food Final Rule	Final Rule published April 6, 2016	219
Mitigation Strategies to Protect Food Against Intentional Adulteration Final Rule	Final Rule published May 27, 2016	228

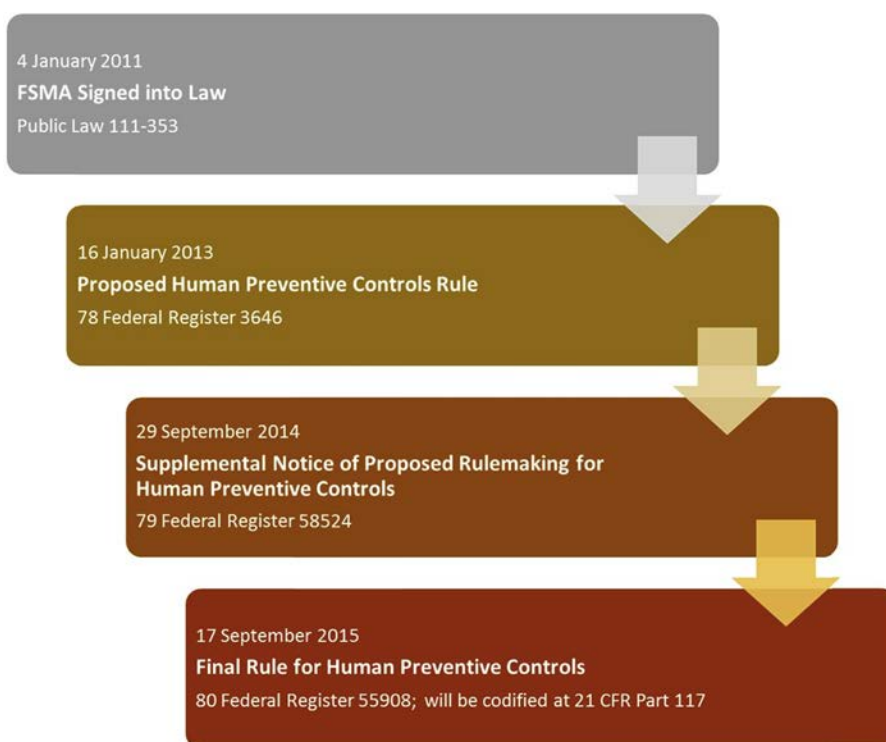


Figure 2.2

Rulemaking process for human preventive controls regulations.

Table 2.2: Components of the final regulation on current good manufacturing practice, hazard analysis, and risk-based preventive controls for human foods (21 CFR Part 117).

Subpart	Title
A	General Provisions
B	Current Good Manufacturing Practice (cGMP)
C	Hazard Analysis and Risk-Based Preventive Controls for Human Foods (PCHF)
D	Modified Requirements
E	Withdrawal of an Exemption Applicable to a Qualified Facility
F	Requirements Applying to Records that Must Be Established and Maintained
G	Supply-Chain Program

From U.S. Food and Drug Administration, 2015c. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods; Final Rule. 80 Fed. Reg. 55908 (September 17, 2015).

of Federal Regulations (CFR) required modification to 12 different parts of 21 CFR, including the creation of a new Part 117. The bulk of the new hazard analysis and preventive controls requirements are located in 21 CFR Part 117, Subpart C. The old cGMPs for food were moved from Part 110 (which has now been removed) to a revised cGMP section in 21 CFR Part 117 Subpart B. Additionally, the Final Rule also made modifications to 21 CFR Part 1, which will change the definition of “farm.” This modification has implications for which food establishments are exempt from the preventive controls requirements; see [Section 2.6](#).

Five subparts comprise new 21 CFR Part 117, as shown in [Table 2.2](#).

Subpart A includes a large collection of useful definitions as well as detailed information about the types of facilities to which the Final Rule applies. The revised cGMPs are found in Subpart B, while the “meat” of the rule, the hazard analysis and preventive control requirements for human foods, is found in Subpart C. Subpart D describes the modified requirements for certain categories of food facilities, especially “qualified” facilities that are subject to fewer requirements, while Subpart E details circumstances under which qualified facilities may lose “qualified” status. Subpart F describes requirements for records and documentation that must be maintained. Finally, Subpart G discusses the supply-chain program that is required when a supply-chain control is used to prevent a raw material or ingredient hazard.

The Final Rule also indicates that it may be formally abbreviated as the “Human Preventive Controls Rule,” which again illustrates how important Subpart C is within the regulation. In practice, the regulation as codified in 21 CFR Part 117 has become widely known as “preventive controls for human food” and abbreviated as PCHF. Within this book, the phrase “preventive controls for human food” and the abbreviation PCHF should be understood to

encompass both the hazard analysis and the risk-based preventive controls as well as the related provisions of 21 CFR Part 117.

The PCHF regulations intentionally are written with much flexibility. There are few situations where exact ways of complying with the regulations are specified. The goal was to provide manufacturers with the ability to develop Food Safety Plans that would be most suitable for their products and their company's previous experience and procedures. The regulations do not detail specific hazards that need to always be addressed, nor do they specify exactly how a company should address a particular hazard.

The focus of this book will be on PCHF (21 CFR Part 117). Within PCHF are requirements for the following:

- A written Food Safety Plan
- Hazard analysis
- Preventive controls
- Monitoring
- Corrective actions and corrections
- Verification
- Supply-chain program
- Recall plan
- Associated records

As many readers will be aware (and will be discussed in the next section), hazard analysis and preventive controls are not a new approach to food safety. Hazard analysis and preventive controls are the foundations of HACCP systems.

2.3 Hazard Analysis and Critical Control Point is Foundational to Preventive Controls for Human Food

As already discussed in [Section 1.1](#), the Final Rule for Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Foods and the regulation found in 21 CFR Part 117 includes revisions to the cGMP for foods. An argument could be made that the hazard analysis and preventive controls rule is in itself a major update to the cGMP for food, as it fundamentally changes manufacturing practices to improve the safety of food.

The Summary of the Final Rule states, “The rule is intended to build a food safety system for the future that makes modern, science- and risk-based preventive controls the norm across all sectors of the food system” ([U.S. Food and Drug Administration, 2015c](#)). This statement acknowledges that risk-based preventive controls are already in use for certain types of foods because of past realizations that more controls were needed for those types of foods. HACCP is the main risk-based preventive control system that is and has been used to manage food safety.

Key to HACCP is that rather than a reactive assessment of risks, HACCP uses a scientific and systematic approach to prevent them. It requires the producer to conduct a careful, upfront analysis of potential hazards inherent to the product and how it is produced and to identify steps and control points that can mitigate those risks. Monitoring and managerial control practices must be implemented to ensure that risk mitigation steps are performed correctly and that hazards are effectively controlled at critical control points.

Before comparing HACCP with PCHF, a brief history of HACCP may be useful. The initial use of HACCP for food safety is linked to the National Aeronautics and Space Administration (NASA) and the need to ensure the safety of food aboard manned space flights. At that time, finished product testing was used as a primary way to ascertain food safety. However, the extensive testing for pathogens in food destined for astronauts' meals left little food remaining for the astronauts. In addition, finished product testing cannot absolutely prove the absence of hazard in the remaining product. A preventive approach that did not rely on finished product testing, such as that used in engineering projects that were NASA's specialty, was needed. In collaboration with scientists at Pillsbury Company and the US Army, NASA adopted the use of CCPs and failure modes and effects analysis (FMEA) to food safety (Sperber and Stier, 2009).

Pillsbury began using the CCP/FMEA approach in its own food production. FDA took notice and in the early 1970s asked Pillsbury to assist them as they developed new regulations to prevent botulism outbreaks arising from underprocessed, low-acid canned foods. The term HACCP was first used at this time (Sperber and Stier, 2009).

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF, which provides scientific advice and recommendations to the US Secretary of Agriculture and the US Secretary of Health and Human Services) together with the international Codex Committee for Food Hygiene developed HACCP definitions and guidelines, which were harmonized in 1997 (Sperber and Stier, 2009; National Advisory Committee On Microbiological Criteria for Foods, 1997). These efforts resulted in the current seven principles of HACCP that are still used today (Table 2.3).

HACCP principles can be applied to any food production process, including growth and harvest, processing, manufacturing, and in various environments, including manufacturing facilities or retail food establishments (National Advisory Committee On Microbiological Criteria for Foods, 1997). The seven HACCP principles are recognized worldwide by government and industry as effective tools to minimize foodborne disease hazards (Ropkins and Beck, 2000).

In the United States, a HACCP system is required when producing a number of different types of food products (Table 2.4). In most cases, these systems became required in response to food safety concerns arising in those specific foods. In addition to the required HACCP programs, voluntary HACCP programs for Grade A dairy products and retail and food service establishments have

Table 2.3: Seven principles of hazard analysis and critical control point (HACCP).

HACCP Principles
<ul style="list-style-type: none"> • Conduct a hazard analysis • Determine the critical control points (CCPs) • Establish critical limits • Establish a system to monitor control of the CCPs • Establish correction actions to be taken when monitoring indicates a CCP is not under control • Establish procedures for verification to confirm that the HACCP system is working effectively • Establish documentation concerning all procedures and records appropriate to these principles and their application

From Sperber, W.H., Stier, R.F., 2009. Happy 50th birthday to HACCP: retrospective and prospective. *Food Safety Magazine* 15 (42), 44–46 and National Advisory Committee on Microbiological Criteria for Foods, 1997. HACCP Principles and Application Guidelines (Online). Available from: <http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm#execsum>.

Table 2.4: US food products that require a hazard analysis and critical control point (HACCP) (or similar) system for production.

Product	HACCP (or Similar) Regulation	Date of Final Rule Publication	Lead Regulatory Agency
Thermally processed low-acid canned foods ^a	21 CFR Part 113	1979	FDA
Shelf-stable acidified foods ^a	21 CFR Parts 108.25 and 114	1979	FDA
Seafood	21 CFR Part 123	1995	FDA
Meat and poultry	9 CFR Part 417	1996	USDA FSIS
Juice	21 CFR Part 120	2001	FDA

^aRegulations for these products are considered to be “HACCP-like” (in other words, specific hazards and required preventive controls are specified in their regulations).

been promoted by FDA (U.S. Food and Drug Administration, 2015d), and many companies voluntarily adopt HACCP programs, especially for higher risk foods such as infant formula.

HACCP programs can be initially labor-intensive and costly for an organization to implement (Herath and Henson, 2010), but they are also effective ways to strengthen food safety (and in some cases eventually can enable cost savings through reduced failure costs). Several studies have assessed the effectiveness of HACCP programs, as shown in the examples in Table 2.5.

The acceptance and success of HACCP in improving food safety in other areas likely influenced the FDA to adopt a similar approach as part of its overhaul of the food safety regulations, which had not seen major updates in 70 years.

Table 2.5: Studies of hazard analysis and critical control point (HACCP) effectiveness.

Type of Establishments	Results	References
Japanese milk processing plants	Microbial food safety was better at companies with HACCP	Sampers et al. (2012)
Latin America fish processing plants	HACCP improved quality and reduced failure costs	Lupin et al. (2010)
Mexican meat producers	HACCP implementation reduced microbial counts	Maldonado et al. (2005)
Australian meat producers	HACCP implementation reduced out-of-spec product and customer complaints	Khatri and Collins (2007)
US meat industry	Incidence of infections caused by <i>Salmonella</i> , <i>Listeria</i> , <i>Campylobacter</i> , and <i>Yersinia</i> declined during the first 5 years of HACCP implementation	Consumer Federation of America (2015)
US broiler industry	Rates of hospitalization of elderly patients with <i>Salmonella</i> infections declined in some (but not all) regions of the United States following HACCP implementation	Chui et al. (2009)
US juice industry	Juice-related outbreaks declined following HACCP implementation	Vojdani et al. (2008)

The requirements for the new PCHF share many similarities with HACCP principles, as can be seen in [Fig. 2.3](#).

As shown by the solid lines in the above figure, many of the key principles of HACCP can be found in components of the PCHF requirements. Dotted lines indicate areas where some differences exist. Key differences between HACCP and PCHF include the following:

- PCHF has a slightly different set of risks that must be covered; for example, it includes intentional adulteration for financial incentive and radiological hazards (as a chemical hazard), which are not required to be evaluated in HACCP programs ([Food Safety Preventive Controls Alliance, 2016](#)).
- PCHF requires additional types of “preventive controls” for hazards that occur in a food facility beyond what is required by HACCP:
 - Process Preventive Controls (applied at CCPs, as in HACCP)
 - Allergen Preventive Controls
 - Sanitation Preventive Controls
 - Supply-Chain Preventive Controls
- Since preventive controls under PCHF include more than just process-related preventive controls, the idea of a “critical limit” does not always apply; instead, “parameters and values,” which may not be always expressed in numerical units, are required.

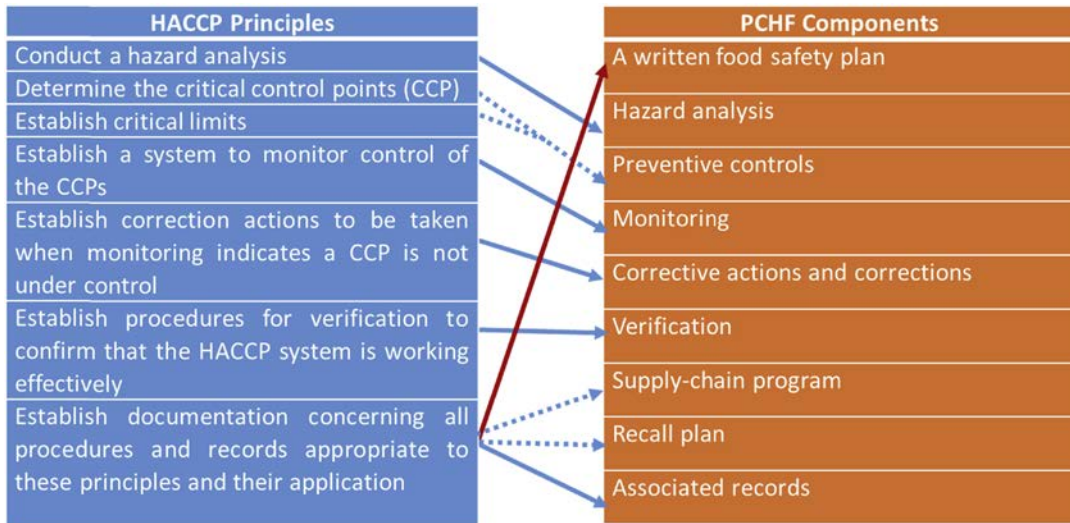


Figure 2.3

Comparison of main requirements of hazard analysis and critical control point (HACCP) and preventive controls for human food (PCHF).

Similarly, monitoring, verification, and record-keeping activities will be different for the new types of controls considered under PCHF.

- In HACCP, if preventive controls are not properly implemented, a corrective action is required. Under PCHF, there are situations where only a correction (not a corrective action) is needed if the problem is an isolated event that does not directly impact product safety ([Food Safety Preventive Controls Alliance, 2016](#)). Corrective actions and corrections (with examples) will be discussed in more detail in [Chapter 7](#).
- PCHF Food Safety Plans need to include a supply-chain program that includes documentation of preventive controls made in the supply chain before ingredients and products are distributed to a food facility; this is not specified in HACCP requirements, but could be considered part of HACCP documentation and records (control of supply chain may be considered a prerequisite program that would need to be documented in HACCP).
- PCHF Food Safety Plans need to include a recall plan. HACCP does not specifically require a recall plan, although it might be mentioned as part of some corrective action plans under HACCP.

2.4 What is the Food Safety Plan?

The written Food Safety Plan required under the human preventive controls rule (21 CFR Part 117.26) is similar to a HACCP plan. In fact, the Final Rule (Response 382 on page 56024) states that existing HACCP plans will need only minor supplementation to fully comply with human preventive controls requirements ([U.S. Food and Drug Administration, 2015c](#)).

An example of a Food Safety Plan can be found in the public version of the Food Safety Preventive Controls Alliance's (FSPCA) Preventive Controls for Human Food Participant Manual, which is available for free online ([Food Safety Preventive Controls Alliance, 2016](#)). This document also contains many sample forms and templates that can be used or modified within a Food Safety Plan by a supplier to a retail buyer.

As of August 2016, FDA has begun issuing guidance documents that include information regarding Food Safety Plan content and organization ([U.S. Food and Drug Administration, 2016](#)). However, the regulations allow for much flexibility regarding the exact format of Food Safety Plans.

Many examples of HACCP plans are available online and may be of some use for suppliers and as specifications of retail buyers ingredients/products when developing Food Safety Plans ([USDA Food Safety and Inspection Service, 2015](#); [Penn State College of Agricultural Sciences Department of Food Sciences, 2016](#); [University of Wisconsin–Madison Center for Meat Process Validation, 2009](#)). In addition, FDA's guidance documents on Seafood (<http://www.fda.gov/food/guidanceregulation/ucm2006764.htm>) and Juice HACCP (<http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006803.htm>) contain much information that may be of use in putting together a Food Safety Plan.

As is the case for HACCP plans, food types or production methods can be grouped together under a single Food Safety Plan if hazards, CCPs, critical limits, required monitoring procedures, etc. are similar. This means that a new Food Safety Plan is likely not necessary for every product that a facility produces. However, any features of a plan unique to a specific ingredient, product, or production method (e.g., supply-chain ingredient preventive controls that differ from two different suppliers or ingredient changes that add new hazards to an existing product) will need to be specified clearly within the plan ([U.S. Food and Drug Administration, 2013](#)). In addition, since a Food Safety Plan must be reanalyzed every 3 years or whenever a change occurs, there may be some value in maintaining certain plans either combined or separate for your particular organization.

A brief description of each component of the Food Safety Plan follows.

2.4.1 Written Hazard Analysis (21 CFR Part 117.130)

The hazard analysis must be documented in writing. It must identify and evaluate, based on experience, illness data, and scientific reports, known or suspected hazards for the food type being produced. The types of hazards that should be considered include the following:

- Biological hazards (parasites, pathogens, other microbial hazards)
- Chemical hazards (radiological hazards, pesticides and drug residue, natural toxins, decomposition, unapproved food or color additives, food allergens). Radiological hazards previously have not been considered chemical hazards in other HACCP programs and

could include produce grown in regions known to suffer radiological contamination as an example.

- Physical hazards (stones, glass, bones, metal fragments)

Naturally occurring hazards that either are introduced unintentionally or are intentionally introduced for purposes of economic gain need to be considered. The latter hazards might include, for example, the possibility of melamine contamination since its use could make watered-down milk appear to have the protein content of normal milk. Olive oil diluted with soybean oil could introduce food allergy risks. However, intentional adulteration without a motive of economic gain (for example, possible terrorist motives) would not necessarily need to be included in the hazard analysis nor would intentional adulteration for economic gain that does not introduce risk (for example, honey diluted with high-fructose corn syrup).

The hazard analysis must assess the severity of the illness or injury if the hazard were to occur as well as the probability that the hazard would occur in the absence of preventive controls. It must also consider hazards that might be associated with any part of food production, packaging, distribution, storage, etc., as well as how the food product might be used. If a food product could conceivably be eaten raw instead of cooked (when labeling indicates it should be cooked), new risks might occur; for example, frozen peas, which could harbor *L. monocytogenes*, typically are not considered “ready-to-eat,” but they might be given to children as “healthy” snacks.

Chapters 3 and 4 of this book discuss hazards that might be considered for manufactured foods, while Chapter 5 provides more detail on conducting a hazard analysis.

An example of a hazard analysis (as well as the other components of a Food Safety Plan) is included within the model Food Safety Plan in Appendix 3 of the FSPCA’s Preventive Controls for Human Food Participant Manual ([Food Safety Preventive Controls Alliance, 2016](#)).

2.4.2 Written Preventive Controls (21 CFR Part 117.135)

The written preventive controls must identify and implement preventive controls to provide assurance that any hazards will be minimized or prevented.

Preventive controls should include controls for any CCPs as well as other process controls, food allergen controls, sanitation controls, supply-chain controls, a recall plan, and other controls as necessary.

Chapter 6 of this book provides a detailed discussion of preventive controls.

2.4.3 Written Supply-Chain Program (21 CFR Part 117.405)

A risk-based supply-chain program for raw materials and other ingredients received at a facility is required. The program should include the use of approved suppliers as well as

determine and conduct appropriate supplier verification activities (such as audits, sampling, testing, etc.), and the program must be documented. Supply-chain controls are discussed in [Chapter 6](#).

2.4.4 Written Recall Plan (21 CFR Part 117.139)

A written recall plan must be established that describes the steps to be taken and assigns responsibility for taking those steps to notify direct consignees of the food being recalled, as well as the general public, to conduct checks to verify that the recall is being carried out effectively, and to appropriately dispose of the recalled food. Recall plans are discussed in [Chapter 6](#).

2.4.5 Written Procedures for Monitoring the Implementation of the Preventive Controls (21 CFR Part 117.145)

These procedures must be written and appropriate to the preventive control and its role in the food safety program. Monitoring must be done with adequate frequency to provide assurance that the preventive controls are being done consistently, and the monitoring must be documented. Monitoring provides data that can be used in verification activities (discussed in detail in [Chapter 8](#)) for the manufacturer and data for the retail buyer to ensure preventive controls are effective during each product production.

2.4.6 Written Corrective Action Procedures (21 CFR Part 117.150)

Written corrective actions that are appropriate to the nature of the hazard and the nature of the preventive control must be established and implemented. The regulations do not specifically identify the types of corrective actions that need to be taken for various hazards to give manufacturers flexibility in how they choose to address them. In addition, the regulations do not specify when corrective actions are needed. Specific situations where corrective actions might be appropriate include the presence of a pathogen in a ready-to-eat product detected during product testing, the presence of an environmental pathogen on a food contact surface detected through environmental sampling, or the detection of an allergen in a product that is supposed to be free of that allergen.

All corrective actions taken need to be documented, including the actions taken to identify and correct the problem and prevent it in the future. A safety evaluation of affected food should be conducted and documented, with details sufficient to demonstrate that unsafe food did not enter commerce ([Food Safety Preventive Controls Alliance, 2016](#)). Following a corrective action, the Food Safety Plan should be reviewed and potentially modified to ensure the problem does not occur again.

Corrective actions are discussed further in [Chapter 8](#) of this book.

2.4.7 Written Verification Procedures (21 CFR Part 117.155)

Verification activities (discussed in more detail in [Chapter 8](#)) must include the following:

- Validation that the preventive controls identified are adequate to control the hazard. (While it may seem confusing to consider validation a form of verification, it may make sense if you realize that until a control itself is shown to be effective, you cannot verify that a hazard is being managed no matter what monitoring or other verification activities are being performed.)
- Verification that monitoring is being conducted as required
- Verification that appropriate decisions about corrective actions are being made
- Verification that the preventive controls are being implemented consistently and are effectively minimizing or preventing hazards
- Verification that the Food Safety Plan is reanalyzed at least once every 3 years

2.5 Who is Responsible for the Food Safety Plan?

According to the Final Rule, “The owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written Food Safety Plan. This individual must sign and date the Food Safety Plan upon its completion and whenever it is modified” (21 CFR Part 117.310). The Food Safety Plan must also be reanalyzed in its entirety at least once every 3 years (21 CFR Part 117.170). Applicable portions of the plan must be reanalyzed when changes occur that create new hazards, new hazards are realized, and after unanticipated food safety problems.

The Food Safety Plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals, or PCQIs. The Final Rule and regulations further describe a “preventive controls qualified individual” as someone who has “successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.”

A straightforward way to become a PCQI is to take and receive a certificate of completion from the FSPCA’s PCHF course ([Bedale, 2017](#)). As discussed in the Preface, the FSPCA is a public–private alliance formed to educate industry and others on PCHF and other foundational rules of FSMA. The other way to become a PCQI is to have job experience that provides an individual with knowledge at least equivalent to that provided in the standardized curriculum. No further definition of the “job experience” that would be considered necessary to be a PCQI is given or is expected to be specified by FDA, although experience with HACCP and an understanding of the PCHF requirements may be sufficient.

PCQI does not have to be employed by the company and may be a contractor or consultant to the company. In addition to being responsible for the Food Safety Plan, a PCQI must also be responsible for (i.e., do or oversee) the following (21 CFR Part 117.180):

- Review of records
- Validation of preventive controls (or determinations that validation is not required)
- Written justification for certain activities not done within timeframes specified in the regulations (completing initial validation within 90 days of initial production, reviewing monitoring and corrective action records within 7 days)
- Reanalysis of the Food Safety Plan and related activities

PCQIs are different from qualified individuals. A “qualified individual” also is defined in 21 CFR Part 117.3 as “a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual’s assigned duties.” A qualified individual is, therefore, someone (not necessarily employed by the establishment) qualified to actually perform the activities specified in the Food Safety Plan.

2.6 How Will FDA Implement Preventive Controls Under the Food Safety Modernization Act?

As mentioned earlier, nearly all food manufacturers eventually will need to comply with the hazard analysis and preventive controls requirements of FSMA. However, several exceptions/exemptions exist for many of the suppliers from which retail food businesses source ingredients and products:

- **Qualified facilities** are very small businesses that meet certain requirements outlined in 21 CFR Part 117.3. They are subject to modified requirements described in 21 CFR Part 117.201, which consist primarily of attesting that the facility meets the qualified facility requirements, that potential hazards have been identified, that preventive controls have been implemented and are being monitored to address the hazards, and that the facility is in compliance with all other state and local laws. These attestations must be submitted to the FDA.
- Some facilities already are required to comply with other HACCP or similar regulations, including the **seafood HACCP regulations**, the **juice HACCP regulations**, and the **thermally processed low-acid food regulations**; facilities of acidified foods are NOT exempted. Note that facilities may still need to follow preventive controls to address physical and chemical hazards that may not be addressed by these other regulations.
- **Dietary supplement** facilities, although dietary ingredients used in dietary supplements do appear to require compliance to PCHF and other parts of FSMA ([Sapsin, 2015](#)).
- **Facilities that produce alcoholic beverages, under** certain conditions (21 CFR Part 117.5(i)).

- Facilities that have to comply with the **Produce Safety** standards.
- Food produced on a **farm**, except foods that have undergone certain processing steps as defined in 21 CFR Part 117.5.
- Facilities only engaged in storage of **unexposed packaged foods**.
- **Off-farm facilities** engaged in the packaging and holding of raw agricultural commodities.
- Facilities whose products are regulated by **USDA (meat, poultry, and egg products)**.

The FDA has set staggered compliance dates for the human preventive controls rules, with the earliest compliance date (which covers most food establishments) having occurred on September 19, 2016. Groups that have been granted exceptions to this date, along with their compliance dates, are listed in [Table 2.6](#).

Implementation of the PCHFs will be a huge and expensive task for FDA. In addition to training its own inspectors, FDA expects to leverage state, local, tribal, and other resources to fulfill the agency's responsibilities.

Although it is too early to know exactly how FDA will enforce preventive controls, the agency likely will take a combined educational and regulatory approach during inspections initially as companies and inspectors adapt to the new requirements. However, compliance will be expected at the time the rule goes into effect. FSMA does bring FDA new enforcement powers that could eventually come into use when the preventive control requirements are not met, including mandated inspection frequency based on risk, access to Food Safety Plans and supporting documentation, mandatory recall, expanded administrative detention, and suspension of registration ([U.S. Food and Drug Administration, 2015a](#)).

Table 2.6: Compliance dates for preventive controls for human foods rule.

Compliance Date	Type of Business	References
September 19, 2016	Most food establishments , unless they meet one of the exceptions	U.S. Food and Drug Administration (2015c)
September 18, 2017	Small businesses with fewer than 500 full-time employees business wide (including subsidiaries and affiliates) and other qualified facilities ^a	21 CFR Part 117.3
September 17, 2018	Very small businesses , ^a defined as A business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee)	21 CFR Part 117.3
September 17, 2018	Facilities that comply with the Grade "A" Pasteurized Milk Ordinance	U.S. Food and Drug Administration (2015b)

^aA business must retain records to support its status as a qualified facility starting on January 1, 2016.

2.7 A More Comprehensive Focus on Hazards in Human Food Manufacturing Can Help Improve Retail Food Safety

FDA, like other regulatory organizations in other industries and countries (Lozier, 2016), is moving more toward a risk-based approach to ensure product safety. Risk-based approaches to food safety are not new, and most food companies will have some familiarity already with HACCP. What is new is that all human food–manufacturing facilities must now provide the FDA with evidence (documentation) of the execution and corrective action of significant hazards associated with all human food ingredients and products made within their regulated facility, not just foods being made during an FDA facility inspection. As new hazards continue to be identified (unexpected pathogen/food combinations, terrorism or food fraud–related adulteration, new methods in food manufacturing, etc.), new hazard identification and continuous verification that preventive controls will prevent the hazards must now become a foundation of every food business. Because a retail food business sources many of its food ingredients and products from food manufacturers, knowledge of and requirement for implementing Hazard Analysis and Risk-Based Preventive Controls for each of its ingredients and products will significantly improve its business.

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What Potential Food Ingredient Hazards Occur in Human Food Manufacturing?

3.1 Introduction

A retail food business that sources ingredients, foods, and packaging used for food products that are distributed and used in its retail sales and service establishments must have assurance that each of these items is safe for products meant for human consumption. The FDA Food Code, adopted by most states, requires that a retail food service and sales business obtain and show evidence that the food that is served was obtained from sources that comply with food safety laws ([Food and Drug Administration, 2015a](#)).

Many of the food safety specifications that retail food businesses demand of their suppliers are already required by government regulatory rules (e.g., FDA's Good Manufacturing Practices or USDA Food Safety and Inspection Service rules), industry certification standards (e.g., Safe Quality Food Institute specifications of Global Food Safety Initiative), and the supplier's food manufacturing business requirements (such as hazard analysis and critical control point).

Even with these specifications in place and regular inspections and third party audits, however, gaps in prevention of potential hazards can occur during food processing, including in the validation and verification of the methods used for preventive controls of potential hazards. These gaps continue to cause foodborne disease outbreaks and recalls of foods from retail food service and sales establishments.

A retail food business can address these food safety gaps leveraging the same hazard analysis and risk-based preventive controls process its suppliers are now required to use. This may sound counterintuitive (and redundant) when the food manufacturers already are required to perform a hazard analysis and risk-based preventive controls process for each of the products they manufacture under the Food Safety Modernization Act (FSMA). However, the hazard analysis that a food manufacturer conducts must also assess how the food product will be used (e.g., no further cook step) and who will consume it (children). The best means for you, as a retailer, to ensure the safe manufacture of food products you source is to perform your own hazard analysis and consider preventive controls that could be used for each of your products. The results of this analysis can be used to define food safety specifications for each of your products. In addition, this assessment will also help you track risks associated with

future changes (e.g., an ingredient change) and provide a resource for your internal and third-party supplier audits, especially when product defects are discovered and corrective actions are required.

The process of hazard analysis and risk-based preventive controls starts with defining all of the potential hazards associated with each ingredient that will be used in the final food product. In [Chapter 4](#), we will provide resources to help you define process and facility-related hazards, which are also important to consider when performing your own hazard assessments ([Chapter 5](#)) based on the foods you will sell to your consumers. You can then use this information to help define which specifications you should require of each of your suppliers to identify the preventive controls and related activities you need performed to ensure all ingredients, foods, and packaging delivered to your establishments are safe for your customers.

3.2 Defining a Hazard and Its Significance in Food Manufacturing

Adulterated food associated with food manufacturing is caused by hazards. The FDA's hazard analysis and preventive controls regulations define a "hazard" in 21 CFR Part 117.3 as "any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury." The FDA further defines a "hazard requiring a preventive control" as "a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system" ([Food and Drug Administration, 2015c](#)).

Hazards can adulterate food anywhere in the supply chain, but the most common adulteration occurs or is established and then becomes a hazard (e.g., toxin production in food after bacterial growth) during manufacturing of the food in a food facility.

Most hazards in foods are discovered after they have caused illness or injury. Oftentimes, their association is discovered only after a foodborne disease outbreak investigation led by the Centers for Disease Control and Prevention (CDC). Many of the specific biological, chemical, and physical hazards are well known due to their historic association with foodborne disease illnesses, injuries, and deaths ([Table 3.1](#)).

From the most recent (at the publication time of this book) surveillance data reported by the CDC, only "unknown hazards" come close to biological hazards in causing the most foodborne

Table 3.1: Examples of hazards found during food manufacturing.

Hazard Category	Hazard Subcategory	Examples
Biological	Bacteria	<i>Bacillus cereus</i>
		<i>Campylobacter jejuni</i>
		<i>Clostridium botulinum</i>
		<i>Clostridium perfringens</i>
		Shiga toxin-producing <i>Escherichia coli</i> such as <i>E. coli</i> O157:H7
		<i>Listeria monocytogenes</i>
		<i>Salmonella</i> spp.
		<i>Shigella</i> spp.
		<i>Staphylococcus aureus</i>
Biological	Protozoa and parasites	<i>Cryptosporidium parvum</i>
		<i>Cyclospora cayetanensis</i>
		<i>Giardia lamblia</i> (<i>Giardia intestinalis</i>)
Biological	Viruses	<i>Trichinella spiralis</i>
		Norovirus
		Hepatitis A
		Rotavirus
Chemical	Pesticide residues	Organophosphates
		Carbamates
		Chlorinated hydrocarbons
		Pyrethroids
Chemical	Heavy metals	Lead
		Arsenic
		Cadmium
		Mercury
Chemical	Drug residues (veterinary antibiotics)	Chloramphenicol
		Beta-lactams
Chemical	Industrial chemicals	Ammonia
Chemical	Environmental contaminants	Dioxins
Chemical	Mycotoxins	Aflatoxin
		Patulin
		Ochratoxin
		Fumonisin
		Deoxynivalenol

Continued

Table 3.1: Examples of hazards found during food manufacturing.—cont'd

Hazard Category	Hazard Subcategory	Examples
Chemical	Allergens	Milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans (commonly called “the Big 8”)
Chemical	Unapproved colors and additives	Red #4 Melamine
Chemical	Substances associated with a food intolerance or food disorder	Lactose Yellow #5 Sulfites Carmine and cochineal Gluten
Chemical	Radionuclides	Radium 226 and 228 Uranium 235 and 238 Strontium 90 Cesium 137 Iodine 131
Physical	N/A	Metal Glass Hard plastic

Adapted from Food and Drug Administration, 2016. Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food. Appendix 1. <https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM517402.pdf>.

Table 3.2: Biological adulterations cause the most reported foodborne disease outbreaks.

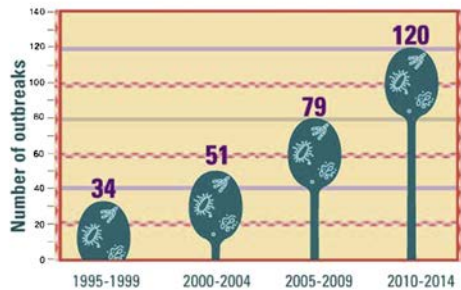
Hazards	Outbreaks
Biological	2545
Chemical	163
Physical	Not measured
Unknown	1204

Adapted from CDC Surveillance of Foodborne Disease Outbreaks in the United States Annual Reports in 2009–2013.

disease outbreaks in the United States (Table 3.2). Thus, biological hazards seem to be the most probable hazards to adulterate food (Fig. 3.1). One could argue, however, that because allergy-related injury or deaths are not routinely monitored via surveillance and reported by the CDC (something that the authors believe should be initiated, especially in light of the large number of product and ingredient recalls that occur annually due to undeclared allergens), the number of chemical (allergens) hazard-associated outbreaks may be larger.

More multistate outbreaks are being found

Why? Better methods to detect and investigate, and wider food distribution.



Multistate outbreaks: less common, but more serious

Why? The deadly germs *Salmonella*, *E. coli* and *Listeria* cause **91%** of multistate outbreaks.

Only 3%
of all US foodborne outbreaks are multistate, but they cause more than their share of outbreak sicknesses, hospitalizations and deaths:



Vital^{CDC}**signs**[™]

www.cdc.gov/vitalsigns/foodsafety-2015



Figure 3.1

Example of bacterial hazards and their impact due to multistate foodborne disease outbreaks. From Centers for Disease Control and Prevention, 2015c. *Safer Food Saves Lives Infographics*. <https://www.cdc.gov/vitalsigns/foodsafety2015/infographic.html#graphic>; CDC National Outbreak Report System, 1995–2014; CDC Vital Signs MMWR, November 2015.

Single-state foodborne disease outbreaks, many of which are due to operational defects in single retail food service and sales establishments, are much more common than those that occur across state lines (Centers for Disease Control and Prevention, 2015a). However, 91% of multistate foodborne disease outbreaks are associated with just three foodborne bacterial pathogen hazards (Fig. 3.1), and the outbreaks they cause are the most lethal, according to the CDC.

Nevertheless, the focus should be on all hazards and how best to prevent them, regardless of the place where the hazard is introduced into the food. Some hazards are best prevented at retail food sales and service establishments (e.g., receiving processed raw poultry at retail and handling and cooking it to eliminate *Campylobacter* bacteria). Other hazards may be best managed via other food safety management principles established for food retail businesses (King, 2013). The best place to start is to define the source of the hazards associated with ingredients and foods by identifying food ingredient–hazard pairs.

Most human food ingredients in their raw (not processed) state have some level of biological, chemical, or physical hazard associated with them due to the nature of their development (e.g.,

exposed to the unprotected environment). Many hazards associated with specific foods are well known due to the numbers of foodborne disease outbreaks they cause and the severity of disease that results. Some hazards are common across many different types of ingredients, while several ingredients are associated with multiple types of hazards that must be prevented. For example, *Salmonella* spp. can be found as a contaminant on raw nuts, produce, and poultry (Table 3.3), whereas raw nuts, produce, and poultry can also each have chemical (pesticides, heavy metals, dioxins, Table 3.4) and physical hazards (bones, farm field debris, shell fragments; Table 3.5) associated with them. Of course, not every **possible** hazard that can be associated with an ingredient is **probable**, and thus each ingredient–hazard pair must also be evaluated for the probability of its presence in the ingredient via a hazard analysis (see Chapter 5).

3.3 Food Ingredient–Hazard Pairs

To more comprehensively determine which hazards are likely associated with the final products a retail food service or sales business will sell, it is helpful to consider each ingredient type and its known hazards. Using this information, you can identify those food ingredient–hazard pairs for which preventive controls should be considered. For example, suppose a raw double chocolate cookie dough will be distributed to all your retail establishments where it is then cooked and served. Some retail establishments may also serve the raw cookie dough to customers or use it in desserts in its raw state. The supplier uses eggs, white flour, cocoa powder, yeast extract, salt,

Table 3.3: Food ingredient–hazard pairs (biological hazards).

Biological Category	Hazard	Food Ingredient Associated With Hazard
Bacteria	<i>Salmonella</i> spp.	Poultry, produce, nuts
	<i>Escherichia coli</i> O157:H7 and other Shiga toxin–producing <i>E. coli</i>	Ruminant animals, dropped fruit, sprouts
	<i>Campylobacter</i> spp.	Poultry and raw milk
	<i>Bacillus cereus</i>	Rice and other grains
	<i>Clostridium botulinum</i>	Root crops (contaminated via spores found in soil)
	<i>Clostridium perfringens</i>	Spices, produce (contaminated via spores found in soil)
	<i>Listeria monocytogenes</i>	Raw agricultural commodities such as apples, other contaminated products used as ingredients
Parasites	<i>Cryptosporidium parvum</i>	Water
	<i>Cyclospora cayetanensis</i>	Berries
	<i>Toxoplasma gondii</i>	Meat
Viruses	Norovirus	Produce, shellfish
	Hepatitis A virus	Produce, fruits

Table 3.4: Food ingredient–hazard pairs (chemical hazards).

Hazard	Food Ingredient Associated With Hazard
Pesticide residues	Raw agricultural commodities
Drug residues	Milk
Heavy metals	Produce, raw agricultural commodities
Environmental contaminants (e.g., dioxins)	Animal products
Mycotoxins	Grains, raw agricultural commodities
Histamine	Aged cheeses, fish
Radiological hazards	Foods produced from areas near where a nuclear accident occurred
Unapproved food or color additives	Processed and artificially colored foods
Unapproved disinfectants and sanitizers	Produce, ready-to-eat foods
Food allergens and substances associated with a food intolerance or disorder (e.g., sulfites, gluten)	Various foods

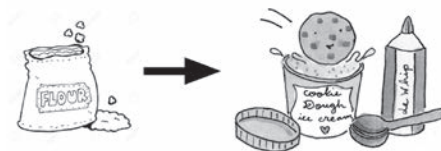
Table 3.5: Food ingredient–hazard pairs (physical hazards).

Hazard	Food Ingredient Associated With Hazard
Farm field debris such as stones	Raw agricultural commodities
Metal fragments	Precut, ground, injected, or sliced items
Pits or pit fragments, shells	Fruit and nuts
Bones	Meat, poultry, fish
Packaging material	Packaged foods

butter, sugar, and almond extract to make the cookie dough. Based only on potential ingredient-based hazards, you identify the following food ingredient–hazard pairs:

- Liquid eggs—*Salmonella*
- White flour—**Shiga toxin–producing *Escherichia coli* (STEC)/*Salmonella*, mycotoxins**
- Cocoa powder—*Salmonella*
- Yeast extract—**Soy (allergen)**
- Iodized salt—**Arsenic, copper, lead, cadmium, mercury, tin, and sulfate**
- Butter—*Listeria monocytogenes*, milk (allergen)
- Sugar—**Mycotoxins**
- Almond extract—**Tree nuts (allergen)**

What food *ingredients* will be used to produce the product in the food manufacturing facility



What are the known *hazards* associated with these *ingredients*

(list each Food Ingredient-Hazard Pair)



Are any of these Food Ingredient-Hazard Pairs already under preventive controls before they are received by each facility pre-production

(list and document each from each supplier)



List each Food Ingredient-Hazard Pair that needs a Preventive Control specification

Figure 3.2

Preventive controls for food ingredient-hazard pairs.

First, you consider the potential food ingredient-hazards for each ingredient (Fig. 3.2). You note that the salt and almond extract suppliers have already eliminated all possible hazards associated with those ingredients. (Salt is a mineral and could have chemical hazards that exceed safety limits for arsenic, copper, lead, cadmium, mercury, tin, and sulfate.) You know that the sugar is produced and held in large silos where mycotoxins could be produced by fungal contamination. In the past, the key potential hazard associated with white flour would be *Salmonella*, but recent outbreaks of STEC (Centers for Disease Control and Prevention, 2016) associated with flour add a new potential hazard to this ingredient.

Many of these hazards can be best prevented by identifying suppliers who already have preventive controls in place. For example, sugar and flour can be tested by the supplier for mycotoxins after storage and prior to shipment, and the cocoa powder can be tested for *Salmonella* before shipping. Yeast extract could be produced in a facility without using soy (an allergen) to grow the yeast, or soy protein testing could be performed on each batch/lot if yeast is grown in a non-soy substrate but the yeast extract is made in a

facility that also uses soy before the ingredient is shipped. Liquid eggs and butter can be pasteurized. Each of these supply-chain preventive controls can be verified by reviewing testing data, with evidence of the preventive controls provided in a batch/lot-based Certificate of Analysis (CoA).

You also note that your supplier randomly verifies these ingredients via its own third-party testing, which increases your confidence that the product ingredient hazards are under preventive controls. By relying on your suppliers to have appropriate preventive controls in place for the ingredients you purchase, you can focus your efforts on the preventive controls necessary to prevent hazards likely to be associated with the manufacture of your final product or those not controlled by your supplier (such as STEC *in flour*). The butter–*Listeria* and liquid eggs–*Salmonella* ingredient–hazard pairs would be managed by a supplier preventive control.

Note that many domestic suppliers that import ingredients (e.g., spices) for products that will be produced for you will also be required to ensure hazard analysis and risk-based preventive controls are in place for these ingredients according to the Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals ([Food and Drug Administration, 2015d](#); see also [Chapter 2](#)).

Excellent, comprehensive information from food safety experts from around the globe on the major hazards associated with food ingredients can be found in the book, *Food Safety Management: A Practical Guide for the Food Industry*, edited by [Motarjemi and Lelieveld \(2014\)](#) (Elsevier). Some of these hazards are listed here to aid in the development of your food ingredient–hazard pairs list.

Note that not all product ingredient–hazard pairs are known, and many unfortunately will become known only due to new outbreaks of foodborne diseases (e.g., white flour and *E. coli*). While this chapter is not intended to be comprehensive to all known ingredient–hazard pairs, we encourage you to investigate what is known about potential hazards associated with each ingredient you use by utilizing this book and other important resources described here and elsewhere (see below).

3.3.1 Animal Feed and Environment (Hazards Introduced Internal to Meat Tissues)

All animal proteins, whether raw or ready-to-eat (RTE), have some sort of potential hazard associated with them. Most of these hazards are microbial and include those listed in [Table 3.3](#) that contaminate the outside of the meat anywhere along the growing, distribution, and processing of animals for food. However, there are other biological, chemical, and physical hazards that can be introduced directly into the meat itself via animal feed and from exposure to the environments where the animals are raised for food. Animal feed production involves extremely complex supply chains, including multiple ingredients from agricultural commodities (fish, corn, straw, grass, silages, bone

meal, animal fats, bread meals, minerals, etc.), chemical companies (antibiotics, pesticides, etc.), by-products of the biofuel processing industry (beet pulp, bran, soybean meal, etc.), and food product waste (e.g., produce or meats past their expiration date for human consumption), which are prepared by compound feed manufacturers, farmers, and premix businesses. Many of the known hazards have been identified previously ([Table 3.6](#)). These and other feed hazards should be considered for all of your meat suppliers to ensure known hazards are not introduced into meat ingredients ([AFIA, 2017](#)).

The FDA regulates feed for millions of chickens, turkeys, cows, pigs, sheep, and fish. The Federal Food, Drug, and Cosmetic Act requires animal feed, just like human foods, to

- be pure and wholesome;
- be produced under sanitary conditions;
- contain no harmful substances; and
- be truthfully labeled.

FSMA's Final Rule on preventive controls for animal food also will play a role in food animal feed safety as it relates to animal health (see [Food and Drug Administration, 2015c](#)). The FDA also approves the additives or drugs used in feed products. Animal feed manufacturers are responsible for ensuring that

- feed is truthfully labeled;
- feed does not contain unsafe additives or contaminants; and
- if the feed contains drugs, the drugs are approved by FDA for use in animal feeds.

Table 3.6: Hazards that can contaminate meat tissues due to feed.

Animal Product	Hazard in Meat Tissues
Pork and beef	<ul style="list-style-type: none"> • Endoparasites (e.g., <i>Echinococcus</i>, <i>Sarcocystis</i> spp., <i>Toxoplasma gondii</i>, <i>Trichenella</i> spp., <i>Cyptosporidium parvum</i>, <i>Giardia duodenalis</i>) • Prions (bovine spongiform encephalopathy) • Radionuclides • Heavy metals (arsenic, cadmium, lead, mercury, nickel) • Dioxins, polychlorinated biphenyls • Organochlorine pesticides • Veterinary drugs • Plant toxins (tremetone, alkaloids) • Mycotoxins (from feeding moldy feeds to animals) • Hormones • Antibiotics

Adapted from Motarjemi, Y., Lelieveld, H., 2014. Food Safety Management: A Practical Guide for the Food Industry, Elsevier.

Table 3.7: Biological hazards associated with meat and meat products.

Biological Hazard	Associated Meat or Meat Product
<i>Bacillus cereus</i> (via toxin)	Raw beef, pork, lamb
<i>Campylobacter</i> spp.	Raw beef, pork, lamb
<i>Clostridium perfringens</i> (via toxin)	Raw beef, pork, lamb
<i>Clostridium botulinum</i> (via toxin)	Raw beef, pork, lamb
<i>Escherichia coli</i> (Shiga toxin-producing <i>E. coli</i> or other pathogenic strains)	Beef, pork, lamb
<i>Listeria monocytogenes</i>	Ready-to-eat (RTE) ^a Beef, pork, lamb
<i>Salmonella enterica</i>	Beef, pork, lamb
<i>Staphylococcus aureus</i> (via toxin)	RTE ^a Beef, pork, lamb
<i>Yersinia enterocolitica</i>	Pork
<i>Lactobacillus</i> spp. (via spoilage and biogenic amine production)	Beef, pork, lamb

^aRTE products acquire hazards through the processing environment after meats have been cooked.

Adapted from Motarjemi, Y., Lelieveld, H., 2014. *Food Safety Management: A Practical Guide for the Food Industry*, Elsevier.

Federal and state regulatory agencies work cooperatively to provide the rules, guidance, and oversight to assist the animals for food industry in producing and distributing safe animal feed and feed ingredients. It will be important to ask your food animal suppliers to validate the safety of their animal feed according to these standards to ensure all hazards, such as those in Table 3.6, are considered.

3.3.2 Meat and Meat Products (Hazards Introduced External to Meat Tissues)

As mentioned above, some potential biological and chemical hazards associated with meats are introduced within internal meat tissue from animal feeds or the environment where the animals are raised. There are also significant potential hazards associated with external contamination of raw meats as evidenced by the numerous foodborne disease outbreaks and recalls that continue to occur year-to-year due to these hazards. The majority of these hazards are biological; specifically, microbial pathogens associated with the live animal husbandry (e.g., the animal and its environment; Table 3.7). The main source of external meat contamination with microbial hazards is the animal's hide, which carries high amounts of bacteria that originate from animal feces, soil, pastures, and water during all phases of animal production (growth, transportation, and holding in pens/cages). Bacterial pathogens can cause disease in humans either via infection or intoxication (where the bacteria secrete toxins either during infection or in the temperature-abused meats prior to consumption). Some spoilage bacteria (not considered pathogenic to humans) also secrete chemicals such as biogenic amines (e.g., histamine, tyramine, cadaverine, 2-phenylethylamine, spermine, spermidine, putrescine, tryptamine, and agmatine) that can cause adverse allergic reactions after consumption (Naila et al., 2010).

Other chemical and physical hazards associated with meats will be discussed in [Chapter 4](#) as many are related to the processing environment.

3.3.3 Milk and Dairy

Many of the potential biological, chemical, and physical hazards associated with milk and dairy ingredients are similar to those found in raw meats internal and external to meat tissues. Additional hazards can be associated with animal milk when used as ingredients in other dairy products. For example, when butter is used as an ingredient, hazards associated with the milk are introduced into the butter and then the final product. Milk is the primary ingredient in other dairy ingredients and products, including cream, butter, cream cheeses, powdered milks, casein, infant formula, cheeses, whey, whey protein hydrolysates, lactose, caseinates, meat extenders, yogurt, buttermilk, acidophilus milk, bioyogurts, and ice creams. Because most of the hazards natively associated with raw milk could be found in these dairy ingredients, all the possible hazards associated with raw milk should be considered.

Many of the milk hazards can cross into the milk during milk production within the animal or from animal hides, feces, unsanitary milking equipment, and the herd containment environment during the milking process. Pasteurization of milk and better animal health programs have been the primary means to reduce the biological hazards caused by microbial pathogens. These efforts have practically eliminated many of the “old” milk-related diseases (such as Q-fever caused by *Coxiella burnetii* or tuberculosis caused by *Mycobacterium bovis*) that occurred for two centuries in the United States.

However, many “new” microbial hazards have taken their place within the last 20 years. An even larger number of bacterial hazards now cause foodborne disease outbreaks and illnesses in the United States ([Table 3.8](#)). Several bacterial pathogens among these newer hazards are passed into milk when a cow, for example, has mastitis, an infection caused by *Staphylococcus aureus*, *Streptococcus* spp., and *Corynebacterium bovis*.

Preventive controls by the supplier can eliminate many of these hazards (e.g., all bacterial hazards would be eliminated in raw milk after proper pasteurization and sanitary preparation). The debate on legal sales of raw milk continues to this day. Health officials have demonstrated that outbreaks linked to raw milk are more common in states where raw milk sales are legal, but some consumers claim better nutrition from raw milk than pasteurized milk ([Centers for Disease Control and Prevention, 2015b](#)). It is highly recommended that raw milk never be used as an ingredient in foods except when the food will be pasteurized, and it actually reduces risk during processing of other products (as facility-related hazards; [Chapter 4](#)) if the raw milk is pasteurized before being brought into the production facility.

Table 3.8: Biological and chemical hazards associated with milk and dairy ingredients.

Bacterial (Biological)	Chemical
<i>Bacillus cereus</i>	Antimicrobials
<i>Brucella</i> spp.	Pesticides
<i>Campylobacter jejuni</i>	Hormones
<i>Clostridium botulinum</i>	Dioxins and polychlorinated biphenyls
<i>Coxiella burnetii</i>	Aflatoxin M1
<i>Cronobacter sakazakii</i>	Heavy metals
<i>Cryptosporidium parvum</i>	Radionuclides
Enterohemorrhagic <i>Escherichia coli</i>	
<i>Listeria monocytogenes</i>	
<i>Mycobacterium bovis</i>	
<i>Mycobacterium</i>	
<i>Paratuberculosis</i>	
<i>Salmonella</i> (nontyphi)	
<i>Staphylococcus aureus</i>	
<i>Yersinia enterocolitica</i>	

Adapted from Motarjemi, Y., Lelieveld, H., 2014. *Food Safety Management: A Practical Guide for the Food Industry*, Elsevier.

3.3.4 Poultry and Eggs

Poultry and egg ingredients contribute to large numbers of foodborne disease outbreaks globally each year. The frequency of the most common bacterial hazards (*Salmonella*, *Campylobacter*) associated with these ingredients consistently correlate with the actual numbers of infectious diseases they cause in humans. These diseases result from the association of these pathogens with live birds via infection and colonization in their rearing house environments before 3 weeks of age. Sources of these infections include feed, water, ground litter, infected birds, rodents, insects, or wild birds. A few bacterial pathogen hazards such as *L. monocytogenes* normally are not associated with live birds (and are less prevalent in raw poultry and egg products) but are prevalent in RTE poultry and egg ingredients due to facility-related introduction of the pathogen into these foods.

Some pathogens may colonize birds within regions of their gastrointestinal tract (e.g., the appendix-like organ called the cecum). With only a few exceptions, the poultry meat is not itself contaminated with the pathogens but becomes contaminated during processing of the poultry in the processing facility when the **pathogens are released into and onto processing equipment and the facility environment** (to be covered in more detail in [Chapter 4](#)). Some

processing steps and how they can result in pathogen contamination of poultry meat are listed below:

- Live bird distribution and receiving—**pathogens released from feces onto feathers**
- Stunning birds—**pathogens released from feces from live birds**
- Bleeding carcasses—**pathogens in blood (if active infection exists in birds)**
- Defeathering carcasses—**pathogens released from feces on feathers**
- Electrical stimulation of carcasses—**pathogens in the processing environment**
- Evisceration of carcasses—**pathogens released from internal organs**
- Inspection handling of carcasses—**pathogens in the processing environment**
- Chilling carcasses—**pathogens in the processing environment**
- Aging carcasses—**pathogens in the processing environment**
- Portioning and cutting carcasses—**pathogens in the processing environment**
- Marinating whole and pieces of meats—**pathogens in the processing environment**
- Packaging—**pathogens in the processing environment**

The majority of chemical and physical hazards associated with poultry and egg ingredients are associated with feed (described above) or the processing facilities, including bone removal as a process.

3.3.5 Seafood

Fish, crustaceans, and mollusks from wild catch or aquaculture sources have numerous potential biological and chemical hazards associated with the seafood tissues consumed as food (Table 3.9). Seafood also has a very short shelf life after slaughter and processing, especially after any temperature abuse, and becomes quickly perishable because of the nature of the tissues and enzymatic changes that occur. Many of the crustacean and mollusk biological (e.g., *Vibrio cholerae*) and chemical contaminations (e.g., dioxins) are caused by the environments in which the animals grow due to untreated wastewater, sewage, and agricultural manure and chemicals. When these fish and shellfish are raised using closed aquaculture methods, the risk of these hazards can be augmented, especially in unsanitary and mixed-use environments (e.g., where poultry or swine may be raised in cages near or over lakes used for aquaculture of fish and shellfish).

Interestingly, a chemical hazard called histamine poisoning is the most common foodborne disease in many countries, with the majority of outbreaks from fish consumption a result of histamine intoxication (Dickey and Plakas, 2009; EFSA, 2012). Histamine (associated with scombrototoxin) is an allergen-like substance produced by natural bacterial flora found on fish that metabolize natural histidine into histamines at elevated temperatures that are above the refrigeration temperatures used to hold fish. Because certain fish (e.g., tuna, mackerel, mahi-mahi, sardines, anchovies) have high concentrations of histidine in their tissues, these types of fish cause the majority of histamine poisonings after temperature abuse of the processed fish.

Table 3.9: Biological and chemical hazards associated with seafood ingredients.

Biological	Chemical
Bacteria: <i>Salmonella</i> spp. <i>Shigella</i> spp. <i>Escherichia coli</i> <i>Aeromonas hydrophila</i> <i>Clostridium botulinum</i> <i>Clostridium perfringens</i> <i>Bacillus</i> spp. <i>Staphylococcus aureus</i> <i>Listeria monocytogenes</i> <i>Vibrio cholerae</i> <i>Vibrio vulnificus</i> <i>Vibrio parahaemolyticus</i> <i>Yersinia enterocolitica</i> <i>Campylobacter</i> spp.	<ul style="list-style-type: none"> • Histamine (bacterial) “allergen” • Toxins produced by pathogenic bacteria • Marine biotoxins like ciguatera (from algae or phytoplankton) • Aquaculture drugs • Heavy metals (mercury, cadmium, arsenic, lead)
Viruses: Norovirus, hepatitis A	
Parasites: Nematodes, trematodes, cestodes	

Adapted from Motarjemi, Y., Lelieveld, H., 2014. *Food Safety Management: A Practical Guide for the Food Industry*, Elsevier.

Bacterial pathogens (e.g., *Clostridium botulinum*) can also produce toxins in fish under the certain fish production and storage conditions. Other chemical hazards (marine biotoxins) are produced by marine algae and phytoplankton and then consumed by fish where they can remain within tissues later used as food. Ciguatera toxin is produced by the dinoflagellate (a phytoplankton) *Gambierdiscus toxicus* found in coral reefs and lagoons. Wherever tropical fish are consumed in large amounts, ciguatera poisoning is usually the most common nonbacterial fishborne poisoning.

3.3.6 Fruits, Vegetables, and Herbs

Foodborne disease outbreaks arising from fresh and fresh-cut produce continue to occur in the United States and historically cause higher number of foodborne diseases than any other food commodity. In a 2015 analysis of data collected from 2004 to 2013 in the CDC Foodborne Outbreak Database (FOOD), the number of confirmed foodborne disease outbreaks attributed to fresh and fresh-cut produce was greater than for any other single food

category ([Center for Science in the Public Interest, 2015](#)). Only multi-ingredient, nonmeat foods (which likely contained combinations of produce commodities) caused more outbreaks. This same analysis showed that when an outbreak occurred due to fresh produce, it caused more illnesses in each outbreak compared to other food categories.

Because raw agricultural fruits and vegetables are processed in fresh produce processing facilities into RTE produce products, they should be processed according to the FSMA produce safety rule for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. These standards use a preventive approach to control common hazards (as discussed in this chapter) associated with fresh, ready-to-eat produce. Many fruits and vegetables, however, can be used as ingredients in other products, and thus enter a food manufacturing facility like other ingredients (in a cooked, dried, or processed state, e.g., cooked celery and potatoes to be used in production of a soup product), and would require similar consideration of the hazards associated with each ingredient.

3.3.7 Coffee and Cocoa

Out of 40 known different species of coffee plants, only two types (arabica and robusta varieties) of coffee fruit (beans) are used to make nearly all coffee ingredients worldwide. The beans are normally dried, roasted, and ground as coffee ingredients. The drying process results in a low-moisture product that does not support most bacterial growth, while the roasting process (normally 350°F) kills most bacteria and fungus, reducing many of the biological hazards associated with raw beans. The primary biological hazard associated with beans is subsequent fungal growth, which can occur if the processed beans are stored at high relative humidity. Under these conditions, the fungi may produce mycotoxin (mostly commonly ochratoxin A or OTA from *Aspergillus* and *Penicillium* spp.) on the stored beans. Other chemical hazards that arise with coffee ingredients (dioxins, pesticides, fumigants, fungicides) are similar to those associated with other produce or cereal-based ingredients. These hazards may be present on the final roasted beans when they are used as ingredients.

Cocoa and ingredients derived from cocoa beans (the seeds of the tree *Theobroma cacao*) are normally provided to manufacturers in the form of a dried, fermented cocoa bean. Cocoa, like coffee beans, can be contaminated with chemical and biological hazards during the growing, harvesting, and storage processes. As is true for coffee, the drying and fermentation processes remove many of the hazards before further processing. The primary biological hazard associated with cocoa ingredients is *Salmonella* (reviewed in [Podolak et al., 2010](#)). When cocoa beans are used to make cocoa powder, the process does not involve any further hazard control steps for *Salmonella* or other bacterial pathogens. Several species of *Salmonella* can survive in low-moisture powdered ingredients such as cocoa powder and can become more heat resistant and grow when conditions are more favorable as when cocoa powder is combined

with milk to make milk chocolate ingredients. Many of the foodborne disease outbreaks associated with chocolate originated from *Salmonella* associated with dried cocoa powder.

3.3.8 Cereal-Based Ingredients

Raw and baked cereal-based products (e.g., breads from grains derived from wheat, rice, maize, barley, sorghum, millet, oat, and rye) are associated with hazards that originate mainly from the materials and environment where they grow and are milled. Like fresh produce, these grains are exposed to soils, water, birds, animals, and man-made chemicals that can contaminate the cereals before harvesting. Not all cereal-based products are baked into breads; high-moisture batter or dry mixes are used for muffins or cake mixes, and *Salmonella* spp., *E. coli* (STEC), and *Bacillus cereus* can be found as contaminants in milled flour and other grains and are associated with numerous foodborne disease outbreaks and recalls. Additionally, other ingredients combined with milled grains can contribute hazards in these ingredients (butter, milk, cocoa).

Chemical contamination hazards (other than via storage and manufacturing facility contamination) mainly occur through the growth of yeast and molds native to the raw grains that produce heat-stable toxins (those that will not be destroyed by baking). The most common of these is the mold *Aspergillus flavus*, which makes a carcinogenic aflatoxin in many different types of grains stored under high-moisture conditions. Allergens may also be a concern in raw grains if there is cross-contact with equipment used to harvest or store the different grains, such as soybeans and wheat or corn. This, of course, is also a concern in the processing environment where many different milled grains may be made on the same equipment and in the same facility.

3.3.9 Edible Nuts, Oilseeds, and Legumes

Many of the biological hazards associated with nuts, oilseeds, and legumes are the same as those discussed above for produce and other raw agricultural commodities (including *Salmonella* contamination). Because many of these nuts, seeds, and legumes are consumed in raw form, these ingredients could introduce additional biological hazards to products, especially those that will not have an additional microbial control step (cooking) in the food manufacturing process. The greatest hazard, however, and the one most common to these ingredients, is the chemical hazard posed by numerous types of mycotoxins. Mycotoxins can be produced by a variety of fungal species and can include more than 12 different toxins produced by numerous different fungal species. Although it is not the purpose of this book to cover the effects of each ingredient hazard to human health, it is interesting to note that one mycotoxin produced by *Aspergillus* spp., aflatoxin, is estimated to cause between 4% and 28% of all primary liver cancers worldwide (Liu and Wu, 2010). With estimates that 25% of

the world's food crops are contaminated with mycotoxins (CAST, 1989), this and all the other mycotoxin hazards are important to control in all food ingredients, especially in edible nuts, oilseeds, and legumes.

3.3.10 Oils and Fats

Hazards from oils and fats are mostly associated with the crude/raw form of the oil/fat from growing the oilseeds, fruits, kernels, or nuts and can include pesticides, polycyclic aromatic hydrocarbons, hydrocarbons of mineral origin, heavy metals, dioxins, mycotoxins (aflatoxin primarily), and zearalenone toxin from the fungus *Fusarium* spp. The majority of these hazards are chemical in nature because the high temperature processing used to render oils eliminates most if not all biological hazards. These chemical hazards also are removed in fully refined/rendered oils (e.g., many pesticide residuals are removed during oil refining). Therefore, unless you are planning on using crude oils and fats in your products, testing of fully refined oils and fats (and verification of these test results and CoA documentation) should be acceptable to ensure these hazards are not present.

3.4 New Hazards in Food Manufacturing

No book or other reference can be comprehensive, nor should any such reference be used as an exhaustive listing of food ingredient–hazard pairs. Likewise, not all ingredients that may be used to produce human food can be completely covered in any one resource, and each should be researched against the most current regulatory and academic publications to ensure all hazards are considered. Because of the pace of technology and food production changes that occur in the food industry, it is important to establish a process to monitor the food ingredient-hazards list for each of your products to ensure new, previously unknown hazards (which may be the root cause of many outbreaks with unknown causes shown in Table 3.2) that become known do not now impact your product's safety. For example, *L. monocytogenes* has long been recognized as a hazard in dairy products such as butter, cheese, and ice cream and in RTE deli meats and pork and poultry RTE products, but had not been considered a hazard with caramel apples (although they are made with raw produce, wooden sticks, and dairy ingredients). However, a deadly 2014 listeriosis outbreak that caused 36 illnesses and at least three deaths across the United States and Canada was attributed to caramel apples (Centers for Disease Control and Prevention, 2015a; Food and Drug Administration, 2015b). Although caramel apples as the source of this outbreak seemed unlikely as neither apples (which are too acidic) nor caramel (with low water activity) normally support the growth of *L. monocytogenes*, subsequent research showed that significant growth of the outbreak strains of *L. monocytogenes* occurred when the wooden sticks were inserted into the apples, releasing juice and producing a new microenvironment where the bacterial pathogens could grow to hazardous levels to cause disease (Glass et al., 2015).

The best place to review and confirm potential ingredient-related hazards in human foods is in Appendix 1 of FDA's Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food (Food and Drug Administration, 2016). How can you stay abreast of new hazards that are not listed in this guidance when they are discovered? To best track new hazards to ensure each of your food ingredient-hazard pairs are up-to-date, monitor all CDC outbreak investigations, FDA recalls, and any FDA reports on new guidance documents to control foodborne disease risks.

In Chapter 4, we will discuss potential facility-related hazard pairs (facility and equipment related) as a final step in defining all known potential hazards of your products. This information will then enable the hazard analysis of each product (Chapter 5) so that the preventive controls necessary to manage all potential hazards of each product can be defined (Chapter 6).

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What and Where Are Potential Process and Facility-Related Hazards Introduced Into Foods During Human Food Manufacturing?

The likelihood of product contamination with a facility-related environmental pathogen increases as the prevalence of the environmental pathogens in the processing environment increases.

Food and Drug Administration (2016)

4.1 Introduction

One of the largest nationwide foodborne disease outbreaks in the last decade (Centers for Disease Control and Prevention, 2009) was caused by a process and facility-related hazard within a food manufacturing facility in Georgia and Texas. *Salmonella* Typhimurium that was isolated from peanut butter, crackers, and 15 other products from two facilities caused 714 illnesses (Fig. 4.1), 166 hospitalizations, and 9 deaths in 46 states (Cavallaro et al., 2011). A total of 3918 peanut butter-containing products from over 200 companies were recalled over a 4-month period in 2009.

Although raw peanuts as an ingredient have been identified as a likely food ingredient-hazard pair (peanuts-*Salmonella*, see Chapter 2), *Salmonella* is also a biological process hazard that can contaminate other foods during food manufacturing. The ultimate cause of contamination that led to the 2009 outbreak was likely the introduction of *Salmonella* from raw peanuts into the facility that then became a source of environmental contamination of final products. This environmental contamination became a process and facility-related hazard due to improper cleaning and sanitation of production equipment after peanut paste processing, rainwater leakage into storage areas, an unsealed air-handling system that leaked into storage areas, nearby storage of raw and roasted peanuts, and likely inadequate peanut roasting temperatures to eliminate *Salmonella* from this ingredient (Cavallaro et al., 2011). Previously manufactured peanut paste, roasted peanuts, and environmental monitoring samples tested positive for several different *Salmonella* strains from manufacturing facilities in both Georgia and Texas, supporting the expert view that the cause of the outbreak was due to process and facility-related hazards. This single outbreak also led to billions in economic losses for many companies and included



Multistate *Salmonella* outbreak linked to peanut butter and peanut butter-containing products. *From Centers for Disease Control and Prevention, 2009. Multistate outbreak of Salmonella infections associated with peanut butter and peanut butter-containing products – United States, 2008–2009. MMWR, Morbidity and Mortality Weekly Report* 58, 85–90.

This outbreak is a tragic example of how a facility-related hazard (likely brought into the facility as an ingredient-related hazard) can lead to a multistate foodborne disease outbreak. One way for a retail food business to prevent an event like this from impacting their business, as introduced initially in [Chapter 3](#), is for the retail food business to conduct its own hazard analysis and consider what process- and facility-related preventive controls could be used by their suppliers to prevent those hazards.

Hazard analysis begins with defining all the potential hazards associated with each ingredient that will be used in a final food product, as discussed in [Chapter 3](#). In this chapter, we will provide resources to help you define where and how in the facilities and during food processing these and other potential process and facility-related hazards are most likely to occur. This information will enable you to perform your own hazard assessments ([Chapter 5](#)) for the foods you will sell to

your consumers. You can then use this information to help define which specifications you should require of each of your suppliers in each facility and during the processing of each of your ingredients and products. Eventually, this should enable you to identify the preventive controls and monitoring you need done to ensure all ingredients, foods, and packaging delivered to your retail food sales and service establishments are safe for your customers.

4.2 Process and Facility-Related Hazards

Process and facility-related hazards have been and continue to be the cause of foodborne disease outbreaks (Table 4.1) and major food recalls. Many recalls are initiated due to potential process and facility-related hazards when the FDA performs sampling of food production environments (testing areas with direct and indirect contact with food ingredients) and then isolates pathogens such as *Salmonella* and *Listeria*. For example, the FDA communicated a warning letter (Appendix A) to a frozen cookie dough manufacturer in January, 2017 stating that it had observed serious violations of current Good Manufacturing Practice (cGMP) and had isolated the pathogen *Listeria monocytogenes* from four locations within the facility, including locations and equipment adjacent to cookie dough production (Food and Drug Administration, 2017a). This FDA warning letter came after a series of cookie dough-containing products were recalled by other

Table 4.1: Environmental pathogens that became process and facility-related hazards.

Product Causing Outbreak	Environmental Pathogen	Details	References
Chocolate	<i>Salmonella</i> Napoli	Possibly contaminated water used in double-walled pipes, tanks, and other equipment	Gill et al. (1983)
Chocolate	<i>Salmonella</i> Eastbourne	From processing environment	Craven et al. (1975)
Butter (from pasteurized cream)	<i>Listeria monocytogenes</i>	From processing environment	Lyytikainen et al. (2000)
Peanut butter	<i>Salmonella</i> Tennessee	From processing environment	FDA (2007a,b)
Peanut butter	<i>Salmonella</i> spp.	From processing environment	Cavallaro et al. (2011) and FDA (2009b,c)
Whole white pepper	<i>Salmonella</i> Rissen	From processing environment	FDA (2013c)
Cantaloupes	<i>L. monocytogenes</i>	From processing environment	FDA (2012a)
Peanut butter	<i>Salmonella</i> Bredeney	From processing environment	FDA (2012b)
Soft cheeses (from pasteurized milk)	<i>L. monocytogenes</i>	From processing environment	FDA (2013b)

From Food and Drug Administration, 2016. Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm>.

businesses. One of the companies that issued a recall also isolated *L. monocytogenes* from the cookie dough it sourced from the cookie dough manufacturer that was the subject of the FDA investigation (Beach, 2017). Interestingly, the owners of this business chose to shut the facilities down and sell the business rather than continue to work to correct continued issues related to process and facility-related hazards within their facilities.

Hazards associated with incoming ingredients that are not controlled initially by one supplier can then become established hazards in multiple food processing facilities along the supply chain (Fig. 4.2). These hazards will then impact multiple products and businesses when a recall is required. At its worst, such a single hazard can lead to large numbers of consumer illnesses and deaths in a nationwide foodborne disease outbreak such as the peanut butter and cookie dough examples discussed above.

It is important to discuss the differences in a food ingredient hazard and a process and facility-related hazard. Both food ingredient and process and facility-related hazards may be caused by the same biological, chemical, or physical hazards. For example, a food ingredient hazard such as *Salmonella* can “seed” the food processing areas in a facility. The *Salmonella*

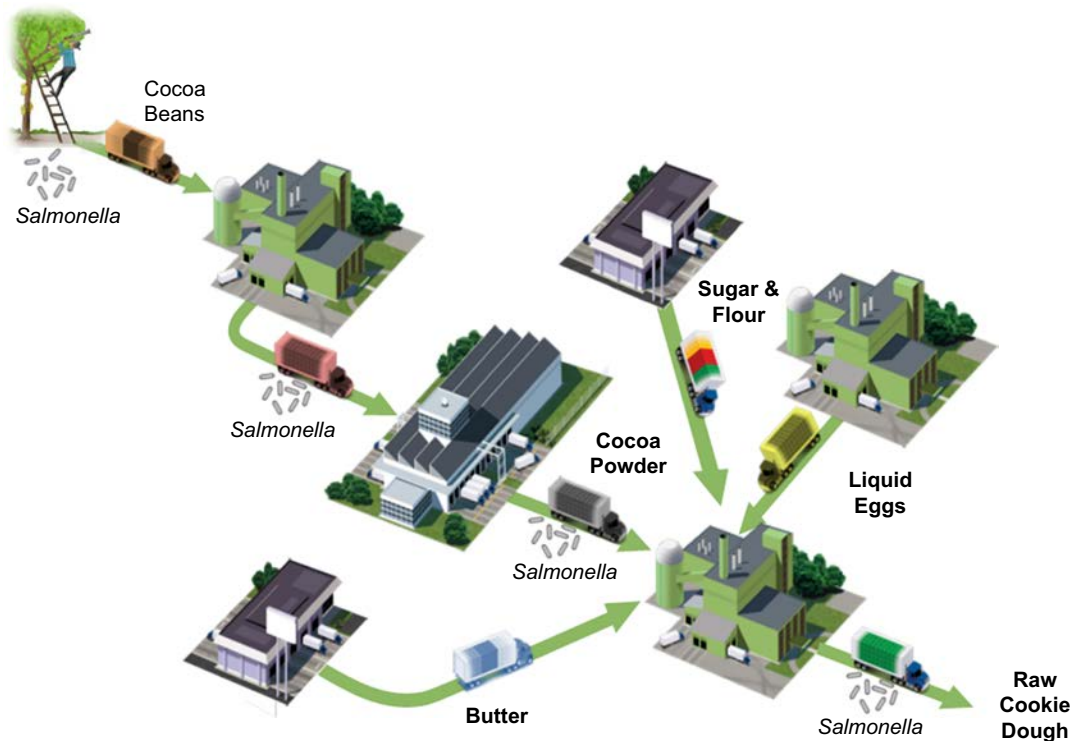


Figure 4.2

Salmonella contamination of a single ingredient (cocoa beans) leads to contamination of raw cookie dough used in many products.

that can develop niches in drains, HVAC systems, floors, and in adjacent processing equipment, then becomes an environmental processing hazard and can contaminate other products over time (as was the case in the peanut products outbreak discussed above).

Many food ingredient hazards described can become process and facility-related hazards. In the example of the double chocolate cookie dough discussed in [Chapter 3](#), three of the ingredient hazards (*Salmonella*, Shiga toxin-producing *Escherichia coli*, and *L. monocytogenes*) that were associated with four ingredients (liquid eggs, white flour, cocoa powder, and butter) could become process and facility-related hazards for any finished product made in that facility:

- Liquid eggs—*Salmonella*
- White flour—**Shiga toxin-producing *E. coli*/*Salmonella*, mycotoxins**
- Cocoa powder—*Salmonella*
- Yeast extract—Soy (allergen)
- Iodized salt—Arsenic, copper, lead, cadmium, mercury, tin, and sulfate
- Butter—*L. monocytogenes*, **milk (allergen)**
- Sugar—Mycotoxins
- Almond extract—Tree nuts (allergen)

In considering process and facility-related hazards, you should therefore also consider all other biological, chemical, and physical ingredient-associated hazards from other raw ingredients that will be used in the same facility as potential process hazards that could contaminate your product during processing. Many ingredient-associated hazards can become process and facility-related hazards ([Table 4.1](#)) due to poor facility design, improper equipment use, and personnel failures in that facility ([Table 4.2](#)).

4.3 Process/Facility–Hazard Pairs

The root cause of many process and facility-related hazards being introduced into foods is often related to the ingredients stored and used, processes performed, and equipment used to make products in a food manufacturing facility. Because so many different types of ingredients, chemicals, and equipment/tools are stored and used to process food products in any given food manufacturing facility, many of the hazards (biological, chemical, and physical) are continually present as potential threats to cross-contact and contamination of any food product made in a facility.

4.4 Biological Process and Facility-Related Hazards

Biological hazards that are most common and must be considered probable process hazards in any food manufacturing facility include the bacterial pathogens associated with incoming ingredients discussed in [Chapter 3](#). Biological process and facility-related hazards also include parasitic and viral pathogens that may be associated with water, pest, and people ([Table 4.3](#)). Many of the biological hazards are sensitive and can be eliminated via proper cleaning and sanitation methods and chemicals. However, several are or become resistant to these methods

Table 4.2: Sources and examples of how ingredient-related hazards can become process and facility-related hazards.

Source	Examples
Food handlers and maintenance personnel	<ul style="list-style-type: none"> • Transfer of biological hazards from one point to another on, for example, shoes and other clothing • Improper hand washing • Transfer of biological hazards to foods through improper handling or maintenance practices
Facility design	<ul style="list-style-type: none"> • Lack of appropriate air filtration for cooling, drying, air conveying • Improper airflow from “raw” to ready-to-eat (RTE) areas • Aerosols from improper cleaning practices • Raw and RTE food processing not separated • Allergen storage not segregated from other ingredients • Footbaths not installed in proper places
Transport equipment decontamination	<ul style="list-style-type: none"> • Forklifts • Trolleys • Racks • Carts

Adapted from Food and Drug Administration, 2016. Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm>.

Table 4.3: Process and facility-related hazard pairs due to biological adulteration.

Primary Source	Bacteria	Parasites	Viruses
Process related (e.g., poor or ineffective process controls, including by a supplier)	<ul style="list-style-type: none"> • <i>Salmonella</i> spp. survive inadequate heat treatment • <i>Clostridium perfringens</i> (improperly cooled cooked foods) • <i>Listeria monocytogenes</i> (raw agricultural commodities, contaminated products) 	<i>Cryptosporidium parvum</i> (contaminated water source)	Norovirus (if on foods such as shellfish or produce) that is difficult to remove using food-grade sanitizers
Facility-related	<ul style="list-style-type: none"> • <i>L. monocytogenes</i> (e.g., reservoirs include floors, cold wet areas, equipment, drains, condensate, coolers, and soil) • <i>Salmonella</i> spp. (from pests) 	N/A	Norovirus (when active shedding occurs in facility through vomiting and diarrhea and poor cleanup and disinfection is not practiced)
People related (individuals who are carriers, showing no signs of disease, who are shedding the hazard, or who are infected and are actively ill)	<ul style="list-style-type: none"> • <i>Streptococcus aureus</i> • <i>Shigella</i> spp. • <i>Salmonella</i> spp. • <i>Bacillus cereus</i> (from soil on employees shoes) 	<i>C. parvum</i>	<ul style="list-style-type: none"> • Hepatitis A virus • Norovirus • Rotavirus

Adapted from Food and Drug Administration, 2016. Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm>.

by forming biofilms. For example, *L. monocytogenes* can form chemical-resistant biofilms over time and continually contaminate foods during processing if the biofilms are not physically identified and removed (Doyle and Beuchat, 2013). Also, pathogens may already be resistant to chemicals used for general food contact surface sanitation (e.g., norovirus is resistant to most chemical sanitizers and must be disinfected using EPA-registered chemicals that are effective against most nonenveloped virus types, see Nigel et al. (2016)).

4.5 Chemical Process and Facility-Related Hazards

Many of the chemical process and facility-related hazards are due to chemicals (for cleaning and sanitation) and ingredients (allergens such as peanut flour) that are stored and used in the food manufacturing facility (Table 4.4). Generally, chemicals used for cleaning and sanitation are used properly and appropriately when instructions for use are followed, and it is rare to have a food product recalled due to contamination with these type of chemicals. However, some chemicals used to clean equipment or floors, for example, are potentially toxic to humans (especially in their concentrated forms). Obtaining a list of all such chemicals that are in use within the facility and ensuring controls are in place (which can include rinsing with potable water after use, storage away from foods, etc.) are necessary.

Some cleaning methods could also contribute to chemical hazards in food processing. For example, clean-in-place (CIP) systems are often used to flush cleaning and sanitation chemicals into liquid food product piping used for production, and these chemicals, if not properly used and flushed/removed, could end up in a final food product. The best means to track these type of chemical hazards within a food manufacturing facility is to request a list of all current (updated regularly) chemicals in use and to test and store retained samples of any foods at high risk of contamination (e.g., those processed in equipment that is cleaned via CIP systems) until its best-by-date/expiration date has passed. In the event that any testing is needed (e.g., a complaint or

Table 4.4: Process and facility-related chemical hazards.

Examples
<ul style="list-style-type: none"> • Undeclared food allergens due to mislabeling or cross-contact • Improper addition of substances associated with a food intolerance (e.g., sulfites) • Improper use of a color additive such as Yellow No. 5 • Contamination with industrial chemicals such as cleaners or sanitizers • Radiological hazards from use of contaminated water supply • Heavy metals due to leaching from equipment, containers, or utensils

Adapted from Food and Drug Administration, 2016. Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm>.

claim that a chemical may be in the product), the retained samples from that lot of production will be available for additional evaluation.

The majority of chemical-related hazards that are probable in human food manufacturing are due to the presence of allergens. Undeclared allergens in foods continue to be a significant cause of food recalls in the United States. Unlike other types of hazards such as biological hazards, though, very little is known about the number of actual illnesses and deaths from undeclared allergens in foods (e.g., those that are recalled on discovery that there are undeclared allergens in the products or the products are not properly labeled to declare the presence of allergens in the food). Over 15 million Americans have food allergies ([Food Allergy Research and Education, 2015](#)). Food allergens can be both an ingredient-related hazard (where the allergen is part of the food product but is not declared via labeling to the consumer) and a process and facility-related hazard (where the allergen should not be in the food product but contaminates the food due to storage and processing errors during food manufacturing).

The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 lists foods and any ingredients that contain protein derived from milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans as major food allergens to humans. These eight foods cause more than 90% of the food allergies in humans in the United States ([Food and Drug Administration, 2010](#)). A 2016 FDA guidance ([Food and Drug Administration, 2016](#)) defines these allergens more specifically as follows:

- **Crustacea:** The class of Crustacea, or shellfish, includes shrimp, crab, lobster, and crayfish. Crab and shrimp are the most commonly consumed shellfish in the United States. The major shellfish allergen is tropomyosin, a muscle protein that accounts for 20% of the dry weight of shrimp ([Grocery Manufacturers Association, 2009](#))
- **Egg:** Most egg allergens are found in the egg white (albumin) rather than the yolk.
- **Fish:** Different fish species (e.g., bass, cod, and flounder) have been found to have structurally related proteins, and this may explain why individuals with a fish allergy are allergic to multiple types of fish. Cooking may reduce the allergenicity of fish, but it does not eliminate it.
- **Milk (Dairy):** Cow's milk contains a number of different proteins that are grouped into two categories: caseins, which constitute 80% of the total protein, and whey proteins, which make up 20%.
- **Peanut:** Peanut seeds contain an average of about 29% protein, classified as albumins or globulins.
- **Soy:** Globulins are the major proteins in soybeans.
- **Tree Nuts:** Tree nuts include almonds, Brazil nuts, cashews, filberts/hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, and walnuts. FDA provides a complete list of the nuts considered "tree nuts" in its "Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer

Protection Act of 2004 (Edition 4)” ([Food and Drug Administration, 2006](#)) and its 2013 Guidance for Industry: A Food Labeling Guide ([Food and Drug Administration, 2013a](#)).

- **Wheat:** Wheat proteins include the globulins, prolamins (i.e., glutenin and gliadin), and glutelins. About 25% of wheat-allergic children react to other cereal grains (i.e., barley, oats, or rye). Wheat, along with other grains such as rye and barley, also contain gluten. Gluten is family of proteins that are associated with celiac disease, which affects as many as 3 million people in the United States by the body’s natural defense system attacking the lining of the small intestine and preventing the proper absorption of nutrients ([Food and Drug Administration, 2015b](#)). While neither celiac disease or other gluten intolerances are food allergies, a diet that strictly avoids gluten is important for the health and well-being of those with these conditions.

There are, of course, many more food ingredient allergens, some of which other countries include in their “top allergen list.” For example, the Canadian Food Inspection Agency includes mustard, sulfites, and sesame among the most common food allergens that should be controlled ([CFIA, 2016](#)). Importantly, the knowledge of which allergens are likely to be present in all ingredients is critical to ensure each is stored and handled properly to prevent cross-contact with food products.

As discussed in [Chapter 3](#) in the double chocolate cookie dough product example, some might not realize that yeast extract could contain an allergen unless it is known that yeast may be grown in soy, potentially resulting in residual soy in the final ingredient. The presence of an allergen in an ingredient is not always evident by just the name of the ingredient. For example, casein ingredients contain milk, cheese powder may contain wheat starch as a free-flow agent, and baking powder may contain carriers such as wheat flour. Therefore it is important to consider each ingredient and its derivatives that will be used in a food manufacturing plant in addition to those specified for your product and to be aware of potential hidden allergens ([Table 4.5](#) and [Appendix B](#)).

Food additives such as colors, preservatives, flavors, and even “generally recognized as safe” (GRAS) chemical ingredients should also be considered as potential hazards during processing of food products. Although many are added to foods purposely to enhance quality and shelf life (e.g., sulfiting agents used to preserve and extend the shelf life of food products), they can be severe processing hazards when they exceed the allowable usage rates or are accidentally introduced into foods in which they are not approved or food products containing them are not labeled properly for consumers. For example, cochineal extract and carmine are permitted in foods as color additives, but they must be listed according to 21 CFR Part 73.100(d)(2) as ingredients in the product labeling because some people may have life-threatening allergic reactions after consumption. Because cochineal extract and carmine are not considered food allergens by the FDA ([Food and Drug Administration, 2016, 2005a,b](#)), they are not subject to the food allergen controls in the Food Safety Modernization Act (FSMA) Preventive Controls for Human Food requirements. These ingredients may not be properly controlled like other food allergens to

Table 4.5: Allergens hidden in ingredients.

Ingredient	Possible Allergen Present
Lactic acid (an acidity regulator)	What is it derived from (e.g., milk , tomatoes, molasses, potato, maize starch, wheat starch)?
Carotenoids such as canthaxanthin (coloring agents)	Check for allergens (e.g., fish , Crustacea).
Cheese powder	Does it contain a free-flow agent? If yes, what is it and what is it derived from (e.g., wheat starch, wheat flour, maize, etc.)?
Xanthophylls (coloring agents)	What is it derived from (e.g., animal, egg , egg yolk, Crustacea , fish)?
Flavor enhancers	What are they derived from? (e.g., meat, sardines (fish) , wheat , soy , maize). If synthesized by microbes, what is the source of the nitrogen and carbohydrate (e.g., wheat , soy , maize, etc.)?
Emulsifiers such as sodium lactylates or calcium stearoyl lactylate	What is it derived from (e.g., peanuts , milk)?
Gelatin	What is the gelatin derived from (e.g., fish (isinglass), beef, pork, chicken, etc.)? Check for the addition of sulfites .
Lecithin	What is it derived from (e.g., soy , egg , etc.)?
Starch (modified—chemically or physically)	What is the starch derived from (maize, tapioca, potato, wheat)? Check for added sulfites .

Adapted from Allergen Bureau, 2011. *Unexpected Allergens in Food*. <http://allergenbureau.net/wp-content/uploads/2013/12/Unexpected-Allergens-in-Food-18-April-2011.pdf>; complete example list in [Appendix B](#) of this book.

prevent cross-contact and contamination of foods, where they could become undeclared process-related chemical hazards in the final products. FDA has provided a list with requirements for the use of food additives that fall into this category of ingredients that could become chemical hazards (both as an ingredient and as an undeclared process hazard) in food products ([Table 4.6](#)).

Chemical hazards may also include ingredients added to foods for the purpose of economic benefit (called intentional adulteration for the purposes of economic gain). The FDA specifically mentions four of these chemical hazards you should consider based on their historical patterns of use ([Table 4.7](#)). Because intentional adulteration for the purposes of economic gain will continue to be a potential hazard in foods, you should always include a hazard assessment for these four ingredients and any others that may be reported as new hazards in the future.

Radiological hazards are rare in foods, but should also be considered as possible process-related hazards depending on where food facilities are located and where water used in the facility is obtained ([World Health Organization, 2011](#)). Some food manufacturing facilities may be located near areas with high concentrations of radionuclides such as radium-226,

Table 4.6: Chemical hazards due to food additives that can be an ingredient hazard or process hazard.

Category	Examples	Key Regulatory Citations
Sulfiting agents	<ul style="list-style-type: none"> Sulfiting agents (sulfur dioxide, sodium sulfite, sodium bisulfite, sodium metabisulfite, potassium bisulfite, and potassium metabisulfite) are used as chemical preservatives in various products. Sulfites can cause diarrhea, headache, difficulty breathing, vomiting, nausea, abdominal pain and cramps in sulfite-sensitive individuals (Timbo et al., 2004). Sulfiting agents are considered to be incidental only if they have no technical effect in the finished food and are present at less than 10 ppm 	21 CFR 101.100(a)(4)
Yellow No. 5	<ul style="list-style-type: none"> Yellow No. 5 (tartrazine) is a color additive subject to color certification. People sensitive to Yellow No. 5 can experience allergic-type reactions (including hives and bronchial asthma). Any food for human use that contains Yellow No. 5 must specifically declare the presence of the color additive by listing it as an ingredient. 	<ul style="list-style-type: none"> Section 721(c) of the FD&C Act (21 U.S.C. 379e) 21 CFR 74.705(d)(2)
Cochineal extract and carmine	<ul style="list-style-type: none"> Cochineal extract and carmine are color additives permitted for use in foods in the United States under conditions of safe use For sensitive consumers, cochineal extract and carmine can cause severe allergic reactions, including anaphylaxis. All human foods containing cochineal extract or carmine are required to declare the presence of the color additive by listing its respective common or usual name, “cochineal extract” or “carmine,” in the statement of ingredients 	<ul style="list-style-type: none"> 21 CFR 73.100 74 FR 207, January 5, 2009 21 CFR 73.100(d)(2) Food and Drug Administration (2009a)

Adapted from Food and Drug Administration, 2016. Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm> and Food and Drug Administration, 2009a. Cochineal Extract and Carmine: Declaration by Name on the Label of All Foods and Cosmetic Products that Contain These Color Additives; Small Entity Compliance Guide. <http://www.FDA.gov/ForIndustry/ColorAdditives/GuidanceComplianceRegulatoryInformation/ucm153038.htm>.

radium-228, and uranium which may leach into the ground water (Szabo et al., 2012) and into wells. According to the US Geological Survey National Water-Quality Assessment Program (United States Geological Survey, 2014), radium is a naturally occurring radioactive element (or radionuclide) that can be present at low levels in any soil, water, and rock materials. Radium accumulates easily in the body when it is ingested in water or food or when it is inhaled. Long-term exposure can increase the risk of cancer.

The US Environmental Protection Association (EPA) has established a Maximum Contaminant Level (MCL) in drinking water of 5 picocuries per liter (pCi/L) for radium.

Table 4.7: Chemical hazards arising from intentional adulteration.

Food Containing Hazard	Hazard	Details	References
Milk	Melamine	Melamine, a nitrogen-rich industrial by-product, was mixed into diluted dairy products to make their protein content appear greater	Food and Drug Administration (2008)
Turmeric	Lead chromate	Lead chromate that has a vibrant yellow color has been added to turmeric to brighten the color of the spice, making it appear to be of a higher quality	Gleason et al. (2014)
Paprika	Lead oxide	Lead oxide is a red chemical that mixed with paprika brighten its color and make it appear to be of a higher quality	Lead Action News (1995)
Chili powder	Sudan I	Sudan I is an orange-red compound that has been used as a coloring agent in chili powder but is now banned in many countries due to its carcinogenic potential	Coulet et al. (2010)

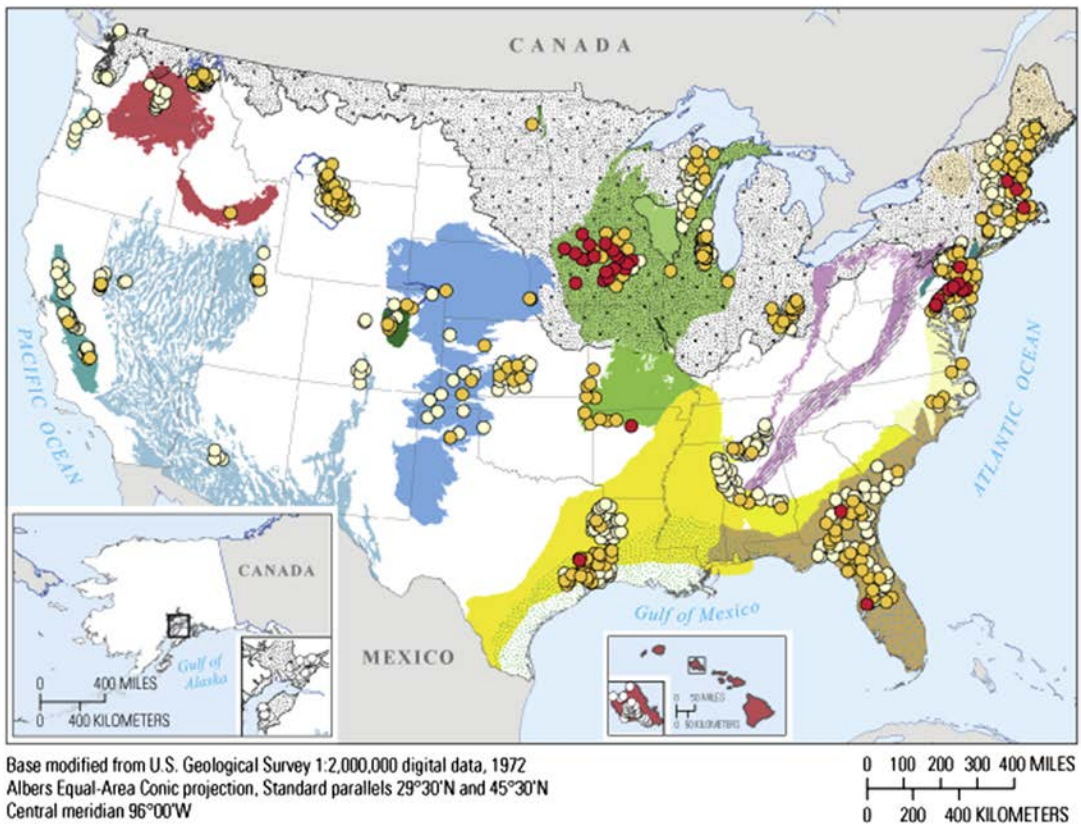
Adapted from Food and Drug Administration, 2016. Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm>.

Fig. 4.3 maps locations in the United States where radium concentrations exceeded the 5 pCi/L drinking water standard. Radium could be a process hazard risk if water from one of these areas is used in a food manufacturing facility. More importantly, although radiological hazards from radium in foods are rare, this discussion demonstrates how one must consider the risk (e.g., where water is sourced from and its safety) for all process- and facility-related chemical hazards in human food manufacturing.

4.6 Physical Process and Facility-Related Hazards

Human food manufacturing involves a great deal of design and engineering to enable equipment and facilities to mass-produce multiple ingredients into food products. Modern food manufacturing equipment is designed to perform these tasks while also being subject to frequent physical/chemical cleaning and sanitation and regular maintenance to ensure efficiency. Unfortunately, these modern technologies and equipment used in food production are sometimes located in aging and poorly designed facilities. For example, a facility may have uncovered glass lighting over production areas or may combine raw and ready-to-eat (RTE) food processing in the same area. Such challenges sometimes unnecessarily increase process and facility-related hazards in foods. Likewise, when equipment is not properly cleaned and maintained, the equipment itself becomes the source of the process hazard.

The majority of physical process and facility-related hazards relate to hard or sharp objects that can cause injury during ingestion or can be choking hazards that block airways and lead to death (Table 4.8).



EXPLANATION

Principal aquifer system

- Glacial sand and gravel
- Crystalline rock New England/New York
- Northern Atlantic Coastal Plain
- Appalachian Piedmont Mesozoic Basins
- Valley and Ridge and Mississippian limestone
- Coastal Plain—Texas Upland, Gulf lowland, Mississippi Embayment
- Floridan and surficial
- Mid-Continent and Ozark Plateau Cambro-Ordovician
- High Plains Tertiary alluvium and fill
- Coastal Plain, Southeastern

- Western Foreland Tertiary/Cretaceous sandstone
- Rio Grande and Basin and Range basin fill
- Pacific Coastal (Central Valley and Willamette Basins) alluvium and fill
- Western alluvium and fill
- Basalt

Well and radium concentration—

In picocuries per liter

- Less than 1
- 1 to 4.99
- Greater than or equal to 5

Figure 4.3

National map showing locations where radium concentrations in ground water exceed 5 pCi/L. *From Szabo, Z., Fischer, J.M., Hancock, T.C., 2012. Principal Aquifers Can Contribute Radium to Sources of Drinking Water under Certain Geochemical Conditions: U.S. Geological Survey Fact Sheet 2010–3113.*

Table 4.8: Process and facility-related hazards due to physical adulteration.

Material	Source of Hazard
Metal	<ul style="list-style-type: none"> • Equipment • Nuts, bolts, screws • Grinders, slicers, knives • Sieves, screens, wire-mesh belts • Mixing paddles • Metal cans (shavings, lids) • Pumps • Cook kettles with swept surface paddles • Drop buckets • Staples
Plastic, ceramic, and glass	<ul style="list-style-type: none"> • Equipment (inspection belts, small wares, buckets) • Facility (glass light fixtures, glass windows in doors, plastic strip curtains) • Glass containers • Scoops • Mixing paddles • Buckets • Conveyor belts • Testing materials
Other	<ul style="list-style-type: none"> • Incomplete removal of pits or pit fragments, nut shells/bones • Poor design (for example, particle size of food inappropriate for consumer and therefore a choking hazard) • Employee jewelry • Stones, dirt, wood splinters • Insects

Adapted from Food and Drug Administration, 2016. Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm>.

4.7 Defining the Environment Where Hazards Occur and Their Significance in Food Manufacturing

The food processing environment for human food manufacturing can be a complex and highly variable operation that also includes non–food-processing work areas such as equipment repair and facilities maintenance rooms, cleaning and sanitation chemical and tools storage, and active pest control management tools and chemicals. Additional challenges include the

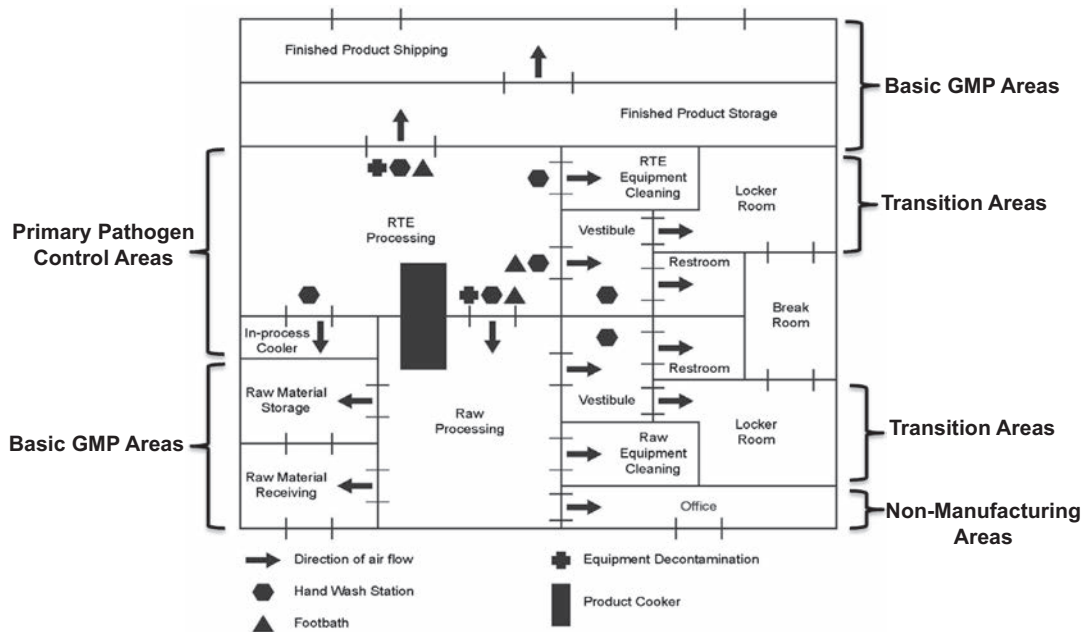


Figure 4.4

FDA guidance on facility design for separation of processes by area. Adapted from Food and Drug Administration, 2017b. *Control of Listeria monocytogenes in Ready-to-Eat Foods: Guidance for Industry, Draft Guidance*. <http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM535981.pdf>.

need to store and use multiple ingredients, the need to accommodate multiple buyers with different process specifications and requirements, the use of multiple suppliers, and reconstruction of facilities to accommodate changes in new business.

The food-processing environment for human food manufacturing should be designed to define specific areas for the safe production of foods. A segregation and flow of raw ingredients from storage, use, and final product processing (e.g., into RTE foods where no further preventive controls are available except sanitation preventive controls) should be defined by facility barriers (walls) as proposed by the FDA (Food and Drug Administration, 2017b) with proper storage, air handling, and personal hygiene actions enabled (e.g., uniform use, hand washing, boot washing) between each of the areas leading to the final packaging and storage of the finished products (Fig. 4.4).

Process and facility-related hazards can occur anywhere within a food manufacturing facility, and become more likely if the areas are not well defined to segregate storage, movement of employees, and processing of the foods. One of the best means to prevent process and facility-related hazards is to design the facility according to specific areas where each

potential process/facility hazard can be more easily assessed and controlled. These areas have been defined by others ([Food Safety Preventive Controls Alliance, 2016](#); [Food and Drug Administration, 2017a,b](#); [Fig. 4.4](#)) and are defined as:

- **Nonmanufacturing areas** include maintenance areas, offices, and employee break areas
- **Transition areas** include entry doors, locker rooms, and storage areas that open into a GMP area, and small utensil/equipment washing/sanitation/storage areas
- **Basic GMP areas** include raw ingredient receiving and storage areas, general food processing areas using raw ingredients, other food production processes
- **Primary pathogen control areas** (controlled access, often referred to as a **Zone 1** area) include areas where cooked, pasteurized, or RTE products are produced and exposed to the processing environment
- **Sensitive/high hygiene areas** if used, include restricted access areas that produce cooked, pasteurized or RTE products for vulnerable individuals such as infants and foods provided during health care

These separated production areas are also called hygienic zoning areas ([FSPCA, 2016](#)). When using hygienic zoning to enable preventive controls, the basic GMP, primary pathogen control, and sensitive/high hygiene areas may require a sanitation preventive control and corresponding verification activity (such as environmental monitoring for pathogens).

Although the primary pathogen control area is generally most important (and described by the FDA as such) to preventing biological process hazards from being introduced into foods, this area can also be important in the prevention of chemical hazards such as undeclared allergens to ensure proper coordination and segregation of ingredient use. Environmental monitoring (see [Chapter 9](#)) should be used to verify that sanitation control programs designed to significantly minimize or prevent environmental pathogen contamination (a process hazard, see [Table 4.3](#)) of RTE foods are working within a primary pathogen control area. Environmental monitoring should include monitoring for allergens in this area as well.

The key to identifying which process and areas in the facility are most likely to harbor a hazard is to consider the root cause of prior food contamination events in these areas that have led to recalls and/or outbreaks of foodborne diseases (as described, for example in [Table 4.1](#)), and to also consider:

- What processes occur in each area according to designated work (e.g., employee uniform requirements in GMP and primary pathogen control areas vs. transition areas, which employees are trained to work in each area)?
- What food ingredient hazards are already present (as incoming hazards into that area of the facility) that will be stored and/or used to process foods (both yours and other buyers)?
- What food ingredients (allergens or other chemical ingredients) are being stored and used in each area that could pose a process hazard in other foods if introduced into your product?

- What cleaning and sanitation SOPs will be used in each area and with which chemicals?
- What pest control, disinfectant, and deep equipment/floor cleaning chemicals will be used in each area?
- What utensils, tools, transport carts, and equipment will be used in each area, and what maintenance of the equipment is required that could introduce process hazards into the food product?

If a facility is not designed using similar zones for food storage and processing, it will be very likely that there will be biological and chemical process hazards introduced into food products. For example, if a bakery facility includes nuts in many of its products and stores and chops the nuts in the same area where the final product is mixed, baked and packaged, an undeclared allergen could easily be introduced into the products from either employee error, uncontrolled processing tool use, or aerosols of allergens created in the area. Likewise, if employees wear street clothes and shoes in the final mixing and baking area with no segregation for transition, a *Bacillus cereus* (a biological facility-related hazard) contamination of the final product could occur from the soil and dirt that is likely on employee street clothes and shoes.

Preventive controls for process and facility-related hazards are best implemented using designated areas to ensure training of employees and proper use of all designated equipment in each area (not allowing certain equipment to be used in different areas for example). All SOPs for GMP activities that should only be performed in designated areas should be verified via monitoring in these areas.

Following the process we started in [Chapter 3](#) of identifying appropriate preventive controls for the food ingredient hazards in all of your products, we next need to add all likely process and facility-related hazards to the list following the example in [Fig. 4.5](#). For example, you have a final product of double chocolate cookie dough that will be distributed to all your retail establishments where it will be cooked and served to customers. It is possible that the retail establishments may serve the raw cookie dough to customers or use it raw in desserts as well. The supplier will use ingredients to include eggs, white flour, cocoa powder, yeast extract, salt, butter, sugar, and almond extract. In [Chapter 3](#), we determined that the food ingredient-hazard pairs include (based only on ingredient based hazards):

- Liquid eggs—*Salmonella*
- White flour—**Shiga toxin-producing *E. coli*/Salmonella, mycotoxins**
- Cocoa powder—*Salmonella*
- Yeast extract—**Soy (allergen)**
- Iodized salt—**Arsenic, copper, lead, cadmium, mercury, tin, and sulfate**
- Butter—*L. monocytogenes*, milk (allergen)
- Sugar—**Mycotoxins**
- Almond extract—**Tree nuts (allergen)**

What *processes* will be used to produce the product in the food manufacturing facility



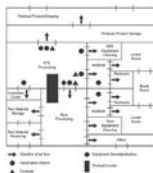
What are the known *hazards* associated with these processes in this facility (e.g., other raw materials)

(list each *Process-Hazard Pair*)



Are any of these *Process-Hazards* already under preventive controls within the food manufacturing facility (e.g., Sanitation Preventive Control verified by environmental monitoring)

(list and document each in the facility)



List each *Process-Hazard Pair* that needs a preventive control specification

Figure 4.5

Identifying process-related hazards and preventive controls.

All the ingredient-related ingredient hazards should also now be considered possible process and facility-related hazards because any pathogen or allergen brought into the facility via these ingredients could potentially cross-contaminate or cross-contact finished product. Now suppose that the food manufacturing facility also makes other baked products with peanuts and tree nuts, and uses cheese powder, emulsifiers, lecithin, and starches in the same production area and equipment. These ingredients would also become potential process and facility-related hazards to your finished product. Suppose also that the facility uses mixing kettles with swept surface paddles (Fig. 4.6) that could introduce metal pieces into the foods.

The list of process-facility hazard pairs would be similar to this list:

- Processing environment—*Salmonella*
- Processing environment—*Shiga toxin-producing E. coli/Salmonella*
- Processing environment—*Salmonella*
- Processing environment—*L. monocytogenes*



Figure 4.6
Mixing kettles with swept surface paddles. *Adobe stock photo 28050915.*

- Processing equipment—**Metal shavings**
- Processing environment/equipment/storage—**Peanut allergens**
- Processing environment/equipment/storage—**Tree nut allergens**
- Processing environment/equipment/storage—Cheese powder (**wheat starch and milk allergens** as agent)
- Processing environment/equipment/storage—Emulsifiers (**milk allergens**)
- Processing environment/equipment/storage—Starch (**added sulfites**)

4.8 Where to Find the Current Science and Best Practices on Process and Facility-Related Hazards in Food Manufacturing

A good place to identify what potential ingredient-related hazards might be present in a food product is by using Appendix 1 of FDA’s Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food ([Food and Drug Administration, 2016](#)).

The FDA has additional resources to help industry identify which product defects are process and facility-related hazards through the FDA's Compliance Policy Guides (CPGs). The CPGs not only advise FDA's field inspection and compliance officers, but they also explain FDA strategy policy on regulatory issues related to FDA laws or regulations and are useful resources. For example, CPG Sec. 555.425, entitled "Foods, Adulteration Involving Hard or Sharp Foreign Objects" ([Food and Drug Administration, 2005b](#)) defines a food as adulterated if the size of any hard or sharp foreign object (metal fragment, bone, etc.) measures 7–25 mm in length.

The FDA also addresses food ingredient and processing adulteration in 21 CFR Subpart G, Part 110.110, entitled "Natural or unavoidable defects in food for human use that present no health hazard." The following italicized paragraphs are cited verbatim from this regulation to reflect the actual requirements and use of the Defect Action Handbook ([Food and Drug Administration, 2005a](#)):

Part 110.110 allows the Food and Drug Administration (FDA) to establish maximum levels of natural or unavoidable defects in foods for human use that present no health hazard. These "Food Defect Action Levels" listed in this booklet are set on this premise--that they pose no inherent hazard to health.

Poor manufacturing practices may result in enforcement action without regard to the action level. Likewise, the mixing or blending of food with a defect at or above the current defect action level with another lot of the same or another food is not permitted. That practice renders the final food unlawful regardless of the defect level of the finished food.

The FDA set these action levels because it is economically impractical to grow, harvest, or process raw products that are totally free of non-hazardous, naturally occurring, unavoidable defects. Products harmful to consumers are subject to regulatory action whether or not they exceed the action levels.

It is incorrect to assume that because the FDA has an established defect action level for a food commodity, the food manufacturer need only stay just below that level. The defect levels do not represent an average of the defects that occur in any of the products--the averages are actually much lower. The levels represent limits at which FDA will regard the food product "adulterated"; and subject to enforcement action under Section 402(a)(3) of the Food, Drug, and Cosmetics Act. As technology improves, the FDA may review and change defect action levels on this list. Also, products may be added to the list. The FDA publishes these revisions as Notices in the Federal Register. It is the responsibility of the user of this booklet to stay current with any changes to this list.

Some might now consider the ingredients/product defect action levels in these regulations as process defects, especially those related to incoming raw ingredients that are only disallowed at certain levels for esthetic purposes. However, mold, shell fragments, parasitic cysts, parasites, rodent filth and mammalian excreta can contain *Salmonella* and other pathogens, so

Table 4.9: Examples of allowable defects in select foods.

Commodity	Defect	Defect Source	Significance	Maximum Allowable Level
Pepper, whole (black and white)	Insect filth and/or insect mold	Insect infested—post-harvest and/or processing infestation	Aesthetics	Average of 1% or more pieces by weight are infested and/or moldy
	Mammalian excreta	Postharvest and/or processing animal contamination	Mammalian excreta may contain <i>Salmonella</i>	Average of 1 mg or more mammalian excreta per pound
	Foreign matter	Postharvest contamination	Aesthetics	Average of 1% or more pickings and siftings by weight
Date material (chopped, sliced, or macerated)	Insects	Preharvest and/or postharvest and/or processing infestation	Aesthetics	10 or more dead insects (whole or equivalent) in one or more subsamples OR Five or more dead insects (whole or equivalent) per 100 g
	Pits	Processing	Mouth/tooth injury	Two or more pits and/or pit fragments 2 mm or longer measured in the longest dimension per 900 g

Adapted from Food and Drug Administration, 1998. *Defects Level Handbook*. <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/SanitationTransportation/ucm056174.htm>.

these foods must meet regulatory limits for such defects (Table 4.9). Many of these and other allowable (action levels) defects can become human health hazards when they exceed the stated levels, so they are regulated by the FDA.

4.9 Conclusions

Retail buyers often use certifications and third-party audits to qualify their suppliers. Such certifications and audits reflect a facility at a particular point in time and show capability but not always continuous compliance to food safety requirements during food product production. The majority of process and facility-related hazards occur due to continual changes in the ingredients received, the foods stored, and processing methods used at each production run of a food product. To properly prevent process and facility-related hazards, the food manufacturing facility should identify each biological, chemical, and physical process hazard and prioritize the management of these hazards based on their probability. To ensure process and facility-related hazards are controlled for its food products, the retail food business must also know the hazards associated with the processes and facilities and continually monitor new potential hazards based on the foods that its suppliers process in their facilities.

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Hazard Analysis in a Human Food Manufacturing Facility

5.1 Introduction

The hazard analysis process starts with defining all of the potential hazards associated with each ingredient that will be used in a final food product, as was discussed in [Chapter 3](#). In [Chapter 4](#), we provided resources to help you define where and how potential hazards may occur in facilities and during food manufacturing. In this chapter, we will enable you to perform your own hazard analysis based on the foods you sell to your consumers. While your suppliers are required under the preventive controls regulations to conduct a hazard analysis, a case can be made (as discussed in [Chapter 3](#)) that a retail buyer should consider conducting their own hazard analysis on the ingredients and food products that it sources from its suppliers. By conducting its own hazard analysis, a retail buyer can better ensure the safety of his/her own products.

Conducting a hazard analysis allows you then to determine which preventive controls are necessary to control these hazards ([Chapter 6](#)). You can use your own hazard analysis and preventive controls assessment to guide and define specifications for your suppliers. You will also be able to monitor and audit the preventive controls your suppliers should have in place to ensure all ingredients, foods, and packaging delivered to your retail food sales and service establishments are safe for your customers. This can also be important if you use nondomestic suppliers that distribute ingredients and/or products directly to your retail establishments.

5.2 Case Study Illustrating the Importance of Hazard Analyses

A 2016 multistate foodborne disease outbreak of Shiga toxin–producing *Escherichia coli* (STEC) was investigated by the Centers for Disease Control and Prevention (CDC) ([Centers for Disease Control and Prevention, 2016](#)). The outbreak lasted over 10 months ([Fig. 5.1](#)) and caused 63 illnesses (17 requiring hospitalization) in people between the ages of 1 and 95 years who lived in 24 states.

The implicated food ingredient–hazard was flour (including unbleached, all-purpose, and self-rising varieties) that was contaminated with *Escherichia coli* O121 or O26 (two Shiga toxin–producing strains). The traceback investigation indicated that the contaminated flour

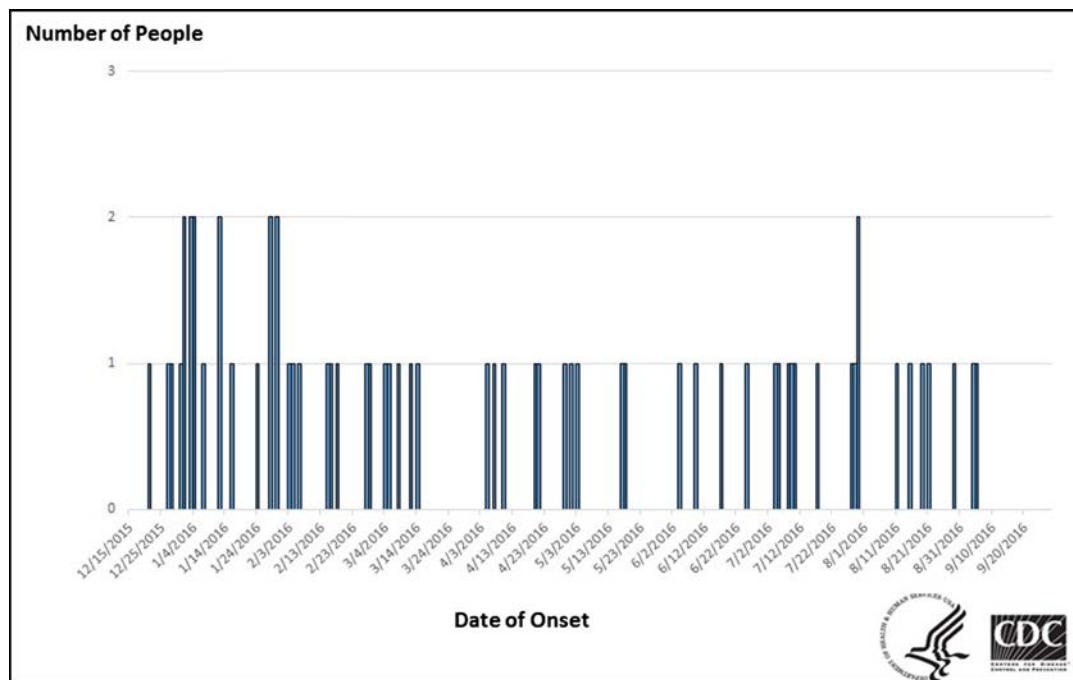


Figure 5.1

Epigraph of 2016 Shiga toxin-producing *Escherichia coli* outbreak linked to flour. From Centers for Disease Control and Prevention, 2016. *Multistate Outbreak of Shiga Toxin-Producing *Escherichia coli* Infections Linked to Flour (Final Update)*. <https://www.cdc.gov/ecoli/2016/o121-06-16/>.

originated at a single manufacturing facility. Fortunately, no deaths were reported, but multiple recalls of products used by consumers and restaurants were initiated, including recalls of flour, biscuit mix, jalapeno breadings, cake mix, pancake mix, bread mix, muffin mix, and brownie mix (Food and Drug Administration, 2016a). In some cases, contaminated flour was used to prepare dough that was distributed to restaurants. This dough sickened some individuals who reported handling or eating the raw or undercooked dough (including undercooked pizza dough).

Because the recalled products were manufactured over a year (with associated illnesses reported over a lengthy 10-month span, Fig. 5.1), one could speculate that the cause of the outbreak was *E. coli* O121 or O26 which came into the flour manufacturing facility in an incoming raw ingredient and became a facility-related hazard, which impacted subsequent batches/lots of products. The pathogen initially present in a raw ingredient may have seeded the facility's processing environment, where many other flour products were then contaminated due to lack of effective facility-related preventive controls.

The conclusion that this outbreak was a facility-related hazard is supported by the multiple flour products found with the outbreak strain(s) over the course of several months of

production outlined in the FDA official statement about the outbreak and traceback investigation (included here verbatim):

FDA's traceback investigation determined that the raw dough eaten or handled by ill people or used in restaurant locations were made using General Mills flour that was produced in November 2015 and select production dates through February 10, 2016 at the General Mills facility in Kansas City, Missouri. Epidemiology, laboratory and traceback evidence available at that time indicated that General Mills flour manufactured at this facility is the likely source of the outbreak. On May 31, 2016, following a conference call among FDA, CDC and the firm, General Mills conducted a voluntary recall of flour products produced between November 14, 2015 and December 4, 2015. Recalled products were sold in stores nationwide but may still be in consumers' pantries and were sold under three brand names: Gold Medal flour, Signature Kitchens flour and Gold Medal Wondra flour. The varieties include unbleached, all-purpose, and self-rising flours. On June 10, 2016, FDA performed Whole Genome Sequencing (WGS) on E. coli O121 isolates recovered from an open sample of General Mills flour belonging to a Colorado consumer who was sickened, and it was found to be closely related genetically to the clinical isolates from human illnesses. The flour came from a lot that General Mills had recalled.

Testing by FDA has identified E. coli O121 in open product samples collected from ill people in Arizona and Oklahoma. FDA's WGS analysis of the E. coli O121 isolates from the Arizona and Oklahoma product samples showed that they were closely related genetically to the outbreak strains. The General Mills flour sample collected from the Oklahoma patient was produced outside of the company's original recall date range. On July 1, 2016, following a call with the FDA and CDC General Mills expanded its recall of Gold Medal flour, Wondra flour, and Signature Kitchens flour. The FDA used WGS to characterize isolates provided by General Mills to FDA. FDA provided characterization information to General Mills that an E. coli O26 isolated from their returned retail flour is closely related genetically to a clinical isolate that was subsequently added to the outbreak cluster. WGS characterization analysis of additional E. coli isolates provided by General Mills to FDA did not return other clinical isolates that were closely related genetically. On July 25, 2016, following a call with the FDA and CDC, General Mills expanded its recall a second time to include products produced on select dates through February 10, 2016.

Food and Drug Administration (2016a)

As described in [Table 4.9](#), the FDA has established tolerance levels for specific hazards in certain foods (e.g., whole black pepper may contain 1 mg/pound of mammalian excreta). There is “zero tolerance” for the presence of any level of certain pathogens, such as *Listeria monocytogenes*, in ready-to-eat (RTE) foods ([Food and Drug Administration, 2016d](#)). However, no tolerance levels have been set for pathogens such as *E. coli* in foods such as flour (which is assumed to be baked by the consumer or the retail food service/sales establishment) because such processing (baking at an appropriate time/temperature) will kill the pathogen. Flour has historically been considered a raw agricultural product, so it has not been

required by regulation to be subjected to a pathogen elimination step during processing. This type of outbreak from what the FDA considers a raw agriculture ingredient highlights the business risks to both the food manufacturer and the retail seller of products made with contaminated flour products.

Following this outbreak, the FDA made the following recommendations to consumers ([Food and Drug Administration, 2016c](#)): “FDA warns against eating raw dough products made with any brand of flour or baking mix before cooking. Consumers should always practice safe food handling and preparation measures when handling flour.” However, regardless of any FDA regulatory requirements or consumer recommendations, pathogen contamination of a product that may be eaten raw (cookie dough, cooked breads dusted with flour, etc.) or not completely cooked (soft breads, pizza dough, etc.) is a hazard that each flour manufacturer and each retail business that sells flour-containing products should understand and prevent in its products.

5.3 Preparing for a Hazard Analysis

A food manufacturing facility is in constant flux; there is employee changeover, equipment use and repair, cleaning and sanitation processes, and food production sometimes over 24-hour periods. In addition, changes to volume/orders, storage processes, contractor use, etc. occur. One must coordinate prerequisite programs, current Good Manufacturing Practices (cGMPs), and hazard analysis and preventive controls into a Food Safety Plan to develop a road map for safe food production.

The focus of Preventive Controls for Human Food (PCHF) is to combine the best means to prevent hazards in foods into a Food Safety Plan that can be monitored and updated regularly as the food facility’s business changes. Once you have identified potential food ingredient- ([Chapter 3](#)) and process and facility-related ([Chapter 4](#)) hazards, the next decision is determining which hazards are reasonably likely to occur and whether their severity is significant. This is normally called a hazard analysis and is similar to the hazard analysis performed in hazard analysis and critical control point (HACCP) ([Mortimore and Wallace, 2013](#)). The hazard analysis will guide you into determining whether the potential hazards require preventive controls or not.

Probably the best resource for conducting a hazard analysis to meet the PCHF requirements is the FDA’s Draft Guidance on Hazard Analysis and Risk-based Preventive Controls for Human Foods ([Food and Drug Administration, 2016b](#)), which we reference throughout this book. Note that although this and other FDA guidance documents may still be in draft form at the time of this writing, we reference them because they represent the current best thinking on the use of preventive controls to prevent hazards in foods.

To ensure it is designed, performed and updated appropriately, a hazard analysis is best conducted by the supplier as a team exercise. The retail buyer should ensure its potential ingredient and process and facility-related hazards are included in this hazard analysis, but allow the supplier to first perform the analysis due to the knowledge of the facility design and personnel who work there. The hazard analysis at the supplier’s facility should be led by an

individual who also knows the facilities and operations. A preventive controls qualified individual (PCQI) who also has experience in HACCP, food safety management, and the facility's food production operations is ideally suited to lead the hazard analysis. The team providing input during a hazard analysis should include the following, as appropriate to the organization:

- Food safety supervisors and managers
- Facility/plant managers
- PCQI(s)
- Production supervisors
- Quality assurance (QA) supervisors
- Trainers
- Packaging supervisors
- Sales managers (those overseeing purchasing orders)
- Warehouse supervisors
- Shipping supervisors
- Receiving supervisors
- Sanitation operators (including any contractor cleaning and sanitation business managers)
- Facility equipment engineers
- Facility maintenance supervisors
- Environmental monitoring supervisors
- Laboratory managers

As discussed in the Preface and in [Chapter 2](#), the FDA has already established important resources and training courses for PCHF via the Food Safety Preventive Controls Alliance (FSPCA). Individuals who take the FSPCA's PCHF course are able to serve as PCQI on the food safety team. The knowledge gained in taking the FSPCA's PCHF course is important to the food safety management within the food manufacturing facility.

Even though the FDA only requires that each facility has a single PCQI, we recommend that each of the supervisors and managers that work in a supplier's facility listed above take the FSPCA PCHF course and gain PCQI status to ensure the best operational execution of preventive controls within the facility. Doing this will also ensure a more comprehensive knowledge of preventive controls within the business to ensure enterprise-level management. Although the cost of training each individual might seem high, a food safety/QA manager/supervisor could become a lead trainer for the PCHF course and then train others in the organization, leading to significant savings in course and travel expenses (and time). For an individual to be certified to be a lead instructor, he/she must first take the basic PCHF course, then apply to a selection committee to be approved to take the 2-day lead instructor ("train the trainer") course. More information on the qualifications needed to become a lead instructor (which are typically met by individuals at the food safety or QA manager level) can be found on the FSPCA website.

We, therefore, recommend that larger organizations consider having one designated lead instructor for the FSPCA PCHF course who can then teach the course to other members of the food safety team. This will instill PCQI-level knowledge in each of the functional areas of the food processing business. In addition, having such broad knowledge across the organization will enable more rapid updates to Food Safety Plans when changes affecting various functional areas occur.

If the food manufacturing facility already has a current HACCP plan for each of the products it makes, the HACCP plans hazard analysis (except for the lack of the PCHF-specific hazards: radiological hazards and hazards associated with intentional adulteration for financial gain) will likely be similar to the PCHF hazard analysis. However, each new food product should be put through the hazards (ingredient- and process and facility-related) identification and analysis process regardless of any existing HACCP plans due to the constant changes that occur in a food manufacturing facility.

5.4 A Plan for the Food Safety of Each Product

Taking a step back, let us consider how a hazard analysis fits into the Food Safety Plan. A brief description of each component of the Food Safety Plan can be found in [Chapter 2](#). As discussed in [Chapter 2](#), food types or production methods can be grouped together under a single Food Safety Plan if hazards and preventive controls are similar. For example, if a facility manufactures 10 different types of raw cookie dough, a single Food Safety Plan may suffice for all 10 products. A separate Food Safety Plan is likely not necessary for every product that a facility produces. However, any features of a Food Safety Plan that are unique to a specific ingredient, product or production method (e.g., ingredient differences that add new hazards to an existing product) will need to be clearly specified within the plan ([Food and Drug Administration, 2013](#)).

Because some products under the same Food Safety Plan will contain different ingredients, even if processed the same and manufactured in the same facility, it is best to ask the supplier to provide you with the Food Safety Plan for each product being made for you and to request updates if any ingredients or processes are changed.

In the remaining sections of this chapter, a hazard analysis for a double chocolate cookie dough is discussed. To introduce you to this product, an example product information sheet and a manufacturing flow diagram from the Food Safety Plan are shown in [Figs. 5.2 and 5.3](#), respectively.

5.5 The Hazard Analysis Process

The FDA requires a written hazard analysis as part of the required Food Safety Plan for all human food products manufactured under its authority, and so should you if you are a retail buyer of food ingredients and products. The FDA together with the FSPCA goes to great lengths to help food manufacturers more easily meet these requirements by providing

PLANT NAME Completely Cookie Inc.	ISSUE DATE February 22, 2017	PAGE 1 of 1
ADDRESS 1500 Cookie Way Denver, CO 23333	SUPERSEDES NA	PRODUCT CODE Double Chocolate Cookie Dough 0099848
PRODUCT DESCRIPTION DISTRIBUTION, CONSUMERS, AND INTENDED USE		
Product Name(s)	Raw chocolate cookie dough- restaurant service portioned	
Product Description, including Important Food Safety Characteristics	Product will be mixed, chilled, and packaged in tubs to make 20 servings (serving size 2.5 oz.)	
Ingredients	Liquid eggs (pasteurized), white flour, cocoa powder, yeast extract, salt, butter, sugar, and almond extract	
Packaging Used	50 oz. plastic tubs	
Intended Use	Mixed with dairy (milkshake base) ingredients in restaurants	
Intended Consumers	Restaurant customers (all ages)	
Shelf Life	3 months refrigerated/6 months frozen	
Labeling Instructions related to Safety	Keep refrigerated after thawing	
Storage and Distribution	Frozen	
Approved by (Name and Signature): Christopher King <i>Christopher King</i>	Date: February 22, 2017	

Figure 5.2
Food safety plan product information sheet.

templates for all parts of a Food Safety Plan, including the hazard analysis. As a retail buyer, you can use the same forms to help track the safety of each ingredient or product you purchase to use in your products or sell to consumers in your establishments.

The steps required to perform a comprehensive hazard analysis your supplier should perform include:

1. List each process step and ingredients used.
2. Identify known or reasonably foreseeable food safety hazard(s) at each process step (the potential ingredient-related or process and facility-related hazard).
3. Determine if the hazard(s) requires a preventive control (and explain what is the threshold for when a preventive control is needed) by looking at the severity and the probability that it might occur if you do not have a preventive control.
4. Justify your decision, especially if you decide a preventive control is not needed for a particular hazard.

5.5.1 List Each Process Step and Ingredients Used

The hazard analysis process begins with listing each process step and ingredient used. Although no specific format is required, a convenient way to do this is to use list this information in a table format such as that shown in Fig. 5.4. A partial list of process steps where different ingredients are used are shown in Column 1.

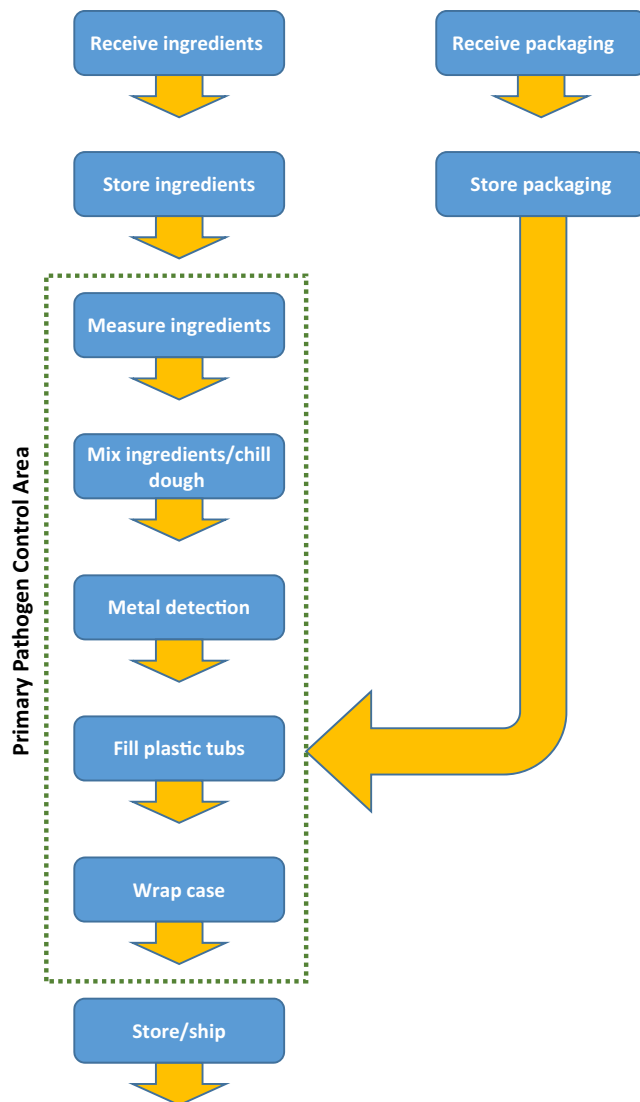


Figure 5.3
Manufacturing flow diagram for double chocolate cookie dough.

5.5.2 Define and List Potential Ingredient and Process and Facility-Related Hazards Related to Each Process Step

The next step in the hazard analysis is the identification and listing of all *potential* hazards associated with the ingredients and process/facilities involved with making a product (those discussed in [Chapters 3 and 4](#)). This needs to be a written list, as shown in Column 2 of [Fig. 5.4](#). You should list potential hazard by their associated ingredient/processing step (Column 1).

HAZARD ANALYSIS - DOUBLE CHOCOLATE COOKIE DOUGH								
(1) Ingredient / Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Receiving Heat-treated flour ingredient	B	Shiga-toxin <i>producing E.coli</i> <i>/Salmonella</i>	X		Flour is a raw agricultural product. Recent outbreaks from flour demonstrate the hazard is probable, but heat treatment should eliminate pathogens			
	C	Mycotoxins	X		Mycotoxins are associated with storage of raw agricultural products like flour.			
	P			X				
Receiving Pasteurized liquid eggs ingredient	B	<i>Salmonella</i>	X		Outbreaks and recall data show the pathogen occasionally is found in this ingredient, but pasteurization should eliminate the pathogen			
	C		X		Egg is an allergen and must be declared on packaging			
	P			X				
Receiving Cocoa powder ingredient	B	<i>Salmonella</i>	X		Cocoa powder is a raw agricultural product. Heat treatment should eliminate pathogens, but recent outbreaks from Cocoa demonstrate the hazard is probable			
	C			X				
	P			X				
Receiving Yeast extract ingredient	B			X				
	C	Soy (allergen)	X		Soy can be found in some yeast extract when the yeast is grown in soy base			
	P			X				
Receiving Iodized salt ingredient	B			X				
	C	Arsenic, Copper, Lead, Cadmium, Mercury, Tin, and Sulfate	X		All chemical hazards are tested by the supplier and COA provided for verification			
	P			X				

Figure 5.4

HAZARD ANALYSIS - DOUBLE CHOCOLATE COOKIE DOUGH								
(1) Ingredient / Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Receiving Butter ingredient	B	<i>Listeria monocytogenes</i>	X		<i>Listeria</i> is often found in dairy products and continues to cause foodborne disease outbreaks			
	C	Milk (allergen)	X		Milk is used to make butter, and milk is an allergen and must be declared on packaging			
	P			X				
Receiving Sugar ingredient	B			X				
	C	Mycotoxins	X		Mycotoxins are associated with storage of raw agricultural products like sugar.			
	P			X				
Receiving Almond extract ingredient	B			X				
	C	Tree nut (allergen)	X		Tree nuts (almonds) are used to make almond extract, and tree nuts are an allergen and must be declared on packaging			
	P			X				
Mixing ingredients in mixer with sweep surface paddles	B			X				
	C			X				
	P	Metal shavings paddles	X		Metal shavings that may come off of the paddles while mixing the ingredients			

Figure 5.4—cont'd

Recommended hazard analysis worksheet. *B*, biological hazard; *C*, chemical hazard; *P*, physical hazard.

For example, in our example of a **double chocolate cookie dough** product made by Completely Cookie Inc. (begun in [Chapter 3](#)) that a retail food service chain plans to purchase to be distributed to its retail establishments, the supplier uses eggs, white flour, cocoa powder, yeast extract, salt, butter, sugar, and almond extract to make the cookie

dough. Based on ingredient-based hazards, you identified the following food ingredient–hazard pairs:

- Liquid eggs—*Salmonella*
- White flour—**Shiga toxin-producing *E. coli*/*Salmonella*, mycotoxins**
- Cocoa powder—*Salmonella*
- Yeast extract—**Soy (allergen)**
- Iodized salt—**Arsenic, copper, lead, cadmium, mercury, tin, and sulfate**
- Butter—*L. monocytogenes*, **milk (allergen)**
- Sugar—**Mycotoxins**
- Almond extract—**Tree nuts (allergen)**

You note that the salt supplier has eliminated all possible hazards (salt is a mineral that could contain contaminants such as arsenic, copper, lead, cadmium, mercury, tin, and sulfate that exceed safety limits). You know that sugar is produced and held in large silos where mycotoxins could be produced by fungal contamination. In the past, the only potential hazard associated with white flour would be *Salmonella* hazard, but recent outbreaks of STEC infections associated with flour ([Centers for Disease Control and Prevention, 2016](#)) add a new hazard to this ingredient.

After identifying food ingredient–hazard pairs, you next identified all likely process and facility-related hazards. Allergens or pathogens brought into the facility via ingredients could potentially cross-contaminate other finished products. If the food manufacturing facility also makes other baked products with peanuts, tree nuts, and uses cheese powder, emulsifiers, lecithin, and starches in the same production area and equipment, such hazards should be considered. The facility also uses stainless steel mixing kettles with swept surface paddles that could introduce metal pieces into the foods as a possible physical hazard.

The list of process and facility-related hazard pairs would be similar to this list:

- Processing environment—*Salmonella*
- Processing environment—**Shiga toxin-producing *E. coli*/*Salmonella***
- Processing environment—*Salmonella*
- Processing environment—*L. monocytogenes*
- Processing equipment—**Metal shavings**
- Processing environment/equipment/storage—**Peanut allergens**
- Processing environment/equipment/storage—**Tree nut allergens**
- Processing environment/equipment/storage—**Cheese powder (Wheat starch and milk allergens)**
- Processing environment/equipment/storage—**Emulsifiers (Milk allergens)**
- Processing environment/equipment/storage—**Starch (Added sulfites)**
- Processing environment/equipment/storage—**Lecithin (Soy allergens)**

Note that [Fig. 5.4](#), for the sake of brevity, does not include all of these process- and facility-based hazards. In a complete hazard analysis, each of these hazards should be identified at each process step and listed in the written hazard analysis.

5.5.3 Evaluate Which Potential Hazards Require a Preventive Control and Provide Justification for Your Decision

Next, you should assess those potential hazards at each process stage to determine if each requires a preventive control. In other words, you need to answer the question “Do any potential food safety hazards require a preventive control?” with a “yes” or “no” on the written hazard analysis (Column 3 of [Fig. 5.4](#)).

In making these decisions, you should consider additional factors in the context of each potential hazard such as product intrinsic factors, processing procedures, microbial content of the product, facility design, equipment design and use, packaging, employee health, hygiene, and education in the facility, storage conditions between packaging and the consumer, and intended use of the final product by consumers. Then you should justify the answer you make for each hazard at each process step (Column 4 of [Fig. 5.4](#)).

The FDA has provided a list of questions that can be helpful as an additional assessment of hazards likely to occur in a food product to aid in the justification of whether the hazard may require a preventive control ([Table 5.1](#)).

A key part of the hazard analysis is to determine if a potential hazard in a food product is already under a preventive control. For example, consider the ingredient of flour in a product that is likely to be consumed raw (e.g., the double chocolate cookie dough that is expected to be used by restaurants without any further processing/cook step in desserts). A hazard associated with the flour ingredient (a raw agricultural product) is contamination with bacterial

Table 5.1: Questions to consider when assessing whether a potential hazard requires a preventive control.

Intrinsic factors (physical characteristics and composition of the product during and after processing)	<ul style="list-style-type: none"> • What hazards may result if the food composition is not controlled? • Does the food permit survival or promote pathogen growth and/or toxin formation during subsequent steps in the manufacturing process or distribution/storage? • Are there similar products already in the marketplace, and if so, which hazards have been associated with those products? What is the food safety record of those products?
Processing procedures	<ul style="list-style-type: none"> • Does the process include a controllable processing step that destroys pathogens? If so, which pathogens? Consider not only vegetative cells but also spores, which are typically more resistant to inactivation treatments compared with their vegetative counterparts. • Is the product susceptible to recontamination between processing and packaging? If so, what are the biological, chemical (including radiological), or physical hazards potentially associated with the process environment?

Table 5.1: Questions to consider when assessing whether a potential hazard requires a preventive control.—cont'd

Microbial content of the food	<ul style="list-style-type: none"> • What is the baseline microbial content of the food? • Does the microbial population change during the normal storage time of the food prior to consumption? • Do changes in the microbial population affect the safety of the food? • Based on the answers to the above questions, is there a significant likelihood of any biological hazards?
Facility design	<ul style="list-style-type: none"> • Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat (RTE) foods when this is necessary for food safety? If not, what are the hazards that could contaminate the RTE product? • Is positive air pressure maintained in product packaging areas? Is this required for product safety? • Is the traffic pattern for people and moving equipment a significant source of contamination?
Equipment design and use	<ul style="list-style-type: none"> • Will the equipment provide the necessary time-temperature control to ensure a safe product? • Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe product? • Is the equipment reliable and maintained in good repair? • Is the equipment easy to clean and sanitize? • Can parts of the equipment contaminate the product and thereby introduce physical hazards? • What product safety devices are used to control the potential for physical hazards to contaminate the product? Examples include: metal detectors, magnets, sifters, filters, screens, thermometers, bone removal devices, dud detectors • Are allergen protocols needed for using the same equipment for different products?
Packaging	<ul style="list-style-type: none"> • Does the method of packaging affect the rate of growth of microbial pathogens and/or the formation of toxins? • Is the package clearly labeled with the appropriate storage instructions, e.g., “Keep refrigerated,” if required for safety? • Does the package include instructions for the safe handling and preparation of the food by the end user? • Is the packaging material resistant to damage and effective in preventing postpackaging microbial contamination? • Are tamper-evident packaging features used? • Are each package and case legibly and accurately coded?

pathogens, particularly Shiga toxin-producing *E. coli* or *Salmonella*. The flour supplier heat-treats the flour. The flour supplier has data demonstrating a 5-log reduction of these pathogens in the flour after the heat treatment method. Although heat-treated flour can reduce the quality of some baking foods, it may still be important to use heat-treated flour if the product in which it will be used will be eaten or handled by consumers in its raw form or if it will not always be baked properly in a restaurant (as occurred in the case study at the beginning of this chapter).

You may have confidence that a particular hazard associated with flour is already under preventive control (heat treatment) instituted by the supplier as long as you can verify this preventive control (for example, by pathogen testing that the supplier conducts) for each lot of flour your supplier receives. By having this justification written in the hazard analysis in the Food Safety Plan, you can easily track that this hazard is under a preventive control at all times (i.e., the flour ingredient is heat treated before receiving) in case something changes (e.g., Completely Cookie sources flour from a different supplier that does not heat-treat the flour).

Without this one step of writing and tracking the safety of the flour ingredient in the hazard analysis, your product could be a “ticking time bomb.” It could be subject to a required recall if FDA discovers that the flour was not heat-treated when the cookie dough may be served to consumers in the raw form. The flour could also become a source of environmental contamination of the facility with Shiga toxin-producing *E. coli* or *Salmonella*. The flour could trigger a serious foodborne disease outbreak causing illness or deaths to many consumers (including children, who are most vulnerable to these pathogens and may be most likely to be served underbaked cookies or frozen desserts with raw cookie dough).

One excellent resource to use when justifying whether a hazard requires a preventive control is Appendix 1 of the FDA’s Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food ([Food and Drug Administration, 2016e](#)). This appendix contains over 200 pages of tables with information on potential biological, chemical, and physical hazards that are food related and process and facility related. The potential hazard information in the appendix covers these ingredients and raw materials categories: bakery, beverage, chocolate and candy, dairy, dressings and condiments, egg, food additives, fruits and vegetables, game meat, grains, multicomponent foods (such as a refrigerated entrée or a sandwich), nuts, oil, snack foods, soups, spice, and sweeteners.

To help you identify/justify food-related and process-related hazards for the food categories listed above, the FDA groups the tables in Appendix 1 of the draft guidance document into three areas:

- **Tables 1A through 1Q** contain information that you should consider for potential food-related biological hazards.
- **Tables 2A through 2Q** contain information that you should consider for potential food-related chemical hazards.
- **Tables 3A through 3Q** contain information that you should consider for potential process-related biological, chemical, and physical hazards.

The assessment of those potential hazards as to whether or not they require a preventive control should also include the following:

- Evaluating the actual severity (the illness and disease) of the hazard after human consumption (e.g., <https://www.cdc.gov/foodsafety/diseases/index.html>)
- Evaluating the likely occurrence of the hazard via:
 - Past and present outbreaks (e.g., <https://www.cdc.gov/outbreaks/>)
 - Past and present recalls (e.g., <https://www.fda.gov/Safety/Recalls/>)
 - Scientific literature on the hazard (e.g., <https://www.cdc.gov/foodsafety/>)
 - The manufacturing facility's historical information (e.g., FDA warning letters to the facility, e.g., <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/>)
- Environmental pathogens and monitoring in RTE areas data (e.g., <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073110.htm>)

Thankfully, the FDA and CDC provide easy to access, extensive, and comprehensive resources to aid in this evaluation (see links above).

The evaluation of severity and occurrence of hazards in foods has already been performed for the majority of the known hazards available through these resources. However, as illustrated by the flour-associated Shiga toxin-producing *E. coli*/Salmonella outbreak described at the beginning of this chapter, hazards may become associated with new food ingredients, requiring new preventive controls. A review of the CDC and FDA resources above can quickly identify new hazards or old hazards associated with new ingredients/products. Another source of information on new and emerging hazards is PubMed. PubMed (<https://www.ncbi.nlm.nih.gov/pubmed>) is a free resource that is developed and maintained by the National Center for Biotechnology Information (NCBI), at the US National Library of Medicine (NLM). A simple search on PubMed for any hazard can be performed to stay abreast of the latest scientific literature on the severity and occurrence of the food hazards (and research on their root cause and the best means to prevent them).

As a retail buyer you should also carefully evaluate the food processing facility where your products will be produced by two important criteria: FDA warning letters (for example, see [Appendix A](#)) and environmental monitoring data. Many retail buyers also require additional reports about the facility where their products are produced including reports from Global Food Safety Initiative (GFSI) or ISO audits, internal audits, third-party audits, etc. These data can be important to compare with other potential suppliers of your products as well (e.g., if you have not selected a supplier yet) for the assurance of hazard prevention via capability. FDA warning letters about any facility can be found by searching at the website above. You can more easily stay abreast of all future warning letters by signing up to receive updates via email.

If a facility performs monitoring for environmental pathogens in RTE areas, these data can be useful in evaluating where an ingredient- and process-related hazard (even those not associated with your product, e.g., other ingredients with potential hazards used by the supplier in this

facility) in this facility may be an issue. These data should be used to determine if a potential hazard must have a preventive control in the hazard analysis.

5.6 Additional Factors That FDA Requires in the Evaluation of Potential Hazard That May Require a Preventive Control

These factors must be considered in all potential hazard evaluations to ensure the safety of the finished food product and are listed verbatim from the FDA's Draft Guidance on Hazard Analysis and Risk-based Preventive Controls for Human Foods (FDA, 2016b), which is not final at the time of this publication here (thus you should check the FDA website for any changes to this requirement).

When evaluating hazards, you must consider the effect of the following on the safety of the finished food for the consumer (21 CFR 117.130(c)(2)):

- ***The formulation of the food:*** The addition of certain ingredients such as acids and preservatives may be critical to the safety of the food, because they may inhibit growth of, or kill, microorganisms of public health significance. This could impact the evaluation at steps during production and storage with respect to the hazard of “pathogen growth.” A multicomponent food may have individual ingredients that do not support growth of undesirable microorganisms (e.g., because of pH or a_w), but when put together there may be an interface where the pH and a_w change (e.g., pies, layered breads). The formulation may contain an ingredient (e.g., a flavoring, coloring, or incidental additive) that is (or contains) an allergen that requires label control and possibly controls to prevent cross-contact.
- ***The condition, function, and design of the facility and equipment:*** The condition, function, or design of a facility or its equipment could potentially result in the introduction of hazards into foods. For example, older equipment (e.g., older slicing, rolling and conveying equipment) may be more difficult to clean (e.g., because of close fitting components or hollow parts) and, thus, provide more opportunities for pathogens to become established in a niche environment than modern equipment designed to address the problem of pathogen harborage in niche environments; in such instances enhanced sanitation controls may be appropriate. Equipment designed such that there is metal-to-metal contact may generate metal fragments; a preventive control such as metal detectors may be appropriate. A facility that manufactures, processes, or packs an RTE product such as fresh soft cheese may have cold, moist conditions that are conducive to the development of a niche where the pathogen *L. monocytogenes* can become established and contaminate food-contact surfaces and, eventually, foods; enhanced sanitation controls may be appropriate for such facilities. Facilities with closely spaced equipment should consider the impact of the close spacing on the potential for allergen cross-contact to be a hazard; targeted food allergen controls may be appropriate.

- **Raw materials and other ingredients:** A food can become contaminated through the use of contaminated food ingredients. Ingredients such as flavorings, colorings, or incidental additives may contain “hidden” allergens. Machinery-harvested produce may be contaminated with physical hazards, because the machinery can pick up foreign material from the field.
- **Transportation practices:** The safety of a food can be affected by transportation practices for incoming raw materials and ingredients or for outgoing finished product. For example, when a food requires time/temperature control for safety, time/temperature controls would be important during transportation. Distributing a food in bulk without adequate protective packaging makes the product susceptible to contamination during transportation—e.g., from pathogens or chemicals present in an inadequately cleaned vehicle or from other inadequately protected foods that are being co-transported and are potential sources of contamination.
- **Manufacturing/processing procedures:** Hazards may arise from manufacturing/processing processes such as cooling or holding of certain foods due to the potential for germination of pathogenic spore-forming bacteria such as *Clostridium perfringens* (*C. perfringens*) and *Bacillus cereus* (*B. cereus*) (which may be present in food ingredients) as a cooked product is cooled and reaches a temperature that will allow germination of the spores and outgrowth. Hazards also may arise from manufacturing/processing processes such as acidification due to the potential for germination of spores of *C. botulinum*, with subsequent production of botulinum toxin, if the acidification is not done correctly. Toxins can be produced by the bacteria *Staphylococcus aureus* (*S. aureus*) or *B. cereus* in a product that has been heated and held at room temperature during the manufacturing process if the product formulation supports growth and toxin formation by the bacteria and *S. aureus* or *B. cereus* is present in the ingredients of the product or is introduced by poor employee hygiene (e.g., *S. aureus*). Physical hazards may occur from metal fragments generated during the manufacture of food on equipment in which metal (e.g., wires, saw blades or knives) is used to cut products during manufacturing.
- **Packaging activities and labeling activities:** Preventive controls for glass may be needed for products packed in glass. Preventive controls for *C. botulinum* may be needed when packing certain foods in modified atmosphere packaging. Label controls may be needed to ensure all food allergens are listed on the label of packaged foods that contain allergens.
- **Storage and distribution:** Biological hazards are more likely to require a preventive control during storage and distribution in foods that require refrigerated storage to maintain safety than in shelf-stable foods.
- **Intended or reasonably foreseeable use:** Some foods that are intended to be cooked by the consumer may also have uses that do not include cooking, such as soup mixes

used to make dips. Whenever an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen, hazards such as *Salmonella* spp., *L. monocytogenes*, and *Escherichia coli* O157:H7 (*E. coli* O157:H7) must be considered to determine if they require a preventive control. (See 21 CFR 117.130(c)(1)(ii).)

- ***Sanitation, including employee hygiene:*** Sanitation measures and practices can impact the likelihood of a hazard being introduced into a food. For example, the frequency with which a production line is shut down for a complete cleaning can impact the potential for food residues to transfer pathogens from equipment to foods (e.g., pathogens present on raw produce that could carry over into the next production cycle on a line). Practices directed at worker health and hygiene can reduce the potential for transfer of pathogens such as *Salmonella* spp., hepatitis A, and norovirus.
- ***Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins):*** Hazards such as aflatoxin are subject to a weather-dependent effect in that aflatoxin levels in some raw agricultural commodities are more of a problem in some years than in others.

5.7 Keeping the Hazard Analysis Current

It will be important to continually verify that information within the written hazard analysis is correct (e.g., the flour is sourced from a supplier that heat-treats the ingredient, and verification that this supplier control is effective) so that you may have confidence that each hazard is under a defined and effective preventive control. Each preventive control should be monitored and verified during the processing of the ingredients into the final products, and this should be documented during each product production run ([Chapter 8](#)).

A hazard analysis must be updated not only regularly (every 3 years at an absolute minimum per 21 CFR Part 117.170) but also if there are any ingredient, process, facility, or other changes that may introduce additional hazards or if you become aware of new hazards. A change requiring a reanalysis of the Food Safety Plan including the hazard analysis can be as simple as a change in how the consumer/restaurant will use the food product, as in our example of a double chocolate cookie dough product that normally would be baked (a kill-step that would eliminate pathogenic bacteria), but is sometimes used in its raw form as an ingredient in RTE desserts.

To fully ensure each food product's hazard analysis is current, you should monitor for this information on a regular basis:

- Regular review of each specific product Food Safety Plan and its hazard analysis
- Regular assessments of all other products being made in the facility

- New/change in ingredients
- New/change in processes
- New/change in equipment and use
- New/change in facility use and products made (e.g., assessment of facility environment segregation still intact)
- New/change in secondary suppliers for any ingredient
- New potential hazards associated with ingredients or food products from academic, government, and industry trade group reports

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Preventive Controls

6.1 From Hazard Analysis to Risk-Based Preventive Controls

As introduced as a scenario in [Chapter 3](#), imagine you work for a quick service restaurant (QSR) chain, Bobbie's Burgers. You know the intoxicating aroma of freshly baked chocolate cookies is impossible for customers to resist, so you decide to supply your restaurants with double chocolate cookie dough that can be used to make freshly baked cookies on-site. You also know how popular your restaurant's frozen dairy desserts are and realize that the raw cookie dough could also be used as a spectacular add-in to those products as well.

You have identified a small company, Completely Cookie Inc., which can make the cookie dough for you. They will make it from liquid eggs, white flour, cocoa powder, butter, and sugar, with yeast extract, iodized salt, and almond extract added. The cookie dough will be mixed, chilled, and shipped in 50-oz plastic tubs, and shipped to your restaurants. The dough at some restaurants will be baked, but some restaurants may also use the raw dough in a frozen dairy dessert.

What kinds of preventive controls should Completely Cookie have in place for the cookie dough that they supply to your restaurants?

As detailed in [Chapter 5](#), the hazard analysis that Completely Cookie's food safety team performed as they developed their Food Safety Plan (FSP) identified significant food safety risks, including risks related to how restaurants will use the final product (as raw cookie dough) that they realized required preventive controls. As a retail buyer and/or food safety professional, you may not have as much expertise in identifying specific hazards that might be associated with cookie dough manufacturing as Completely Cookie's food safety team has.

You can, however, get a good idea of what hazards might be associated with a particular ingredient by visiting the FDA's Appendix 1 of their Draft Guidance Document on Preventive Controls ([U.S. Food and Drug Administration, 2016a](#)). The detailed tables and lists in this massive appendix outline specific biological, chemical, and physical hazards that might be considered for a large variety of food products. The key word here is "might": not every hazard in this table may be applicable nor will every hazard be identified within this document.

Searching through the FDA's table, you identify a number of ingredient-related hazards that could affect the cookie dough that Completely Cookie will be making for your restaurants.

Based on these ingredient-based hazards (Chapter 3), you identified the following food ingredient–hazard pairs:

- Liquid eggs—*Salmonella*
- White flour—**Shiga toxin–producing *Escherichia coli*/*Salmonella*, mycotoxins**
- Cocoa powder—*Salmonella*
- Yeast extract—**Soy (allergen)**
- Iodized salt—**Arsenic, copper, lead, cadmium, mercury, tin, and sulfate**
- Butter—*Listeria monocytogenes*, **milk (allergen)**
- Sugar—**Mycotoxins**
- Almond extract—**Tree nuts (allergen)**

Pathogenic *E. coli* (from flour), *Salmonella* spp. (from flour and cocoa), and *L. monocytogenes* (from butter) are biological hazards associated with raw cookie dough. Mycotoxins are a potential chemical hazard, primarily arising from the ingredient of sugar and flour. Because yeast extract is sometimes derived from yeast grown in a soy-containing media, the potential exists for soy to be present in the yeast extract as an undeclared allergen. Process-related hazards identified (Chapter 4) include recontamination with environmental pathogens such as *L. monocytogenes*, *Salmonella*, or Shiga-toxin producing *E. coli*. Mislabeling the dough or cross-contact with other products (such as a peanut butter cookie dough or cheese biscuits dough) made at the same facility could lead to the presence of an undeclared allergen (tree-nut allergens or peanut allergens, wheat and milk allergens from cheese powder) in the cookie dough. Other hazards might be introduced via processing aids such as milk allergens from emulsifiers, soy allergen from lecithin, or added sulfites from starch. Metal is a possible physical hazard since metal paddles are used to mix the dough, and the metal paddles may release metal fragments as they scrape the mixing bowl during the dough-making process.

It is important to remember that the FDA has indicated that the goal of preventive controls is to significantly **minimize** hazards or prevent them; it is not feasible to **eliminate them completely** (U.S. Food and Drug Administration, 2016a). However, a failure to identify and implement a preventive control for a significant hazard can result in a food being considered adulterated or misbranded. How does a food safety team determine which of the possible hazards identified for a food require a preventive control? How do you know when the risk for a particular hazard is significant enough to warrant a preventive control?

The FDA has said that preventive controls are needed to minimize the risk of **known and reasonably foreseeable** food safety hazards **that may cause illness or injury** if they are present in the products that you produce (U.S. Food and Drug Administration, 2016a). The FDA does not expect a manufacturer to have preventive controls in place for a hazard that was previously unknown. However, it is important that the organization keep abreast of new food safety hazards that arise in similar products made elsewhere because the Preventive Controls for Human Foods (PCHF) regulations at 21 CFR Part 117.170(b)(2) require that a manufacturer revises the FSP whenever new hazards are identified.

As a retail buyer, you will want to be aware of new risks as well and to ensure that your suppliers have a system that alerts them to new hazards and that their FSP is updated accordingly. FDA's food recalls, market withdrawals, and safety alerts ([U.S. Food and Drug Administration, 2017](#)), CDC outbreak list and alerts ([Centers for Disease Control and Prevention, 2017](#)), [foodsafety.gov](#), the USDA's current recall and alert list ([USDA Food Safety and Inspection Service, 2017](#)), annual reports of the FDA Reportable Food Registry ([U.S. Food and Drug Administration, 2016d](#)), and CDC's Foodborne Outbreak Online Database (FOOD Tool) ([Centers for Disease Control and Prevention, 2016](#)) are excellent online, up-to-date resources to monitor new and trending food safety concerns. Many of these websites have searchable databases ([Fig. 6.1](#)) to simplify finding the most relevant information. You can also sign up for email update services that bring summaries of new concerns to your email inbox as they occur.

These website and email services can also be used to assess how much risk a specific concern may be for a particular food. A supplier's food safety team may determine that a particular risk is minimal enough that a preventive control is not needed. As a retail buyer, you will want to make sure you agree with such assessments. [Chapter 5](#) also discusses some key considerations for determining which identified potential hazards should or should not include a preventive control.

Completely Cookie's hazard analysis (which should exist as a written document within their FSP) has identified a variety of hazards as risks that require preventive controls ([Fig. 5.4](#)). Once the hazards that need preventive controls are recognized, the next task for a food safety team as they develop their FSP is to **identify** and **implement** preventive controls for each of these hazards. What preventive controls should Completely Cookie be using to reduce risks from these hazards?

This chapter will discuss what preventive controls are, including the different types of preventive controls (process preventive controls, food allergen preventive controls, sanitation preventive controls, supply-chain controls, recall plans, and other controls). Subsequent chapters ([Chapters 7 and 8](#)) will discuss validation and implementation of preventive controls (including monitoring, verification, and corrective actions). Each of these activities will be important to retail food businesses as they develop food safety specifications for their products and consider the best means to manage the food safety of their products via their food safety management systems (e.g., supplier facility internal and third-party audits).

6.2 What Are Preventive Controls?

The PCHF regulations define “preventive controls” in 21 CFR Part 117.3 as follows:

*Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to **significantly minimize** or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis*

U.S. Food and Drug Administration (2015a)

U.S. Department of Health and Human Services

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Recalls, Market Withdrawals, & Safety Alerts

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The list below provides information gathered from press releases and other public notices about certain recalls of FDA-regulated products. Not all recalls have press releases or are posted on this page. See [Additional information about recalls](#) for a more complete listing.

For recall notices older than 60 days, see the [Recall and Safety Alerts Archive](#).

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Date	Brand Name	Product Description	Reason/ Problem	Company
02/15/2017	Veggie Noodle Co	Butternut Spirals	Listeria monocytogenes	Veggie Noodle Co
02/14/2017	Guggisberg	Cheese	Listeria monocytogenes	Guggisberg Cheese Inc.
02/14/2017	Private Selection	Pie	Undeclared almonds and eggs	Legendary Baking
02/14/2017	Synergy Rx Pharmacy	Human Chorionic Gonadotropin (HCG) for	Lack of Sterility Assurance	Synergy Rx Pharmacy

Spotlight

- Frozen vegetable products (Listeria monocytogenes) CRF related Recalls
- Undeclared Peanut (from Cumin Ingredient) Recalls
- Enforcement Reports
- Recalls of Raw (Fresh and Fresh Frozen) oysters, clams, mussels, and whole and roe-on scallops

Industry Resources

- Guidance for Industry: Product Recalls, Including Removals and Corrections
- Industry Guidance: Information on Recalls of FDA Regulated Products
- ORA District and Headquarters Recall Coordinators
- Industry Notices and Guidance Documents

Consumer Resources

- Identifying Recalled Products
- Major Product Recalls

Figure 6.1

Screenshot of the FDA’s recalls, market withdrawals, and safety alerts webpage. From *U.S. Food and Drug Administration, 2017. Recalls, Market Withdrawals, & Safety Alerts (Online)*. Available from: <http://www.fda.gov/Safety/Recalls/>.

The FDA also defines “significantly minimize” within that same section of the regulations as “to reduce to an acceptable level, including to eliminate.”

As discussed in [Chapter 2](#), preventive controls will be a familiar concept to anyone familiar with hazard analysis and critical control point (HACCP). Activities such as heat-treating foods to kill pathogens (biological hazards), weighing a food additive to ensure it is present at appropriate (i.e., nontoxic) levels (chemical hazard), or using a metal detector to ensure the absence of metal fragments (physical hazard) are common controls implemented within a HACCP plan.

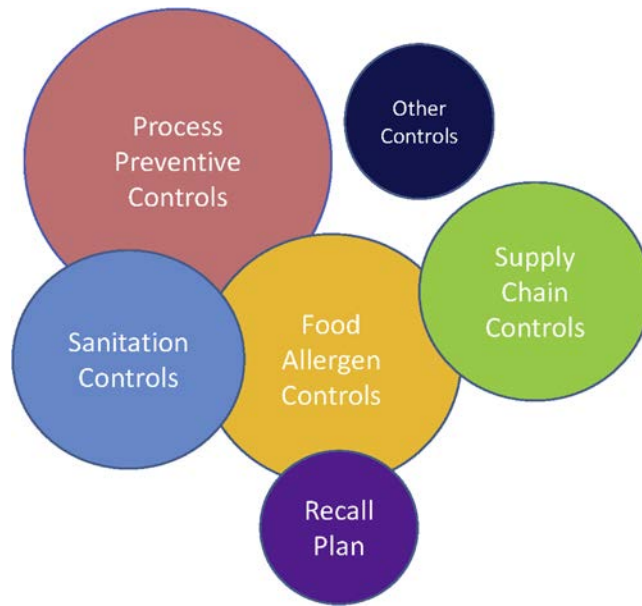


Figure 6.2

The six different types of preventive controls.

However, the FDA goes further in the preventive controls regulations and defines additional preventive controls beyond the process preventive controls that are the foundation of HACCP. Now all of the previously mentioned activities and more are considered preventive controls. For example, the following activities are now considered preventive controls under PCHF:

- The use of color-coding to indicate that a particular tool should only be used on products that do not contain any allergens such as tree nuts or peanuts (two major allergens)
- The review of a Certificate of Analysis for chili powder to ensure it does not contain wheat flour, an allergen
- The defined use of a particular sanitizing solution to clean and sanitize a piece of equipment used to slice ready-to-eat meats prior to packaging (to reduce the possibility of environmental *L. monocytogenes* contaminating the meat)
- The audit and approval of a supplier of flour to ensure that the flour received by a manufacturing company such as Completely Cookie, Inc. is heat-treated to inactivate pathogens such as Shiga toxin-producing *E. coli* and *Salmonella*
- A detailed, written plan for a recall in the event that a hazard is identified in a food product after it has reached the marketplace

The preventive controls regulations identify six different types of preventive controls (21 CFR Part 117.135(c)), as shown in Fig. 6.2. The categories of preventive controls are depicted in Fig. 6.2 as overlapping circles to emphasize that some of these control categories overlap and

the definitions do not always delineate black-and-white categories. As will become clear in subsequent sections of this chapter, you (or your manufacturers) may consider a particular control a process preventive control, while others might classify the same activity as a food allergen control or a sanitation control. The name of the category is not important except in the organization of the documentation; what is important is that each identified hazard has a preventive control that is properly implemented to control the hazard.

The control categories in [Fig. 6.2](#) are also shown as circles of different (somewhat arbitrary) sizes. The relative importance of each type of control will vary considerably according to the food product, its associated hazards, and a manufacturer's own facilities and food safety management systems. However, in most cases, process preventive controls will represent a major type of control used. In contrast, the recall plan, while required by the PCHF regulations whenever a hazard analysis indicates a preventive control is needed ([Food Safety Preventive Controls Alliance, 2016b](#)) should be considered a preventive control to be used of last resort (other controls should be used whenever possible to prevent the need for a recall).

As an aside, a retail food business should have a robust recall program as well to ensure any recalled products from its suppliers can be removed from sales to customers across its chain. The recall program should also be able to respond when ingredients are used to produce new products as prepared foods in the restaurant (e.g., by communicating to each quickly and tracking product lots removed from sale).

Each of the types of preventive controls is discussed further in [Sections 6.3–6.8](#).

6.3 Process Preventive Controls

Process preventive controls are those control activities that are performed on food directly. They represent the most familiar type of preventive control, as they are analogous to the types of controls found in HACCP plans. Process controls, quite simply, involve activities that can be done during the manufacturing process to reduce the risk of a particular hazard.

Examples of process controls include the following nonexhaustive list:

- Lethality treatments:
 - Heat treatments (to control biological hazards such as *Salmonella* from flour or eggs in cookie dough, *L. monocytogenes* in milk used to make butter)
 - High-pressure processing (to control biological hazards)
 - Irradiation (to control biological hazards)
- Time/temperature control (to control biological hazards, including refrigeration or freezing to prevent growth of *L. monocytogenes* in a ready-to-eat product)
- Formulation process controls: Water activity, pH, acidification, addition of antimicrobial agents such as sodium lactate (to control biological hazards)
- Dehydration, drying (to control biological by reducing water activity)

- Recipe management: ensuring addition of the correct amounts of certain food ingredients or additives (that can cause toxicity at higher levels) to control ingredient-related chemical hazards, or adding asparaginase to bread dough to prevent formation of acrylamide (a chemical hazard) during baking (Xu et al., 2016)
- Storage of grains, tree nuts, peanuts, fruits to control moisture to prevent fungal growth, which could generate mycotoxins (ingredient-based chemical hazards), or physical sorting of nuts to remove those that appear to have fungal growth on them
- Postprocessing controls such as elimination of dark-colored potato chips via optical sorting to reduce acrylamide hazards (a process-based chemical hazard) (U.S. Food and Drug Administration, 2016c; FoodDrinkEurope, 2011)
- Running a product through a metal detector, X-ray device, or examination of processing equipment for damage after using it in a way that could have resulted in metal fragments being introduced into a product (to control a process-based physical hazard)

6.3.1 Linking Process Preventive Controls With Hazards in the Hazard Analysis

Let us return to some of the hazards identified in Hazard Analysis Worksheet from Chapter 5 for the double chocolate cookie dough. What **process** preventive controls could be applied for some of the identified hazards that need preventive controls (Fig. 6.3)?

The new information on preventive controls is incorporated into the hazard analysis as shown in Columns 5 and 6 [yellow highlighted (light gray in print versions)]. Completely Cookie, Inc. will control the physical hazard of metal shavings that might arise from the mixer paddles by using metal detection, so they have indicated this process control in Column 5.

HAZARD ANALYSIS-DOUBLE CHOCOLATE COOKIE DOUGH								
(1) Ingredient / Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Mixing ingredients in mixer with sweep surface paddles	B			X				
	C			X				
	P	Metal shavings	X		Metal shavings that may come off of the paddles while mixing the ingredients	Process control: Metal detection		X

Figure 6.3

Process preventive controls in hazard analysis. *B*, biological hazard; *C*, chemical hazard; *P*, physical hazard.

Metal detection will not be performed until just before the cookie dough is packaged (a later step), so this is indicated by the X in the “No” subcolumn under Column 6.

6.3.2 Critical Control Points and Critical Limits

Process preventive controls will usually have critical limits (a parameter or maximum and minimum values) at its critical control point (CCP) (a step in processing where a preventive control is being performed) that needs to be monitored and documented. For example, you may be trying to eliminate a bacterial pathogen such as *Salmonella* (potentially present in flour or in eggs) from cookie dough by using heat (baking). The baking process would be the CCP. The critical limit could be the internal temperature of the cookie during baking required to ensure that the *Salmonella* hazard will be eliminated.

In some cases, there may be more than one critical limit; for example, you may use a combination of temperature and time to ensure that a pathogen is inactivated when cooking. Critical limits may not have numerical values; for example, if you are using a metal detector to test for physical hazards, the critical limit could be “no metal fragments greater than 1 mm present that could cause injury.”

How is a critical limit determined? As will be discussed in more detail in [Chapter 7](#) (Validation), there should be documentation supporting the choice of the preventive control, including any critical limits, and that documentation should be applicable to the specific product that the control is being applied to in the FSP. For example, a bakery would want to reduce risks from *Salmonella* that might be present in the raw ingredients or that were introduced as the bread dough was being prepared. Heat is a well-known lethality treatment for bacterial pathogens. How do they know the baking process is effective in eliminating *Salmonella*? The bakery could use a predictive models such as the online Baking Process Kill Step Calculator ([AIB International](#)) and conduct tests within their commercial ovens to demonstrate that their preventive control (the baking process) reached temperatures sufficient to kill off any *Salmonella* that might be present in their bread dough. The specific temperature that each loaf needs to reach to kill off all *Salmonella* would be defined in this validation study and represents a critical limit for the CCP of baking ([Chapter 7](#) discusses validation of preventive controls in more detail).

Additional examples of critical limits include the following:

- For cooking: the temperature, possibly also the time, the humidity, the water activity, the thickness or composition of the food, etc.
- For mycotoxin testing: the maximum level that is allowed in an ingredient should be specified and be within allowable limits
- For bone detection via X-ray: no bone fragments larger than ½ in.² should be detected in any product during a manufacturing run

6.4 Food Allergen Preventive Controls

Just as the PCHF regulations expand the types of hazards that need to be considered, they also expand the types of preventive controls that need to be considered to manage significant risks. Food allergen preventive controls are a second type of preventive control that should be considered whenever any food allergen is present in a food manufacturing facility.

Food allergen controls generally fall into two categories:

- What you do to ensure that foods containing allergens are correctly labeled
- What you do to ensure that unexpected (undeclared) allergens do not get into foods that are not labeled to contain allergens

For many food products, both types of controls may be needed. Declared allergens (those that are supposed to be in the product) need to be listed correctly according to Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 ([U.S. Food and Drug Administration, 2004](#)). A product that is supposed to be free of an allergen but which is manufactured in a facility where a particular allergen is used in other products needs to have controls in place to ensure that product will not contain that allergen (as an undeclared allergen).

Some examples of food allergen preventive controls are found in [Table 6.1](#).

Table 6.1: Food allergen preventive controls.

Category of Food Allergen Preventive Control	Examples
Controls to ensure protection of food from allergen cross-contact	Identifying and marking allergen-containing ingredients at receiving
	Segregating and storing allergen-containing materials at receiving and warehousing
	Scheduling production of products based on allergen-containing recipes
	Physical separation of processes for nonallergen-containing and allergen-containing products
	Sanitation and cleaning practices
	Using full wet cleaning to remove allergenic materials prior to producing a nonallergen-containing product on the same line
Controls for labeling of finished foods	Using dedicated cleaning utensils and equipment for removing allergenic materials from food processing equipment
	Performing label review for each new batch of labels received at the facility
	Implementing procedures for application of correct label to product

From U.S. Food and Drug Administration, 2016a. Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food.

Completely Cookie realized that they needed to ensure that the ingredients they used did not contain any undeclared allergenic ingredients. The type of preventive controls (which overlap to some extent with supply-chain controls) to give such assurance are sometimes known as allergenic ingredient controls. For example, the yeast extract should not include any soy, as yeast extract is sometimes made from yeast grown in a soy-containing medium. The absence of soy in yeast extract is ascertained each time Completely Cookie receives a new lot of yeast extract from its supplier. Completely Cookie may also have a letter of guarantee from their yeast extract supplier that promises that no soy will be present in any yeast extract that they supply to Completely Cookie, with periodic testing of yeast extract ingredient required.

The food safety team at Completely Cookie also needed to develop a plan that ensures that the correct labels were placed on all the products they manufactured. Label controls represent one of the most critical food allergen preventive controls. A flowchart that summarizes food allergen preventive controls that can be used to ensure labeling is performed correctly is shown in [Fig. 6.4](#). Although this figure was designed for USDA-regulated products that must follow HACCP, the overall strategy shown could be used in any food manufacturing facility where the labels of incoming and/or outgoing products require careful attention to prevent food allergen hazards.

For example, Completely Cookie also needs to ensure that they use the correct recipe every time they make the raw cookie dough since they produce other products that contain other major allergens (peanuts and tree nuts) in the same facility. The food safety team at Completely Cookies determined that these food allergen risks (and likely others) were significant hazards that require food allergen preventive controls. An example of how Completely Cookie could list the **food allergen hazards** they identified and the preventive controls they plan to use to control them in their FSP is shown in [Fig. 6.5](#).

Note that several of these preventive controls straddle different categories: using a defined cleaning regimen to prevent allergen cross-contact from products made on shared equipment could be considered a food allergen control or a sanitation control (which will be discussed more in [Section 6.5](#)). Similarly, if Completely Cookie relies on their supplier to ensure that their yeast extract is free from soy, this control could be considered either a food allergen control or a supply-chain control (discussed in [Section 6.6](#)).

PRECAUTIONARY ADVISORY LABELING

Precautionary advisory labeling (PAL) is the voluntary use of statements such as “may contain peanuts” or “made in a facility that processes tree nuts” on labels. PAL can alert the consumer to the potential presence of an unintended allergen in a food product.

Can PAL be considered a preventive control?

No, according to the FSPCA PCHF Participant’s Manual (Food Safety Preventive Controls Alliance, 2016b). The FDA advises that PAL should not be considered a substitute for following cGMPs (U.S. Food and Drug Administration, 2006). Other food allergen controls and sanitation controls, together with GMPs, should be used to minimize or eliminate the risk of allergen cross - contact for a food product.

As a retail buyer, you will want to know what other food products your supplier makes within the same facility that your ingredient or food product is being manufactured. If you were purchasing raw cookie dough from a company such as Completely Cookie, you should know all the other products that they make at the facility where your cookie dough was being made and whether the other products contained allergens that could impact your cookie dough. Other questions related to food allergens that you (as a retail buyer) should consider include the following:

- Are other products containing allergens manufactured on the same equipment or using the same utensils as your products? If so, what are the manufacturer’s cleaning and scheduling processes?
- Do the same personnel work with different products made from different food allergen ingredients during a single shift?
- Is any allergen testing performed on equipment between runs or after cleaning steps?
- Is there a map that shows the movement of various products through the production facility to identify where allergen cross-contact might occur?

A comprehensive FSP should contain the information needed to address these questions. In addition, as was illustrated by the example in [Chapter 1](#), a facility walk-through may help a retail buyer understand how well product segregation is controlled and may allow a better assessment of whether their food allergen preventive controls are sufficient to ensure the safety of your final product.

More examples of food allergen preventive controls can be found in the draft FDA guidance ([U.S. Food and Drug Administration, 2016a](#)) and the Food Safety Preventive Controls Alliance (FSPCA) PCHF Participant’s Manual ([Food Safety Preventive Controls Alliance, 2016a](#)).

6.5 Sanitation Preventive Controls

Sanitation has long been a part of the current Good Manufacturing Practice (cGMP) requirements for food manufacturing facilities. Sometimes, however, sanitation becomes even more important and actually controls a significant risk in a food facility. For example, in our double

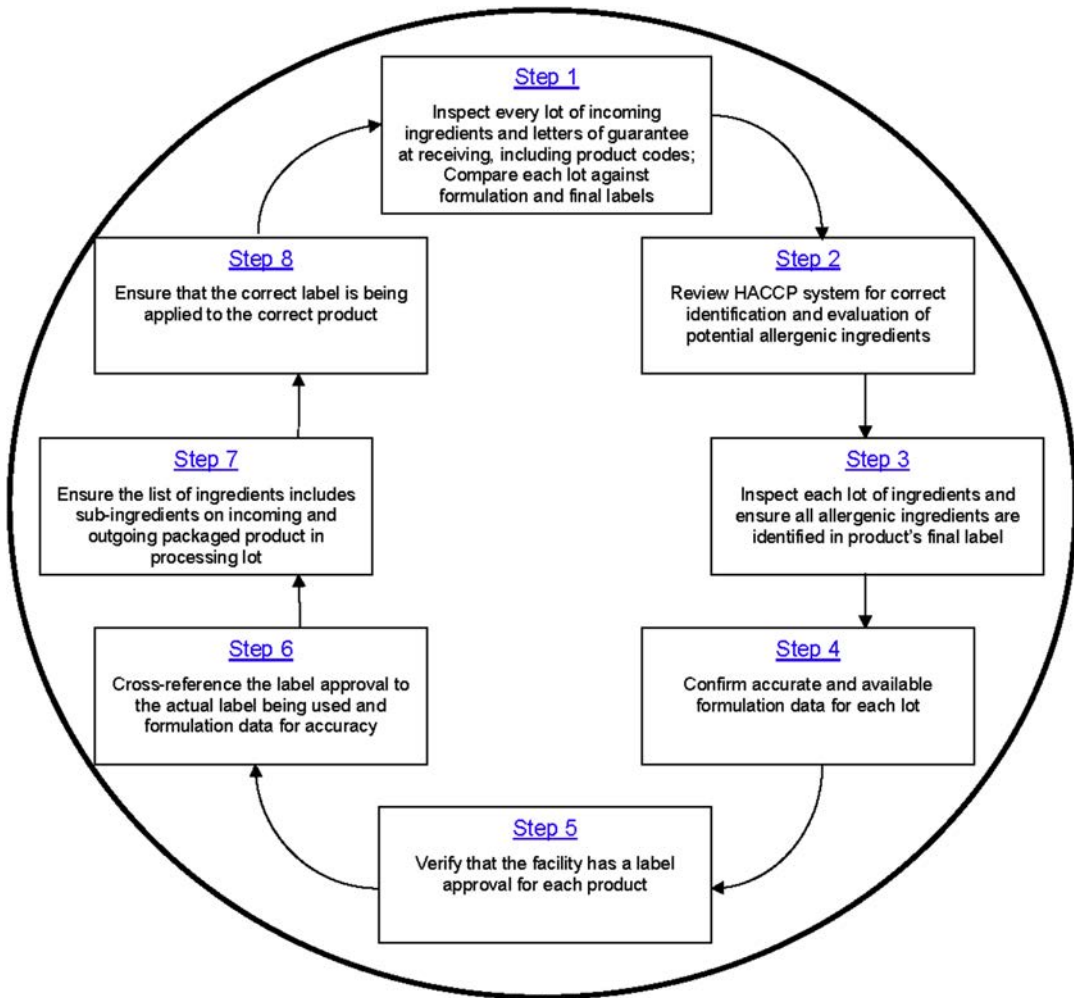


Figure 6.4

Food allergen preventive controls for labeling. From USDA Food Safety and Inspection Service, 2015. *FSIS Compliance Guidelines: Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling* (Online). Available: <https://www.fsis.usda.gov/wps/wcm/connect/f9cbb0e9-6b4d-4132-ae27-53e0b52e840e/Allergens-Ingredients.pdf?MOD=AJPERES>.

chocolate cookie dough example, the dough may be eaten raw by some consumers. There is no “kill-step” that occurs once the ingredients are mixed. Environmental pathogens that may be present in the manufacturing facility could contaminate the cookie dough, potentially causing illness or even death to consumers who eat contaminated product. A real-world example of an environmental pathogen leading to many illnesses and several deaths occurred recently with the *L. monocytogenes* outbreak that likely resulted from environmental contamination of a ready-to-eat product (ice cream) (Centers for Disease Control and Prevention, 2015). This outbreak will be discussed more in Chapter 9.

HAZARD ANALYSIS-DOUBLE CHOCOLATE COOKIE DOUGH							
(1) Ingredient / Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Receiving heat-treated flour ingredient							
	Wheat (allergen)	X		Egg is an allergen and must be declared on the packaging	Allergen control: allergen labeling to ensure the correct product labels are in place		X
Receiving Pasteurized liquid eggs ingredient	B						
	C Egg (allergen)	X		Egg is an allergen and must be declared on the packaging	Allergen control: allergen labeling to ensure the correct product labels are in place		X
	P						
Receiving Yeast extract ingredient	B						
	C Soy (allergen)	X		Soy can be found in some yeast extract when the yeast is grown in soy base	Allergen and supplier control: review of certificate of analysis for each lot of yeast extract to ensure soy was not used in the production of the yeast extract, supplier agreement	X	
	P						
Receiving Butter ingredient	B						
	C Milk (allergen)	X		Milk is used to make butter, and milk is an allergen and must be declared on packaging	Allergen control: allergen labeling to ensure the correct product labels are in place		X
	P						
Receiving Almond extract ingredient	B						
	C Tree nut (allergen)	X		Tree nuts (almonds) are used to make almond extract, and tree nuts are an allergen that must be declared on the packaging	Allergen control: allergen labeling to ensure the correct product labels are in place		X
	P						
Labeling	B						
	C Undeclared allergen: Peanuts and tree nuts	X		The manufacturing facility makes other cookie doughs which contain peanuts and tree nuts which use similar labels	Allergen control: allergen labeling to ensure the correct product labels are in place	X	
	P						

Figure 6.5

Food allergen preventive controls in Completely Cookie's hazard analysis. *B*, biological hazard; *C*, chemical hazard; *P*, physical hazard.

Sanitation preventive controls are procedures, practices, and processes that keep food contact surfaces clean and prevent both biological contamination and allergen cross-contact. Hygienic zoning and cleaning/sanitation strategies designed to reduce or eliminate specific hazards are examples of sanitation preventive controls.

The sanitation preventive controls that are part of the FSP for Completely Cookie's double chocolate cookie dough are shown in [Fig. 6.6](#).

HAZARD ANALYSIS-DOUBLE CHOCOLATE COOKIE DOUGH								
(1) Ingredient / Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the preventive control applied at this step?	
							Yes	No
Mixing, chilling, and packaging	B	<i>Listeria monocytogenes</i>	X		The cookie dough may be eaten in a raw form sometimes, and environmental contamination with <i>L. monocytogenes</i> is possible	Sanitation controls: follow defined environmental sanitation procedures to prevent establishment of environmental pathogens, verified by environmental monitoring	X	
	C	Undeclared allergen: Peanuts and tree nuts	X		The manufacturing facility makes other products which contain peanuts and tree nuts; cross-contact with these food allergens is possible	Sanitation and allergen controls: prevent cross contact by using separate storage areas, equipment lines, and personnel	X	
	P							

Figure 6.6

Sanitation preventive controls in Completely Cookie's Food Safety Plan. *B*, biological hazard; *C*, chemical hazard; *P*, physical hazard.

You may notice a gray area exists between regular sanitation and sanitation preventive controls. The FDA draft guidance document does advise that “you determine which hazards require a sanitation control, rather than cGMPs, through your hazard analysis” ([U.S. Food and Drug Administration, 2016a](#)). In other words, if you are using a sanitation process to control a specific hazard identified in your hazard analysis, the procedure is elevated from regular sanitation to a sanitation preventive control. Some sanitation procedures will be “sanitation preventive controls” while others will be just part of your cGMPs. Cleaning of food contact surfaces or cleaning that is done to prevent allergen cross-contact between runs of product would likely be considered sanitation preventive controls rather than just cGMPs. Hygienic zoning to ensure raw ingredients (which may contain pathogens) are kept separate from work-in-progress or finished product would also be a sanitation preventive control. Environmental monitoring (discussed in detail in [Chapter 9](#)) is a method of verification (a topic to be discussed in [Chapter 8](#)) for sanitation preventive controls that manage pathogens.

A gray area can exist between sanitation controls and food allergen controls since cleaning can serve as an important preventive control to prevent cross-contact when products with different food allergens are made on the same equipment or in a nearby location. As seen in [Fig. 6.6](#), the way that Completely Cookie prevents cross-contact of their double chocolate cookie dough with other allergens (peanuts and tree nuts) that are used in other flavors of doughs is through the use of sanitation controls. This preventive control could also be considered a food allergen preventive control. Do not worry about what a particular preventive

control is called when either is appropriate; it is mostly semantics. What is most important is that preventive controls are identified, performed, validated ([Chapter 7](#)), verified, monitored, and documented appropriately ([Chapter 8](#)).

6.6 Supply-Chain Preventive Controls

As a retail buyer, you need to monitor your suppliers to ensure they have effective preventive controls to ensure the food you produce from their ingredients and products is safe. In today's complicated and increasingly global supply chains, your supplier will also have its own suppliers, and they may have their own suppliers, and so on. Understanding where your suppliers source their ingredients can have a big impact on the safety of the food that you sell. As discussed in [Chapter 1](#)'s (fortunately fictitious) example, the QSR did not know that the supplier of their chocolate candy obtained the milk chocolate they used from a company that used peanut flour in many of their products.

As a retail buyer, you are concerned about your own supply chain because it directly affects your business and your customers. Even if the supply-chain preventive controls do not apply to you directly (and you do not have to worry about FDA inspections at your retail locations), you do have to monitor your suppliers to ensure the safety of your food. The kinds of activities that you, as a retail buyer, will be doing to check up on your suppliers to protect the safety of your products are very similar to the types of activities that your suppliers are required to do by the supply-chain program rules.

A supply-chain preventive control is needed by a manufacturer whenever they rely on a supplier to control a hazard. For example, Completely Cookie knows that some of its retail customers may serve their cookie dough raw in frozen dairy desserts. As a result, Completely Cookie purchases flour that has been heat-treated to kill any pathogens that might be present in this raw agricultural product. Completely Cookie must ensure that that hazard is being controlled by the flour supplier and will need to verify ([Chapter 8](#)) and document that their supplier is really controlling the hazard.

Supply-chain preventive controls can take a variety of forms and can include the following:

- A formal approval process for suppliers
- Agreements with suppliers not to change ingredients within a product
- Requesting certificates of conformance
- Review of ingredient specifications to control chemical hazards such as pesticides, drug residues, heavy metals, mycotoxins
- On-site audits of suppliers (or possibly a government inspection report, and maybe eventually a Global Food Safety Initiative or other audit) ([Hermida, 2016](#))
- Sampling and testing of the ingredient
- Review of the supplier's food safety records for that ingredient

Some of these supply-chain controls are also included in the new supply-chain program requirements, which is a part of FSMA separate from the preventive controls regulations. The supply-chain program requirements include the following, per 21 CFR Part 117, Subpart G:

- The requirement to establish and implement a supply-chain program
- General requirements applicable to a supply-chain program
- Responsibilities of the receiving facility
- Requirements for determining appropriate supplier verification activities (including determining the frequency of conducting the activity)
- Requirements for conducting supplier verification activities for raw materials and other ingredients
- Requirements for an on-site audit
- Requirements for records documenting the supply-chain program

Details regarding the supply-chain program requirements (which are not a focus of this book) will be found in the FDA's draft guidance (not available at the time of writing) "Supply-Chain Program for Human Food Products: Guidance for Industry" ([U.S. Food and Drug Administration, 2016a](#)).

[Fig. 6.7](#) demonstrates how Completely Cookie, Inc., might link hazards that will be controlled by supply-chain controls to specific supply-chain controls in their FSP.

Note that in some cases a retail buyer may be required to control a final hazard (for example, final baking of cookie dough if the cookie dough is not made from heat-treated flour and pasteurized liquid eggs). The supply-chain preventive controls regulations allow a manufacturer to kick requirements downstream to their buyer, with certain requirements. In such a situation, the retail buyer must provide the supplier with a letter and supporting documentation at least annually to provide written assurance that the retail buyer has established and is following procedures to ensure the identified hazard is being controlled (21 CFR Part 117.136(a)(4)). The documentation provided by the retail buyer to the supplier is not specified in the regulations or the currently available draft guidance, but would likely consist of the same types of documentation that a manufacturer would have in a FSP, including a description of the control, how the control was validated, and how it will be monitored and verified. In addition, the supplier must appropriately label the food so that it is clear that it has not been processed to control that particular hazard.

As an aside, if your supplier imports any ingredients directly from a country outside of the United States, your supplier must have a Foreign Supply Verification Plan (FSVP) in place. For example, Completely Cookie may purchase their cocoa directly from a company located in Mexico. Completely Cookie must conduct a hazard analysis on any ingredients they directly import and ensure that any hazards requiring a control are being controlled. More

HAZARD ANALYSIS-DOUBLE CHOCOLATE COOKIE DOUGH								
(1) Ingredient / Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Receiving heat treated flour ingredient	B	Shiga toxin producing <i>E. coli</i> <i>/Salmonella</i>	X		Flour is a raw agricultural product. Outbreaks of Shiga toxin-producing <i>E. coli</i> and <i>Salmonella</i> have been attributed to flour	Supply-chain control: Flour supplier will heat- treat the flour; the certificate of analysis for each incoming lot will be reviewed		X
	C	Mycotoxins	X		Mycotoxins are associated with storage of raw agricultural products like flour	Supply-chain control: flour supplier will test for mycotoxin; the certificate of analysis for each incoming lot will be reviewed		X
	P			X				
Receiving Cocoa powder ingredient	B	Salmonella	X		Cocoa is a raw agricultural product which can harbor pathogens. Heat treatment should eliminate pathogens	Supply-chain control: Cocoa supplier will heat- treat the cocoa; the certificate of analysis for each incoming lot will be reviewed		X
	C							
	P							
Receiving Iodized salt ingredient	B							
	C	Arsenic, Copper, Lead, Cadmium, Tin, and Sulfate	X		Salt can be contaminated with these chemicals which can be toxic at certain levels	Supply-chain control: Salt supplier will test for these chemicals; the certificate of analysis for each incoming lot will be reviewed		X
	P							
Receiving sugar ingredient	B							
	C	Mycotoxins	X		Mycotoxins are associated with storage of raw agricultural products like sugar	Supply-chain control: sugar supplier will test for mycotoxin; the certificate of analysis for each incoming lot will be reviewed		X
	P							
Receiving butter ingredient	B	<i>Listeria</i> <i>monocytogenes</i>	X		<i>Listeria</i> is often found in dairy products and continues to cause outbreaks.	Supply-chain control: Butter will be made from pasteurized milk by the supplier; the certificate of analysis for each incoming lot will be reviewed		X
	C			X				
	P			X				

Figure 6.7

Supply-chain preventive controls. B, biological hazard; C, chemical hazard; P, physical hazard.

details on the FSVP can be found in an excellent summary found on the FDA's website or in the Final Rule itself ([U.S. Food and Drug Administration, 2015d](#)).

6.7 Recall Plan

Recalls are defined as “actions taken by an establishment to remove an adulterated, misbranded, or violative product from the market” ([Food Safety Preventive Controls Alliance, 2016b](#)). In one recent year (2015), FDA's Center for Food Safety and Applied Nutrition (CFSAN) reported approximately 600 recalls for approximately 3000 food products ([U.S. Food and Drug Administration, 2015b](#); [U.S. Food and Drug Administration, Undated](#)).

Prior to FSMA, recalls were voluntary actions by companies. FDA could use various tactics to try to encourage recalls but could not force a company to recall a product. Under FSMA, FDA can now order mandatory recalls. However, FDA must first give the company a chance to halt distribution and conduct a voluntary recall ([U.S. Food and Drug Administration, 2016b](#)).

Recalls are categorized into three classes based mainly on the likelihood that the product could cause serious health problems, with most food recalls categorized as Class I or Class II ([U.S. Food and Drug Administration, Undated](#)):

- Class I: Dangerous or defective products that predictably could cause serious health problems or death. Examples include food found to contain botulinum toxin or food with undeclared allergens.
- Class II: Products that might cause a temporary health problem or pose only a slight threat of a serious nature.
- Class III: Products that are unlikely to cause any adverse health reaction but that violate FDA labeling or manufacturing laws. Examples include a minor container defect or a lack of English labeling on a retail food ([U.S. Food and Drug Administration, 2015c](#)).

The preventive controls regulations require a manufacturer to have a written recall plan for *any* food that requires a preventive control.

A recall plan is a written plan that describes exactly how a recall would be conducted. The plan must make it clear how those that have obtained the product will be notified. This notification should also include information on how to dispose or return the affected product. The plan should also include information on how the public will be notified of any potential hazards stemming from the recalled product and how the company will verify that the recall was effective. Information on how and what will happen to the

recalled food also should be included in the plan ([U.S. Food and Drug Administration, 2016a](#)).

While it is up to each company to come with their plan's exact content, it would likely include the following specific types of information ([Food Safety Preventive Controls Alliance, 2016b](#)):

- Defined roles and responsibilities for individuals involved in the recall
- Draft recall notices and forms
- Contact list for external notification (as a retail buyer, your company and the correct contact person should be on that list!)
- A procedure for identifying affected lots
- Product disposal procedures
- Procedures to ensure the effectiveness of the recall
- Mock recall procedures and records from their performance

The FSPCA PCHF Participant Manual contains a detailed example of a written recall plan that can serve as a template for a manufacturer developing their plan ([Food Safety Preventive Controls Alliance, 2016b](#)).

After an actual recall, the FSP must be reanalyzed. If, for example, the double chocolate cookie dough had to be recalled by Completely Cookie because they found *L. monocytogenes* in a sample collected from the mixer (a food contact surface) used to make the dough, the FSP should be reanalyzed with particular attention to preventive controls related to sanitation if the established preventive control can not be normally corrected.

Retail food businesses should ensure that they also have a recall program/plan that will enable them to promptly contact each of their retail food service and sales establishments that purchased a recalled product and to give notice of the recall and required actions (e.g., list product on-site, remove from sale, and destroy). Also, if a supplier issues a recall for an ingredient/product the retail establishments use as an ingredient in their prepared products, it is important that the individual retail establishments are aware of the recall as soon as possible so that ingredient/product and all other products made with the recalled ingredient/product can be diverted to prevent service/sales to the customers.

6.8 Other Controls

The regulations state that “other controls” are any other procedures, practices, and processes necessary to ensure that any hazard requiring a preventive control are significantly minimized or prevented (21 CFR Part 117.135). This may seem to be a somewhat circular argument. In practice, it means any other controls that do not fall into any of the over five categories of

preventive controls. The regulations give several examples of controls that might fall under this category, including hygiene training and other cGMPs.

Again, it is important to keep in mind that the exact categorization of a preventive control is not as important as that an appropriate preventive control is linked to each identified hazard that needs one.

6.9 How to Identify Appropriate Preventive Controls?

What are additional examples of preventive controls, and how do you know if they are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding? The FDA Draft Guidance Document on Preventive Controls contains several lists of common preventive controls used in the food industry within [Chapter 5](#) of this document ([U.S. Food and Drug Administration, 2016a](#)). While the lists in the guidance document are not intended to be comprehensive or exclusive, they will provide some ideas of the typical types of preventive controls that might be used for various hazards and provide some general idea of the diversity of control methods that a company might employ. For example, [Table 6.2](#) illustrates different types of controls that might be used to control some of the risks identified in the hazard analysis.

In addition to the draft guidance document on PCHF ([U.S. Food and Drug Administration, 2016a](#)), the same documents and resources that may be used for validating a particular preventive control for a hazard (as discussed in [Chapter 7](#)) may also prove useful in identifying appropriate preventive controls for different hazards.

Flexibility exists in which preventive controls may be used for each hazard. There is no **single** “correct” preventive control for a particular hazard; it is up to the manufacturer to identify what will work best for their product and their operation (and to ensure that it effectively minimizes the hazard in the specific product). Retail buyers will want to make sure they agree that the preventive controls chosen by their suppliers are adequate for controlling identified hazards.

6.10 Conclusions

PCHF regulations have expanded the types of controls that can be used to minimize or eliminate hazards beyond process controls (those performed directly to food during the manufacturing process). In addition to process controls, the PCHF regulations describe the use of food allergen controls, sanitation controls, supply-chain controls, recall plans, and other controls, which should be considered. The regulations do not prescribe specific preventive controls that must be used for a particular hazard, but instead, allow the manufacturer to identify those that will work best for a particular product and manufacturing facility. Some preventive controls (process preventive controls) do require validation, which will be discussed in [Chapter 7](#).

Table 6.2: Examples of preventive controls.

Hazard	Preventive Control	Common Procedures, Practices, and Processes
Pathogenic <i>Escherichia coli</i> in bread dough from flour	Process control: lethality treatment	An appropriate heat treatment can eliminate vegetative cells of pathogens
Mycotoxin in flour	Supply-chain program	The bakery approves the flour supplier for their ability to meet the mycotoxin specification. The bakery reviews the Certificate of Analysis (CoA) for every lot of flour that it receives. The CoA includes the results of mycotoxin testing that the flour supplier conducts
Food allergen (milk) in cheese	Allergen control: labeling procedures	Implement procedures for application of correct label to product
Food allergen (tree nuts) from cross-contact with other baked goods	Allergen control: allergen cross-contact	Segregate ingredients and process tree-nut-containing products in a different, designated part of the facility
Metal fragments as a processing hazard	Process control: detection	Use a metal detector to detect and divert foods containing metal
<i>Staphylococcus aureus</i> growth or toxin formation due to lack of time/temperature control after baking and before freezing	Process control: time/temperature of holding	Refrigeration and freezing of cookie dough immediately after mixing
Recontamination with environmental pathogens such as <i>Listeria monocytogenes</i> prior to freezing	Sanitation control: cleaning/sanitizing food contact surfaces	Controlling presence of bacterial pathogens during preparation of the cookie dough through the use of sanitation
	Sanitation control: prevention of recontamination from the environment	Use of hygienic zoning to prevent recontamination of cookie dough

Adapted from U.S. Food and Drug Administration, 2016a. Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food.

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Validation of Preventive Controls

7.1 Introduction

How does a food manufacturing company know that the preventive controls it uses are effective at controlling hazards?

For example, Completely Cookie Inc. manufactures a double chocolate cookie dough that restaurants can use to customize frozen dairy desserts. Completely Cookie purchases the flour they use from a company (All Grains, Inc.) that heat-treats the flour to eliminate pathogens. The heat treatment step is a preventive control that All Grains uses to control microbial hazards (*Salmonella* and Shiga toxin-producing *Escherichia coli*). How does All Grains know that the time, temperature, and equipment that they use when conducting the heat treatment really kills these pathogenic organisms?

Similarly, Completely Cookie uses a large mixer with a metal paddle blade to prepare their cookie dough. Before portioning into 50-oz. tubs, the packaged dough is run through a metal detector to ensure that no metal fragments from the paddle blade end up in the dough. But how does Completely Cookie know that the metal detector is really able to detect metal fragments that might be present?

The scientific data that All Grains uses to demonstrate the effectiveness of their heat treatment and that Completely Cookie uses to show their metal detector can identify the presence of hazardous metal fragments in the packaged cookie dough are both examples of **validation**.

Validation is a concept that is well known to those familiar with hazard analysis and critical control point (HACCP) and or other quality systems. Although different food safety organizations may tweak the definition slightly (Table 7.1), the basic idea is the same: validation is the data that you have that supports the effectiveness of a specific control in preventing a specific hazard. It's the scientific data that say what is being done is going to work.

It is not unusual to confuse “validation” with “verification” or with “monitoring” (the latter two terms will be discussed more in Chapter 8). One useful way of differentiating between these three important terms is to think of the relationship between the three activities and the time when they are being conducted (Surak and Stier, 2009).

- Validation: **Will** the preventive control really work to control that hazard? (**Future**)
- Monitoring: **Is** the control **being** performed? (**Current**)
- Verification: **Was** the work associated with the control done according to plan? (**Past**)

Table 7.1: Definitions of validation.

Definition	Source	References
Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the Food Safety Plan as a whole, when properly implemented, is capable of effectively controlling the identified hazard	Preventive controls regulation	21 CFR Part 117.3
Validation confirms the effectiveness of the Food Safety Plan in controlling food safety hazards	FSPCA PCHF Participant Manual	Food Safety Preventive Controls Alliance (2016)
The scientific or technical support for the hazard analysis and critical control point (HACCP) system design (design)—that is the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards	USDA HACCP	USDA Food Safety and Inspection Service (2015)
The collection and evaluation of scientific and technical information to determine if the treatment when properly applied, will effectively control the hazard	NACMCF	National Advisory Committee on Microbiological Criteria for Foods (2006)
Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specific outcome	Codex Alimentarius	Codex Alimentarius (2008)

Not all preventive controls require validation. In fact, process controls are the only preventive controls that absolutely require validation under the Preventive Controls for Human Food (PCHF) regulations ([Fig. 7.1](#)). The regulations (21 CFR Part 117.160(c)) specify that validation is not required for food allergen controls, sanitation controls, recall plans, or supply-chain controls. Other controls (for example, hygiene training to control a specific hazard) do not require validation as long as the Preventive Controls Qualified Individual (PCQI) (or person working under the PCQI) justifies in writing that validation is not required.

However, there may be situations where validation for food allergen or sanitation controls may be desirable, especially if they are controls to prevent serious hazards.

For example, a retail food business may decide it is important to ensure that the method its supplier uses to remove a peanut allergen during a sanitation procedure is effective because the product the retail food business will sell (candied pecans which will top a salad) will not

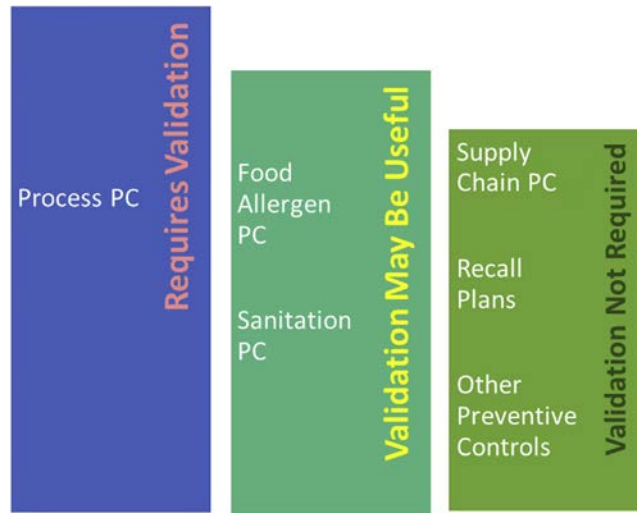


Figure 7.1

Validation requirements for different preventive control types according to the Preventive Controls for Human Food regulations.

have any advisory labeling to caution the customer that an ingredient in the product is made in the same facility as peanut products (a potential hazard of undeclared peanut allergens in the product). The same equipment is used by the manufacturer for both a toffee peanut snack and the candied pecans. The manufacturer may perform a study using various sanitation methods to identify a procedure that works consistently well at removing peanut allergen. The study might involve testing for peanut allergen on swabs taken from the equipment and also in the finished product (the candied pecans). The study included proper controls to show that the test could detect peanut allergen in the candied pecans (i.e., to ensure that the candied pecan product itself did not interfere with the peanut allergen test).

7.2 How Does a Food Processor Validate a Preventive Control?

7.2.1 Obtaining Objective Evidence That Supports the Use of a Specific Control for a Hazard

Every process preventive control that a manufacturer cites in their Food Safety Plan needs to be supported by objective evidence that indicates that the control, as implemented by the manufacturer, is going to work to significantly reduce or eliminate the hazard it is supposed to control. It is not enough to rely on historical data of no incidence (“this is the way we have always done it, and we have never had a problem”), because product formulations, processing methods, and even possible pathogens or other hazards will change over time.

What kind of evidence can be used? What should you, as a retail buyer, expect to see as validation evidence in a Food Safety Plan for a product that you are purchasing from a supplier? Accepted forms of validation support include the scientific literature, government/regulatory safe harbors, in-plant tests, challenge studies, predictive modeling, and expert opinion. Often a combination of these types of support is used to validate a particular preventive control for a specific hazard within a food product. For example, the formulation of a food product may not specifically fit the criteria for the use of a predictive model. The combination of the data from the predictive model with a written opinion from an expert food microbiologist (who has conducted challenge studies with a similar food product, for example) could serve as the basis for validation.

Various types of supporting evidence are discussed in more detail in the following sections.

7.2.1.1 *Scientific Literature*

A variety of resources in the scientific literature may serve as validation for a preventive control within a Food Safety Plan, including (but not limited to) the following:

- Peer-reviewed journal articles, including research papers or review articles
- Book chapters
- Trade association guidance documents
- University extension documents and reports

The methods used in the reference may not exactly match what is being done in the manufacturing facility. There should be justification for why such differences do not affect the ability of the reference to serve as validation. For example, a study may have shown that a particular heat treatment was sufficient to destroy *Listeria monocytogenes* in hot-filled cream cheese. A journal article reporting the details of that study could be used to support the use of that same heat treatment to kill *Salmonella* in a heat-filled cream cheese because *L. monocytogenes* is harder to kill (i.e., requires more time at the chosen temperature) to inactivate when compared with *Salmonella*. The *L. monocytogenes* study report along with a reference demonstrating the higher heat resistance of *L. monocytogenes* relative to *Salmonella* could serve as validation.

7.2.1.2 *Safe Harbors*

In terms of food safety validation, “safe harbors” are regulations or guidelines from a governmental organization that explicitly state that a particular preventive control will prevent a specific risk. One classic example of a safe harbor that many of you may be familiar with (although it applies to USDA-regulated products that fall under HACCP requirements and not FDA’s PCHF requirements) is in Appendix A of the FSIS compliance guideline for ready-to-eat products ([USDA Food Safety and Inspection Service, 2017](#)). These guidelines specify exact time and temperature conditions needed to ensure the destruction of *Salmonella* when cooking beef ([Fig. 7.2](#)). For example, if a beef roast is held

Appendix A Compliance Guidelines for Meeting Lethality Performance Standards for certain Meat and Poultry Products (Appendix A)

Meat products can be prepared using one of the following time and temperature combinations. The stated temperature is the minimum that must be achieved and maintained in all parts of each piece of meat for at least the stated time. Establishments should apply humidity when using this table or additional support should be provided for the process.

Degrees Fahrenheit	Degrees Centigrade	6.5-log ₁₀ Lethality	7-log ₁₀ Lethality
130	54.4	112 min.	121 min.
131	55.0	89 min.	97 min.
132	55.6	71 min.	77 min.
133	56.1	56 min.	62 min.
134	56.7	45 min.	47 min.
135	57.2	36 min.	37 min.
136	57.8	28 min.	32 min.
137	58.4	23 min.	24 min.
138	58.9	18 min.	19 min.
139	59.5	15 min.	15 min.
140	60.0	12 min.	12 min.
141	60.6	9 min.	10 min.
142	61.1	8 min.	8 min.
143	61.7	6 min.	6 min.
144	62.2	5 min.	5 min.
145	62.8	4 min.	4 min.
146	63.3	169 sec.	182 sec.
147	63.9	134 sec.	144 sec.
148	64.4	107 sec.	115 sec.
149	65.0	85 sec.	91 sec.
150	65.6	67 sec.	72 sec.
151	66.1	54 sec.	58 sec.
152	66.7	43 sec.	46 sec.
153	67.2	34 sec.	37 sec.
154	67.8	27 sec.	29 sec.
155	68.3	22 sec.	23 sec.
156	68.9	17 sec.	19 sec.
157	69.4	14 sec.	15 sec.
158	70.0	0 sec.**	0 sec.**
159	70.6	0 sec.**	0 sec.**
160	71.1	0 sec.**	0 sec.**

Figure 7.2

Safe harbor example: USDA's "Appendix A" time and temperature conditions necessary to destroy *Salmonella* in cooked and roast beef. **, the required lethality is achieved instantly. From USDA Food Safety and Inspection Service, 2017. *Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A*. Available from: <https://www.fsis.usda.gov/wps/wcm/connect/bf3f01a1-a0b7-4902-a2df-a87c73d1b633/Salmonella-Compliance-Guideline-SVSP-RTE-Appendix-A.pdf?MOD=AJPERES>.

at a minimum internal temperature of 130°F for 121 min, a 7-log₁₀ reduction in *Salmonella* levels can be assumed.

A safe harbor that applies to FDA-regulated foods is the water activity (a_w) and pH value table found within the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) guide for conducting challenge studies ([National Advisory Committee on Microbiological Criteria for Foods, 2010](#)). This table (along with similar information that is present in the Food Code ([U.S. Food and Drug Administration, 2016b](#))) provides conditions under which pathogen growth is prevented. These data could validate the use of a specific formulation with a defined water activity and pH to control a biological hazard such as the growth of *L. monocytogenes* that may contaminate a ready-to-eat product during the manufacturing process.

The FDA’s draft guidance on Hazard Analysis and Risk-Based Preventive Controls for Human Foods ([U.S. Food and Drug Administration, 2016a](#)) also contains information in its Appendix 3 that specifies certain minimum and maximum conditions (pH, temperature, water activity, etc.) under which various pathogens can grow. The appendix (part of which is excerpted in [Table 7.2](#)) indicates, for example, that *Salmonella* cannot grow at pH values less than 3.7. If a product is formulated to have a pH that is lower than this to prevent *Salmonella* growth, then this appendix could be used as validation documentation for the preventive control (formulation to maintain pH less than 3.7).

Regulatory guidance from other countries may be useful for validation as well. Guidance from Canada and New Zealand, in particular, may be useful because the food safety systems of these countries have been recognized as comparable to the United States ([U.S. Food and](#)

Table 7.2: Minimum and maximum pH and temperatures that support growth of select pathogens.

Pathogen	Minimum pH	Maximum pH	Minimum Temperature	Maximum Temperature
Pathogenic strains of <i>Escherichia coli</i>	4	10	43.7°F (6.5°C)	120.9°F (49.4°C)
<i>Listeria monocytogenes</i>	4.4	9.4	31.3°F (−0.4°C)	113°F (45°C)
<i>Salmonella</i> spp.	3.7	9.5	41.4°F (5.2°C)	115.2°F (46.2°C)

From U.S. Food and Drug Administration, 2016a. Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food.

[Drug Administration, 2016c](#)). Guidance from Australia and the European Union, which are likely to also achieve a similar comparable status soon ([U.S. Food and Drug Administration, 2016c](#)), may also be useful.

7.2.1.3 *In-Plant Tests*

In-plant (facility) tests can be a very effective and efficient method of validation, especially for nonmicrobial hazards. For the example presented at the beginning of the chapter of whether a metal detector would be able to detect metal shards present within a packaged cookie dough product, a study could be conducted where metal fragments of the smallest hazardous size were spiked into the dough and run through the metal detector. The same equipment and settings as would be used in the actual manufacturing process could easily be used in this test, and the product in the validation test would be exactly the same.

In-plant tests have the great advantage of being done in the same facility, often with the same equipment, ingredients, and operators as the actual manufacturing process. Pathogen studies, however, may not be conducted in the actual manufacturing environment, however, in order to prevent environmental contamination of the manufacturing facility. Studies performed with actual pathogens should be performed by qualified microbiology laboratories. A nonpathogenic surrogate organism instead of the pathogen itself may also be used as long as the surrogate has been demonstrated to have characteristics similar to the actual pathogen in terms of growth and sensitivity to the control process under the general conditions being used ([Eblen et al., 2005](#)).

7.2.1.4 *Challenge Studies*

Challenge studies are usually designed to test whether an actual pathogen is inactivated and/or if their growth is inhibited by using certain formulations (modifying pH, use of antimicrobials, etc.) or by specific processes (cooking, cooling, etc.). In addition to formulation and process testing, packaging (and the packaging atmosphere) may also be tested in a challenge study to assess its impact on pathogen inactivation or growth.

Many manufacturers rely on contract laboratories or academic institutions to conduct challenge studies. Some manufacturers may have internal resources (including the laboratory facilities) that will allow them to conduct their own challenge studies. The study should be conducted by appropriately trained individuals (expert food microbiologists) in an objective manner.

It is important that differences in equipment, process, scale, organism tested, etc. be carefully considered to ensure that the challenge study is truly representative of what will be happening in the actual manufacturing process (see also [Table 7.3](#) in [Section 7.3](#) below). Justification for

Table 7.3: Examples of potential sources of variation between validation study and manufacturing conditions.

Source of Variation		Examples
Food	Food product	Is a validation study done in ice cream applicable to ice milk?
	Recipe/formulation	Does a difference in salt or moisture content affect the ability of a heat treatment to inactivate pathogens?
	Source of ingredients	Were the tomatoes obtained from a producer who uses antimicrobials when they are washed?
	Temperature of food	Is the food the same temperature in the validation study as in the manufacturing process?
	pH	Was the pH of the test product the same as that of the product being manufactured?
	Acid type	Does the use of lactic acid instead of acetic acid impact pathogen growth even if the final pH of the product is the same?
	Water activity	Was the water activity (a_w) of the test product the same as that of the product being manufactured?
	Spatial configuration	Does the product form (e.g., sausage links vs. patties) or surface conditions affect the ability of the control from working?
	Packaging	Is the cookie dough packaged in plastic or cardboard tubs?
Process	Equipment	Was the same model of oven used? Have oven cold spots been mapped in both ovens?
	Facility	Did the test facility have the same ambient temperature as the manufacturing facility?
	Time	Was the baking time exactly the same?
	Temperature of process	Is the temperature the same as used in the scientific report?
	Humidity	Was the oven humidity measured and found to be the same?
	Pressure	Was the same pressure used in a high-pressure pasteurization process?
	Equipment settings	Is the metal detector's conveyor speed the same between the validation study and the manufacturing process?
	Operator	Does the operator add the ingredients in exactly the same order as the operator in the validation study did?

why differences between the challenge study and the actual manufacturing process do not affect the ability to extrapolate between the two should be provided in writing within the Food Safety Plan by a food microbiology expert.

Challenge studies often utilize a “worst case scenario” approach using the pathogen and strain that is most difficult to control. In addition, challenge studies generally utilize conditions that are much more permissive than will be used in the actual manufacturing process to ensure that there is some “wiggle room.” Because challenge studies are often difficult and expensive to conduct, a company will not want to have to repeat the study because of a small formulation change to a manufacturing process. Ensuring adequate margins for variation in challenge study parameters may also be helpful later when justifying process deviations.

Some useful resources on challenge studies include the NACMCF guide discussed in [Section 7.2.1.2 \(National Advisory Committee on Microbiological Criteria for Foods, 2010\)](#), FDA resources ([U.S. Food and Drug Administration, 2015](#)), guidance documents from Health Canada on *L. monocytogenes* ([Health Canada, 2012](#)) and *Clostridium botulinum* ([Health Canada, 2010](#)). Conducting a good challenge study requires more than the ability to follow a protocol and inoculate food; an expert food microbiologist is essential (see [Section 7.2.2](#)).

7.2.1.5 Predictive Modeling

Predictive modeling is like doing a virtual challenge study to determine whether or not a pathogen will grow or be inactivated under defined conditions. Predictive models are mathematical formulas that are fit to experimental data for bacterial growth or inactivation under certain conditions. A computer program is generally developed for a predictive model, which allows the user to enter information such as pH, temperature, salt concentration, etc. that correspond to their own product and process. The program then uses that information to predict the rate at which a pathogen will grow or be inactivated, the time until pathogen growth, the probability of illness, or some other parameter.

The usefulness of predictive models requires that their use be validated in the specific food and process. In other words, the predictive models themselves need to be validated. Such validation can be accomplished by comparing the results from a specific challenge study to the results obtained from the model used. Models are usually specific for a bacterial pathogen strain such as *L. monocytogenes* (or type of pathogens such as all *Salmonella*) and a particular food; however, data from the models can be used for other organisms or other foods with appropriate justification. For example, if you know that *Salmonella* is more heat sensitive than *Listeria*, a *Listeria* model of thermal inactivation will likely also provide you with information that can be used to support heat inactivation of *Salmonella*. However,

Salmonella can become more heat resistant at low water activities, so extrapolation from one organism to another (or one food product to another) within a model will require careful consideration of all variables and a written justification in the Food Safety Plan by a food microbiology expert.

Some examples of predictive models include the following:

ComBase Predictor

<http://www.combase.cc/index.php/en/predictive-models/134-combase-predictor>

Perfringens Predictor

<http://www.combase.cc/index.php/en/predictive-models/135-peringens-predictor>

Purac *Listeria* Control Model 2012

<http://www.purac.com/EN/Food/Calculators/Listeria-Control-Model.aspx>

Pathogen Modeling Program (PMP)

<http://ars.usda.gov/Services/docs.htm?docid=11550>

<http://pmp.arserrc.gov/PMPOnline.aspx>

Seafood Spoilage and Safety Predictor (SSSP, version 3.0)

<http://sssp.dtuaqua.dk/>

Microbial Responses Viewer (MRV) for ComBase
(Version Beta 1)

<http://mrv.nfri.affrc.go.jp/Default.aspx#/About>

<http://mrv.nfri.affrc.go.jp/Default.aspx#/Home>

Predictive models can provide fast and inexpensive validation data. However, appropriate predictive models may not be available for the food product/pathogen/preventive control combination of interest. In addition, predictive models may not always accurately predict what happens, and significant deviations from models can occur ([U.S. Food and Drug Administration, 2016a](#)).

Sometimes a predictive model predicts failure (that the control would not control the hazard). A subsequent challenge study might show that the predictive model actually was wrong, and the preventive control is actually effective. It may be useful to include both the predictive model results and the challenge study report in the validation documentation within the Food Safety Plan along with a discussion of why the model may have failed. Conversely, even if the model predicts success, additional supporting documentation for the use of the control for that hazard in that food product should be included as part of the validation documentation.

VALIDATION OF “CLEAN-LABEL” PREVENTIVE CONTROLS

Consumer demand for “clean-label” foods has had a tremendous impact on retail food businesses (Watrous, 2015). The replacement of well-established antimicrobials in food products with clean-label alternatives (including protective cultures, fermentates, phage, celery powder, bacteriocins, etc.) to control pathogens requires that the clean-label strategies be carefully validated. Retail businesses should be aware that some of these clean-label antimicrobials may not be as well studied or characterized as conventional antimicrobials. There may be more variability in efficacy between lots of the antimicrobial, which should be considered during validation. If you have a supplier using a clean-label product as a preventive control, the validation study used to support its use in a food product should be carefully reviewed to ensure the clean-label product will work consistently in your food product.

7.2.1.6 Expert Opinion

When other types of support are not feasible, a manufacturer may rely on expert opinion as validation. If a company is relying on the opinion of an expert as validation for a preventive control, the Food Safety Plan should include a letter or report from that expert who explains his/her opinion. The letter should include references to scientific literature or experimental data that support his/her opinion. Information on the qualifications of the expert should be included (for example, a copy of their professional curriculum vitae (CV)) that demonstrates their education and training as suitable for providing such an opinion.

7.2.2 Who Conducts Validation Activities?

A PCQI must oversee (or perform) validation activities, but the PCQI need not be someone from the company itself; it could be a consultant who is a PCQI or a PCQI from the retail buyer. For some types of validation activities for certain products, the use of a recognized food-processing authority or an expert food microbiologist is recommended to oversee or conduct the work. Such individuals may be associated with food consulting firms, academic institutions, trade associations, or equipment manufacturers, or they may be independent consultants with previous relevant experience in industry or academia. NACMCF has published recommended qualifications for those involved in the design, conduct, or evaluation of microbiological studies such as challenge studies ([National Advisory Committee on Microbiological Criteria for Foods, 2010](#)).

7.2.3 Documentation of Validation

Any validation work that is used to support a preventive control should be included or referenced in the Food Safety Plan. If you are auditing a potential supplier, you should be able to easily access all documents (including

study data, if from an in-house or challenge test) that support the validation of a preventive control. While the Food Safety Plan itself needs to be available within the facility (or accessible online from the facility), other data can be stored offsite as long as they are retrievable within 24 hours during regulatory inspections. Data can be recorded on paper (original or true copy) or in electronic format. Thankfully for food manufacturers, electronic records related to the Food Safety Plan are largely exempt from complying with the FDA's electronic records requirements found in 21 CFR Part 11 (21 CFR Part 117.305(g)).

Copies of any scientific reports from the literature which are cited as validation support should be included in the Food Safety Plan as well. A copy of the full article or book chapter should be included, not simply a citation or abstract. If the document is not in English, a translation should be readily available.

If an in-house study or a contracted challenge study was used for validation, a copy of the validation study report should be included in the Food Safety Plan. The data behind the report may be stored offsite but should be easily accessible.

Records that relate to validation must be kept by a manufacturing facility for at least 2 years after their use (the use of those records to support that validation) is discontinued (21 CFR Part 117.315(b)). This retention requirement is somewhat different from most Food Safety Plan-related documents, which only need to be kept for at least 2 years after they were generated (21 CFR Part 117.315(a)).

7.3 Validation Strategy Considerations

The best validation data arise from conditions that most closely mimic what will occur in the manufacturing facility. Since an exact replica of the manufacturing conditions is generally not practical or possible (nor is it allowed, as you do not want to bring pathogens into a manufacturing facility), a processor must determine how important such differences (such as those shown in [Table 7.3](#)) are in assessing whether a validation study really matches what is being done in the plant.

7.3.1 Validation of a Preventive Control for Multiple Products Within a Single Food Safety Plan

A separate validation does not need to be done for each food product within a Food Safety Plan unless there are differences between products that may affect the relative effectiveness of a preventive control. For example, a Food Safety Plan that covers both a frozen meat lasagna product and a cheese lasagna product could use the same challenge study to demonstrate pathogen hazards are eliminated in a cook step if the challenge study demonstrates that meat-associated pathogens (along with pathogens present in the basic cheese lasagna) are also eliminated during the cook step.

7.3.2 Timing of Validation

Initial validation should be done prior to the time that a Food Safety Plan is implemented. However, the regulations in 21 CFR Part 117.160(b)(1) gives manufacturers two other options:

- Companies have until 90 calendar days after production of a food begins to have validation completed.

OR

- Validation needs to be conducted within a “reasonable timeframe” as long as the Food Safety Plan contains a written justification from the PCQI that explains why validation is not yet complete.

In situations where the validation is not completed before the time that product is being manufactured, it may be prudent for a manufacturer to choose to hold product until validation has been completed and the effectiveness of all preventive controls are established.

Revalidation of a preventive control needs to be performed whenever any changes occur that could impact the ability of a preventive control to prevent a hazard. Many of the parameters cited in [Table 7.3](#) are also factors that, when changed, may impact validation. For example: if a company is changing the formulation of a product to remove high-fructose corn syrup and replace it with sucrose, the water activity (a_w) of the product may change, which may, in turn, affect the ability of pathogens to survive or grow in the product. If revalidation does not occur after a change, the justification for not doing so should be included in the Food Safety Plan.

7.4 Validation Examples

Let us return to two of the process preventive controls that are discussed in the introduction to this chapter: heat treatment of flour to kill vegetative pathogens and metal detection of packaged cookie dough to ensure the absence of metal fragments. How might a company validate these processes?

7.4.1 Validation of Heat Treatment of Flour to Inactivate *Salmonella* and Shiga Toxin–Producing *Escherichia coli*

In our example of Completely Cookie's supplier All Grains uses a heat treatment to ensure that microbial hazards (specifically, *Salmonella* and Shiga toxin–producing *E. coli*) are inactivated. Briefly, this is how they could have validated this heat treatment step for its ability to control these biological hazards:

- All Grains contracted with a nearby university's food safety department to conduct a challenge test on heat treatment of *Salmonella* in flour.
- All Grains reviewed the qualifications of the individuals who would be designing, conducting, and evaluating the study by inspecting their CVs.

- All Grains supplied their own flour for the university to use in the studies. Flour samples with a range of water activity and moisture values were used in the study. The water activity and moisture levels of the flour were measured in the university lab before and after inoculation with pathogen.
- The university lab used a cocktail of heat-adapted *Salmonella* strains covering a wide variety of the characteristics observed in *Salmonella* serotypes. An appropriate inoculum load was selected ([Anderson and Lucore, 2012](#)). The study protocol prospectively identified what “success” would be in terms of microbial load reduction following heat treatment.
- The university lab designed the heat treatment they would conduct to include a range of conditions that would mimic those that could be present at All Grains facilities during the planned heat treatment process. The temperature, time, humidity, and many other factors (as discussed in the Grocery Manufacturers Association/Alliance for Innovation & Operational Excellence/PMMI document by [Anderson and Lucore \(2012\)](#)) were considered when designing the study.
- The microbiological testing was performed according to established methods and appropriate controls were included. An adequate number of replicates under each tested condition were performed, and the data were analyzed using appropriate statistical techniques.
- The results of the study demonstrated that the conditions chosen by All Grains for their heat treatment would be more than sufficient to kill *Salmonella* at levels much higher than those that had been reported to have been found in flour in the past (and these references were included in the reported).
- Because *E. coli* is similar to (but more susceptible than) *Salmonella* in terms of heat resistance, the *Salmonella* data were assessed by the university lab’s principal investigator to also cover inactivation of *E. coli*. This assessment, along with supporting references describing the relative heat susceptibilities of *E. coli* and *Salmonella* from the scientific literature, was included in the final validation report which was included in the Food Safety Plan.

7.4.2 Validation of Metal Detection to Identify Metal Fragments From Mixer Paddle

- Completely Cookie conducted a validation study in their manufacturing facility to determine how well their metal detector worked at identifying metal fragments in cookie dough.
- The study tested a range of sizes and shapes of metal fragments (of the same material as the mixer paddle) in a variety of cookie dough formulations (of various moisture content and pH) at all thicknesses and consistencies that might be used for actual product.

- The study was conducted at several different ambient humidity levels since this is known to impact the detection of metal by metal detectors. Other variables, including placement and orientation of the product containers on the conveyor belt and conveyor belt speed, were tested, as these factors may affect metal detection ability (U.S. Food and Drug Administration, 2011).
- A copy of the validation study report was included in the Food Safety Plan.

7.5 Summary and Conclusions

Validation is the collection and review of scientific and technical data that demonstrate that a preventive control, when conducted properly, will control an identified hazard. The PCHF regulations are flexible in terms of how a food manufacturer can validate a preventive control (scientific literature, in-plant testing challenge study, etc.), but the validation must be done by (or overseen by) a PCQI and must be done within 90 calendar days of the first production date. Retail food businesses should carefully review the validation information within the Food Safety Plans for products they purchase, especially when novel preventive control strategies (such as new clean-label antimicrobial agents for control of pathogens) are used.

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Implementation and Management of Preventive Controls: Monitoring, Verification, Corrective Actions, and Associated Records

8.1 Introduction

Most of the activities discussed in previous chapters of this book represent activities conducted before manufacturing occurs. Identifying hazards, conducting a hazard analysis, identifying preventive controls for hazards, and validating those preventive controls are mostly forward-thinking activities. They require thinking about and planning for how manufacturing activities **are going to be** conducted.

In contrast, the content of this chapter will focus on the actual implementation and management of preventive controls during product manufacture. The activities that will be covered here include monitoring, verification, corrective actions, and documentation and records. These activities are all closely related, and all reflect what is happening in the plant when product is being manufactured. This chapter is not intended to be an exhaustive overview of monitoring, verification, corrective actions, or documentation. Instead, we hope to give you some basic understanding of what the preventive controls for human food (PCHF) regulations require and how those requirements should be documented. By understanding the types of data that will be collected and how they might be recorded in the Food Safety Plan for each food product, a retail food business can better assess how well a supplier is complying with the FDA's PCHF regulations and the buyer's food safety specifications (which should be similar), and whether the food they source will be safe for its retail customers.

Verification, monitoring, corrective actions, and corrections are preventive control management components that apply to most types of preventive controls, including process, food allergen, sanitation, and supply-chain preventive controls (verification is not required for recall plans). This chapter will describe each of these activities and then provide some examples of the types of documentation that could be used for these activities within the Food Safety Plan and in its implementation records.

8.2 Monitoring

Monitoring has been defined as the act of conducting a planned series of observations or measurements of control parameters to assess whether a control measure is under control ([Codex Alimentarius, 2008](#)). The definition in the PCHF regulations for “monitor” is “to conduct a planned sequence of observations or measurement to assess whether control measures are operating as intended” (21 CFR Part 117.3). Monitoring includes the collection of information that indicates whether or not a preventive control is being performed. For example, the collection of temperature data for every batch of a product for which you use heat treatment as a preventive control would be a monitoring activity.

Monitoring for process controls is typically related to the collected data that shows that critical limits are not being exceeded. Some examples of monitoring for process controls include the following:

- Taking temperature measurements during cooking
- Timing the length of a cook step
- Ensure correct addition of an antimicrobial agent (an acid) by measuring pH
- Monitoring the final color of bread by comparison to baked product color standards to minimize acrylamide levels in product
- Ensuring that a metal detector is turned on
- Running product through a metal detector to ensure the absence of metal fragments in fragments that could represent a choking hazard

For other types of preventive controls, monitoring may include some observations that show that a particular procedure is being followed. For example, for a food allergen preventive control, monitoring could be the production worker recording the label number that was applied for a particular run to allow later verification that the correct ones were being applied to a product. For a sanitation preventive control, it could be the act of inspecting all food contact surfaces to ensure that no visible food residue is present, no allergens are present, or collecting samples for microbiological testing of environmental surfaces to verify sanitation preventive controls are functioning properly ([Chapter 9](#)).

As may be apparent from these lists, there is a wide range of types of activities that may be considered “monitoring.” In some cases, depending on the type of preventive control, monitoring may be rather limited (for example, ensuring that the metal detector is turned on).

A manufacturer’s Food Safety Plan should document the following for each preventive control:

- What is going to be monitored?
- How will monitoring be performed?
- How frequently will monitoring be conducted?
- Who will be conducting the monitoring?

Examples for how this information can be documented is found later in this chapter in [Fig. 8.2](#).

Note that the FDA plans to issue detailed guidance on monitoring procedures in Chapters 6–13 of their draft guidance on preventive controls ([U.S. Food and Drug Administration, 2016](#)), which is not available at the time of writing.

8.3 Verification

Verification and monitoring are closely related and sometimes may even appear to be the same thing ([Food Safety Preventive Controls Alliance, 2016](#)).

Verification has been defined as “an ongoing activity used to determine that the control measures have been implemented as intended. Verification occurs during or after operation of a control measure through a variety of activities, including observation of monitoring activities and review of records to confirm that implementation of control measures is according to design” ([Codex Alimentarius, 2008](#)).

The definition in the PCHF regulations for verification is similar: “the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.” Verification includes anything that is done that shows that preventive controls are being performed correctly and that the Food Safety Plan is operating as intended. It can include small, defined activities (such as annual checks on a freezer alarm system) to large, global activities such as the review of the Food Safety Plan itself.

Examples of verification activities include all of the following:

- Review of temperature data following a cook step
- Ensuring that the thermometer you use in a cook step is calibrated (through periodic calibration) and accurate (daily testing of an ice slurry to verify a reading of 32°F)
- Running metal standards through a metal detector at the beginning of every shift to ensure it is functioning correctly to reject metal of a specific size
- Sampling of a ready-to-eat (RTE) product and testing it for pathogens or an indicator organism
- Allergen testing on equipment and/or finished product when using the same equipment for products that contain different allergens
- The quality supervisor reviewing the records created during production each week to ensure that the correct labels were applied to product
- Visual inspection of equipment for cleanliness
- Reviewing data from environmental monitoring for sanitation controls ([Chapter 9](#))
- Auditing a supplier

- Sampling and testing a raw ingredient to ensure the absence of mycotoxin
- Review of records from monitoring, corrective action, and verification activities by a supervisor
- Reanalyzing your Food Safety Plan

The important thing to remember is not the precise differentiation between monitoring and verification, which is not always black and white, even for experienced food safety professionals. Instead, it's more important to ensure that activities are conducted to ensure a preventive control is being implemented and to review and document those activities and any output from them to ensure they are being performed and that the associated outputs are consistent with control of the hazard. As in the words of the Food Safety Preventive Controls Alliance (FSPCA) PCHF Participant's Manual: "Focus on what must be done to control the hazard, rather than what a specific step is called" ([Food Safety Preventive Controls Alliance, 2016](#)).

The Food Safety Plan must have written procedures for verification activities, which includes methods used, the sampling plan, and the timing and frequency with which tests are conducted (which can be documented as discussed later in [Fig. 8.5](#)). Methods used have to be scientifically valid and identify what is being tested; methods developed and published by recognized organizations such as the FDA are good choices. It must be possible to trace verification testing results back to the lots that could be affected.

Some activities such as microbiological testing or equipment calibration may be conducted by a contract testing service or testing laboratory (which needs to have proficiency in testing food samples). The laboratory to be used should be specified in the FSP.

The frequency of verification depends on the activity and level of risk. Thermometer calibration may only occur once a year, while accuracy checks with ice slurries and boiling water may be conducted more than once a day. However, the review of verification records must occur within 7 working days of the time that the record was generated and must be performed (or overseen by) a Preventive Control Qualified Individual (PCQI).

When verification activities indicate a problem, a corrective action or a correction is needed ([Section 8.4](#)).

8.4 Corrective Actions and Corrections

When monitoring and verification activities indicate that a preventive control may no longer be properly working to prevent a hazard, or if a deviation occurs, a corrective action or a correction is needed.

Under the preventive controls regulations, corrective actions are defined as "actions to identify a problem with preventive control implementation, to reduce the likelihood the problem

will recur, evaluate affected food for safety, and prevent it from entering commerce” (U.S. Food and Drug Administration, 2015).

In contrast, corrections are “steps taken to timely identify and correct a minor, isolated problem that occurs during food production” (U.S. Food and Drug Administration, 2015). More formally, the preventive controls regulations (21 CFR Part 117.3) define a “correction” as follow:

an action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce.

Table 8.1 explains some of the key differences between corrective actions and corrections.

Of course, a manufacturer may experience problems with preventive controls that were not anticipated when the Food Safety Plan was developed. In this case, corrective actions still need to be taken and documented. The Food Safety Plan should be reanalyzed to determine if the plan should be modified.

If you are responsible for food safety at a retail food establishment, it is important to pay close attention to corrective action plans and their implementation records when reviewing

Table 8.1: Differences between corrective actions and corrections.

Factor	Corrective Action	Correction
Type of problem covered	Deviations from preventive controls that could directly impact product safety	Minor, isolated problems that do not directly impact product safety
Examples of problems covered	<ul style="list-style-type: none"> • The presence of a pathogen or indicator organism in an ready-to-eat product or during environmental testing • Allergens left on food contact surfaces before product without allergen produced • Common for process preventive controls 	<ul style="list-style-type: none"> • Identification of food residue left on a piece of equipment after cleaning • Most common for sanitation preventive controls
Procedures	<p>Written procedures for the following should be prospectively documented in the Food Safety Plan:</p> <ul style="list-style-type: none"> • Procedures to identify and correct a problem that has occurred with the implementation of a preventive control • Procedures to prevent reoccurrence • Procedures to evaluate the safety of affected food (and if evaluation cannot be done, how affected food would be prevented from distribution) 	Not required

Adapted from Food Safety Preventive Controls Alliance, 2016. Preventive Controls for Human Foods Participant Manual (Online). Available from: http://www.iit.edu/ifsh/alliance/pdfs/FSPCA_PC_Human_Food_Course_Participant_Manual_V1.2_Watermark.pdf.

Food Supply Plans for ingredients and products that you will eventually sell to consumers to feel confident that the procedures they use will be effective to ensure food safety.

8.5 Documentation and Records

The records associated with a Food Safety Plan can be categorized into two types of records: the Food Safety Plan itself and its implementation records.

The Food Safety Plan consists of records listed in Table 8.2.

Implementation records (which are only needed if hazards requiring preventive controls were identified in the hazard analysis) include the following:

- Monitoring data
- Records of corrective actions that are taken
- Verification activities (for example, calibration records or environmental monitoring, hygienic zone site selection, and corrective actions made when positive samples found)
- Validation documentation
- Supply-chain program implementation
- Applicable training records

Table 8.2: Components of a Food Safety Plan.

Document	Requirements
Background information <ul style="list-style-type: none"> • The company and the facility, products made, and list of the food safety team personnel • Product description • Manufacturing flow diagram • Process description 	Although this information is not required, it is very useful for anyone (including regulators and auditors) reviewing the Food Safety Plan
Hazard analysis	Required for all Food Safety Plans
Preventive controls information <ul style="list-style-type: none"> • Process preventive controls • Allergen preventive controls • Sanitation preventive controls • Supply-chain preventive controls 	Only required when hazards requiring a preventive control have been identified in the hazard analysis
Recall plan	
Monitoring procedures	
Verification procedures	
Corrective action procedures	

Based on Food Safety Preventive Controls Alliance, 2016. Preventive Controls for Human Foods Participant Manual (Online). Available from: http://www.iit.edu/ifsh/alliance/pdfs/FSPCA_PC_Human_Food_Course_Participant_Manual_V1.2_Watermark.pdf.

The FDA does not specify an exact format for the Food Safety Plan or any of the required implementation records. The FSPCA has, however, generated useful templates that can be used or adapted for many of these records. These templates are included in Appendix 2 of the FSPCA training manual ([Food Safety Preventive Controls Alliance, 2016](#)) and are also available in Appendix 2 of the draft guidance on preventive controls ([U.S. Food and Drug Administration, 2016](#)).

The Food Safety Plan is required to be kept on-site (or available on-site electronically). Implementation records are not required to be kept on-site with the Food Safety Plan but should be accessible within 24 hours upon request. Records must be originals or true copies or electronic copies and should be retained for at least 2 years after their preparation (21 CFR Part 117.315 (a)(1)). A food retail buyer may work with a supplier to access all implementation records of each product made on a regular basis as a means to ensure each batch/lot of product is produced according to the Food Safety Plan.

An example of a hazard analysis is included in [Chapter 5](#). Examples of other Food Safety Plan records are found in [Section 8.5.1](#), while examples of implementation records are found in [Section 8.5.2](#).

8.5.1 Food Safety Plan Records

The Food Safety Plan spells out in detail the hazards identified in the hazard analysis. It then links those hazards to preventive controls along with the monitoring, verification, and corrective actions.

A process preventive control might be documented in the Food Safety Plan in a table format ([Fig. 8.1](#)), while example documentation for a food allergen preventive control, a sanitation preventive control, and a supply chain are shown in [Figs. 8.2–8.4](#), respectively.

8.5.2 Implementation Records

Implementation records include the “working” records generated during and after the manufacturing run to ensure preventive controls are being correctly implemented and are working appropriately.

Monitoring and verification records should contain the actual values and observations recorded at the time the activities were conducted. Information included should include the date and time when an activity was performed along with the signature or initials of the person performing the activity. The information in the records should be adequate to establish which lots of products are covered. An example of a monitoring and verification log is shown in [Fig. 8.5](#).

Corrective actions also require documentation, a form such as that shown in [Fig. 8.6](#).

PLANT NAME Completely Cookie Inc.		ISSUE DATE March 10, 2017		PAGE 1 of 1	
ADDRESS 1500 Cookie Way Denver, CO 2333		SUPERSEDES NA		PRODUCT AND CODE Double Chocolate Cookie Dough 0099848	
Process Control		Metal detection			
Hazard(s)		Metal shavings that may come off the paddles while mixing the ingredients			
Parameters, values or critical limits		Metal detector is turned on	Metal detector is online with the product line	The conveyor speed is correctly set	No metal fragments larger than 2 mm in size (longest dimension) are detected in product
Monitoring	What	Ensure metal detector is working	Ensure that all product goes through a metal detector	Ensure that the speed is not too fast, which might prevent metal fragments from being detected	Product that the metal detector signals contains metal fragments > 2 mm in size are rejected.
	How	Visual inspection	Visual inspection	Visual inspection of speed indicator	Examine product rejected by metal detector for presence of metal fragments
	Frequency	Beginning of each shift	Beginning of each shift	Beginning of each shift	Beginning of each shift
	Who	Production employee	Production employee	Production employee	Production employee
Corrective Action or Correction		Turn on metal detector	Position metal detector appropriately	Reset speed to the correct setting	Segregate product with metal fragments, and inspect product that went through the detector before and after the metal-containing product. Rework or discard any product as necessary. Identify the source of metal and make necessary repairs to equipment as needed.
Verification		Review of Metal Detector Log within 7 days	Review of Metal Detector Log within 7 days	Review of Metal Detector Log within 7 days	Pass ferrous and non-ferrous wands through detector at start and end of shift to ensure proper functioning
Records		Metal Detector Log	Metal Detector Log	Metal Detector Log	Metal Detector Log Verification Log Corrective Action Log

Figure 8.1

Process preventive control documentation example for Food Safety Plan. *Adapted from Food Safety Preventive Controls Alliance, 2016. Preventive Controls for Human Foods Participant Manual (Online). Available from: http://www.iit.edu/ifsh/alliance/pdfs/FSPCA_PC_Human_Food_Course_Participant_Manual_V1.2_Watermark.pdf.*

8.6 Gaining Access to Supplier's Preventive Controls Documentation

As a retail food business, you can take advantage of the preventive controls–related documentation that a supplier generates to ensure the ingredients and products you purchase from that supplier continually meet your specifications. During an audit or inspection of the supplier, the preventive controls that the supplier has implemented can be reviewed, and you (as a retail food business) can see the types of monitoring or verification data that are collected for each

PLANT NAME			ISSUE DATE			PAGE			
Completely Cookie Inc.			March 10, 2017			1 of 1			
ADDRESS			SUPERSEDES			PRODUCT AND CODE			
1500 Cookie Way Denver, CO 2333			NA			Double Chocolate Cookie Dough 0099848			
ALLERGEN PREVENTIVE CONTROLS									
Allergen Controls	Hazard(s)	Criteria	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving label	Undeclared allergens: Wheat or egg or milk	Presence of allergens (present in formulation) are listed on the labels received	Label matches product specifications and declares wheat, egg, and milk	Visual inspection to label specification	Each receipt before releasing to production	Label coordinator	If allergen statement is incorrect: 1. Segregate and block packaging stock 2. Contact supplier for return, identify root cause, and obtain new labels	QA reviews Allergen Label Receiving Inspection Log and other records weekly and compares results with previous results to look for trends	Allergen Label Receiving Inspection Log Corrective Action records
Fill, weigh, packaging and labeling	Undeclared allergens: Wheat or egg or milk	All finished product must have correct label on packaging	Label is present on product and declares wheat, egg, and milk	Visual check of product labels	Beginning and end of run and when label stock is changed	Line operator	If the label is incorrect: 1. Segregate product, inspect back to last good check, 2. Relabel product 3. Identify root cause and conduct training to prevent recurrence	QA reviews Allergen Label Check Log, Corrective Action records, and Verification records within 7 working days	Allergen Label Check Log Corrective Action records
	Undeclared peanut allergen from peanut butter cookie dough made in same facility	Dedicated mixer and filler equipment for peanut-containing products to prevent cross-contact	Peanut-dedicated mixer and filler are NOT used for this product	Visual check to ensure correct mixer and filler used	Beginning of shift and at each formula change	Line operator	If the wrong equipment was used: 1. Segregate product, inspect back to last good check 2. Discard product or rework into chocolate peanut butter product 3. Replace correct equipment 4. Identify root cause and conduct training to prevent recurrence	QA reviews and initials records within 7 days; records are reviewed to identify trends	Equipment Check Log Corrective Action records

Figure 8.2

Allergen preventive controls documentation example for Food Safety Plan. *Adapted from FSPCA Training Models, Food Safety Preventive Controls Alliance, 2016. Preventive Controls for Human Foods Participant Manual (Online). Available from: http://www.iit.edu/ifsh/alliance/pdfs/FSPCA_PC_Human_Food_Course_Participant_Manual_V1.2_Watermark.pdf.*

PLANT NAME Completely Cookie Inc.	ISSUE DATE March 10, 2017	PAGE 1 of 1
ADDRESS 1500 Cookie Way Denver, CO 2333	SUPERSEDES NA	PRODUCT AND CODE Double Chocolate Cookie Dough 0099848
Sanitation Preventive Controls		
Location	Cookie dough mixing area	
Purpose	Cleaning and sanitizing the cookie dough mixer and the surrounding area is important to prevent contamination of the cookie dough with environmental pathogens	
Frequency	Cleaning: At lunch break and at the end of daily production Sanitizing: Before operation begins, at lunch break, and at the end of daily production. Sanitize after cleaning.	
Who	Sanitation team member	
Procedure	1. Remove gross soil from mixing bowl and mixing area with a squeegee. 2. Clean bowl, metal paddles, and table areas with a clean cloth dipped in XYZ cleaning solution (8 oz. per gallon). 3. Rinse bowl, metal paddles, and table areas with clean water. 4. Spray bowl, metal paddles, and table areas with 200 ppm quaternary ammonium compound solution, ensuring the surface is covered. 5. Allow bowl, metal paddles, and table areas to air dry, about 5 minutes.	
Monitoring	Inspect bowl, paddles, and mixing area for residual soil and cleanliness. Record on Daily Sanitation Monitoring Sheet. Use test strip to measure the sanitizer quantitation before using. Record on Daily Sanitation Monitoring Sheet.	
Corrections	If residual soil is observed on mixer, paddles, or in mixing area, reclean and sanitize. If sanitizer solution is not at the proper concentration, make a new solution.	
Records	Daily Sanitation Monitoring Sheet	
Verification	Supervisor must review and sign the Daily Sanitation Sheet within 7 working days.	

Figure 8.3

Sanitation preventive controls documentation within a Food Safety Plan. *Adapted from Food Safety Preventive Controls Alliance, 2016. Preventive Controls for Human Foods Participant Manual (Online). Available from: http://www.iit.edu/ifsh/alliance/pdfs/FSPCA_PC_Human_Food_Course_Participant_Manual_V1.2_Watermark.pdf.*

product run. It should be possible to request monitoring or verification data for each run of products that a supplier makes for you. For example, you may want to request copies of environmental monitoring data that are used by your supplier to verify a sanitation preventive control for each lot of a RTE product that you will be serving directly to customers in your retail food establishments.

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ADDRESS 1500 Cookie Way Denver, CO 2333	SUPERSEDES NA	PRODUCT AND CODE Double Chocolate Cookie Dough 0099848

SUPPLY-CHAIN-APPLIED CONTROLS PROGRAM

Determination of Verification Procedures

Ingredient 1: Flour

Hazards requiring a supply-chain-applied control	Hazard 1: <i>Salmonella</i> and Shiga-toxin-producing <i>E. coli</i> Hazard 2: Mycotoxin (Vomitoxin)
Preventive controls applied by the supplier	For Hazard 1: Heat treatment of flour For Hazard 2: Supplier tests for vomitoxin using a valid method and lists results on certificate of analysis (CoA)
Verification activities	For Hazard 1: A third-party supplier audit by a qualified auditor is used to verify control of the identified hazards by the supplier. For Hazard 2: A CoA is obtained from the supplier with each lot of flour
Verification procedures	For Hazard 1: A copy of a third-party audit is requested from the supplier on an annual basis. The audit date, auditor qualifications, audit procedures, and audit results are reviewed. Discussion with the supplier occurs as necessary to verify that any corrective actions identified in the audit report are resolved. For Hazard 2: Review the CoA to ensure that the vomitoxin levels is ≤ 1 ppm in the flour
Records	For Hazard 1: Copy of the 3 rd -party audit and report documenting the resolution of corrective actions arising from the audit; Incoming Goods Log For Hazard 2: CoA; Incoming Goods Log

Ingredient 2: Liquid Eggs

Hazards requiring a supply-chain-applied control	<i>Salmonella</i>
Preventive controls applied by the supplier	Heat treatment
Verification activities	A third-party supplier audit by a qualified auditor is used to verify control of the identified hazards by the supplier.
Verification procedures	A copy of a third-party audit is requested from the supplier on an annual basis. The audit date, auditor qualifications, audit procedures, and audit results are reviewed. Discussion with the supplier occurs as necessary to verify that any corrective actions identified in the audit report are resolved.
Records	Copy of the 3 rd -party audit and report documenting the resolution of corrective actions arising from the audit; Incoming Goods Log

Figure 8.4

Supply-chain preventive controls documentation in Food Safety Plan. Adapted from Food Safety Preventive Controls Alliance, 2016. *Preventive Controls for Human Foods Participant Manual (Online)*. Available from: http://www.iit.edu/ifsh/alliance/pdfs/FSPCA_PC_Human_Food_Course_Participant_Manual_V1.2_Watermark.pdf.

Approved Suppliers for Ingredients Requiring a Supply-chain-applied Control

Ingredient Requiring Supply-chain-applied Control	Approved Supplier	Hazard(s) requiring supply-chain-applied control	Date of Approval	Verification method	Verification records
Flour	All Grains, Inc.	Mycotoxin	4/12/2017	Supplier's CoA with each shipment	CoA and Incoming Goods Log
		<i>Salmonella</i> and Shiga-toxin-producing <i>E. coli</i>	4/17/2017	Copy of 3 rd party audit by a qualified auditor obtained from supplier	Copy of audit report and report of the resolution of corrective actions arising from the audit are kept in Supplier Verification File; Incoming Goods Log
Liquid Egg	Sunny Farms Corporation	<i>Salmonella</i>	3/15/2017		

Receiving Procedure for Ingredients Requiring a Supply-chain-applied Control

For each shipment received, the receiving clerk:

- Verifies that the product is from an approved supplier
- Documents the above in the Incoming Goods Log

Figure 8.4
cont'd.

8.7 Reanalysis of Food Safety Plan

A reanalysis of the Food Safety Plan must occur at least once every 3 years (21 CFR Part 117.170). The owner, operator, or agent in charge must sign and date the original Food Safety Plan and whenever modifications to it are made (21 CFR Part 117.310).

A reanalysis of the Food Safety Plan is also required whenever a significant change occurs, which has the potential to impact product safety. Such changes include the following (adapted from [Food Safety Preventive Controls Alliance, 2016](#)):

- Changes to raw materials or to suppliers
- Changes in product (formulation, packaging, etc.) or process
- Changes to the facility, including the introduction of new products (which could introduce allergen hazards, for example), new equipment, construction activities, etc.
- Recurring deviations or corrective actions
- Changes in distribution or consumer handling (new use in infants, for example)

As discussed in [Chapters 5 and 6](#), new food safety hazards continue to occur or to be recognized. It is important for food manufacturers and also retail food companies to remain aware of such issues using some of the tools discussed in those chapters. [Table 8.3](#) lists some food safety hazards that were not initially realized and which now should be considered when developing a Food Safety Plan.

PLANT NAME Completely Cookie Inc.	ISSUE DATE March 10, 2017	PAGE 1 of 1																												
ADDRESS 1500 Cookie Way Denver, CO 2333	SUPERSEDES NA	PRODUCT AND CODE Double Chocolate Cookie Dough 0099848																												
ALLERGEN LABEL LOG																														
<p>Hazard: Undeclared allergens: Wheat or egg or milk</p> <p>Parameters, Values, and Critical Limits: A label must be present on all finished product which declares the following allergens present in the formula: wheat, egg, and milk</p> <p>Procedure: Visual inspection of labels</p> <p>Corrective Action: If label is not correct, segregate product, inspect back to last good check, relabel product, identify root cause, and conduct training as needed to prevent reoccurrence</p>																														
Date	Time	<table border="1"> <thead> <tr> <th>Product</th> <th>Lot Number</th> <th>Proper Label Applied? (Yes/No)</th> <th>Line Operator Initials</th> </tr> </thead> <tbody> <tr> <td>Double chocolate cookie dough</td> <td>17-05728</td> <td>Yes</td> <td>wb</td> </tr> <tr> <td>Double chocolate cookie dough</td> <td>17-05728</td> <td>Yes</td> <td>wb</td> </tr> <tr> <td>Double chocolate cookie dough</td> <td>17-05728</td> <td>Yes</td> <td>wb</td> </tr> <tr> <td>Double chocolate cookie dough</td> <td>17-05728</td> <td>No</td> <td>wb</td> </tr> <tr> <td>Double chocolate cookie dough</td> <td>17-05728</td> <td>Yes</td> <td>wb</td> </tr> <tr> <td>Double chocolate cookie dough</td> <td>17-05728</td> <td>Yes</td> <td>wb</td> </tr> </tbody> </table>	Product	Lot Number	Proper Label Applied? (Yes/No)	Line Operator Initials	Double chocolate cookie dough	17-05728	Yes	wb	Double chocolate cookie dough	17-05728	Yes	wb	Double chocolate cookie dough	17-05728	Yes	wb	Double chocolate cookie dough	17-05728	No	wb	Double chocolate cookie dough	17-05728	Yes	wb	Double chocolate cookie dough	17-05728	Yes	wb
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Double chocolate cookie dough	17-05728	Yes	wb																											
Double chocolate cookie dough	17-05728	Yes	wb																											
Verification Review Name and Signature: Christopher King <i>Christopher King</i>		Date of Review: 5/19/2017																												

Figure 8.5

Monitoring and verification log for allergen preventive control. Based on Food Safety Preventive Controls Alliance, 2016. Preventive Controls for Human Foods Participant Manual (Online). Available from: http://www.iit.edu/ifsh/alliance/pdfs/FSPCA_PC_Human_Food_Course_Participant_Manual_V1.2_Watermark.pdf.

PLANT NAME Completely Cookie Inc.	ISSUE DATE March 10, 2017	PAGE 1 of 1
ADDRESS 1500 Cookie Way Denver, CO 2333	SUPERSEDES NA	PRODUCT AND CODE Double Chocolate Cookie Dough 0099848
CORRECTIVE ACTION FORM		
Date of Record: <i>5/15/2017</i>	Date and Time of Deviation: <i>5/15/27 2:15 pm</i>	Lot Number: <i>17-05728</i>
Description of Deviation: <i>When label stock ran out, it was replaced with more label stock, but it was an incorrect label stock (the peanut butter cookie dough stock) and did not list the milk (and incorrectly listed peanut). The mistake was caught quickly by the line operator.</i>		
Actions Taken to Restore Order to the Process: <i>Cookie dough tubs were inspected in the order they were labeled back to where correct labels were present. Product with the wrong labels had their labels removed and were manually relabeled with the correct labels. New label stock which listed the correct allergen was then obtained and used for the rest of the shift.</i>		
Name of Person Taking Action: <i>Patricia Thompson</i>		Signature: <i>Patricia Thompson</i>
Amount of Product Involved in Deviation: <i>2 tubs of cookie dough</i>		
Evaluation of Product Involved with Deviation: <i>Incorrect labels were initially on 2 tubs of cookie dough. These labels were removed and replaced with the correct labels.</i>		
Final Disposition of Product: <i>The product involved in the deviation was relabeled and released.</i>		
Reviewed by (Name and Signature): Christopher King <i>Christopher King</i>		Date of Review: <i>5/19/2017</i>

Figure 8.6

Example of a corrective action form. Adapted from Food Safety Preventive Controls Alliance, 2016. Preventive Controls for Human Foods Participant Manual (Online). Available from: http://www.iit.edu/ifsh/alliance/pdfs/FSPCA_PC_Human_Food_Course_Participant_Manual_V1.2_Watermark.pdf.

Table 8.3: Unexpected food hazards.

Category	Food	Hazard	Comments	References
New or modified pathogen	Apple cider	<i>Escherichia coli</i> O157:H7	<i>E. coli</i> O157:H7 was shown to be more acid tolerant than other <i>E. coli</i> strains, which did not survive in apple cider	Miller and Kaspar (1994)
	Beef	Bovine spongiform encephalopathy	The possibility of transmission from beef to humans led to changes in the beef industry	Brown (1997) and Dealler and Lacey (1990)
New food-pathogen combination	Caramel apples	<i>Listeria monocytogenes</i>	The interface between two different foods in a combination food may have different characteristics and harbor different pathogens than either food	Glass et al. (2015)
	Ice cream	<i>L. monocytogenes</i>	Very low levels of environmental contamination of ice cream by <i>L. monocytogenes</i> can cause disease in susceptible individuals	Centers for Disease Control and Prevention (2015) and Chen et al. (2016)
New food product	Cashew cheese	<i>Salmonella</i> Stanley	A rare strain of <i>Salmonella</i> was found in a new food product	Centers for Disease Control and Prevention (2014)
New chemical hazard	French fries	Acrylamide	High levels of acrylamide, a probable carcinogen, were unexpectedly found in fried potatoes and other foods	Paul et al. (2016) and Mucci et al. (2003)
	Milk	Melamine	Melamine was an unexpected adulterant in milk products in China	Ingelfinger (2008) and Sharma and Paradakar (2010)
	Cumin	Peanut and almond allergen	Cumin was unexpectedly found to be contaminated to high levels with peanut and almond allergens	Bennett (2015)
	Lychee (<i>Litchi</i>) fruit	Hypoglycin A and methylenecyclopropylglycine toxins	An outbreak of unexplained acute neurological illness in children was linked to <i>litchi</i> consumption, specifically, to the hypoglycin A and methylenecyclopropylglycine toxins naturally present in the fruit	Kaushik et al. (2014)
New physical hazard	Gel candies	Choking hazard	The shape and consistency of the thimble-sized gel candies were a choking hazard in children	Winter (2001)
Unexpected consumer uses of foods	Frozen vegetables	<i>L. monocytogenes</i>	Consumers are increasingly eating frozen vegetables without cooking them (frozen peas as a snack for children, frozen spinach in dips, other frozen vegetables in raw food shakes)	Ingham (2015)
Consumer abuse of foods	Carrot juice	Botulism	Refrigeration was the only barrier to the growth of <i>Clostridium botulinum</i> in a commercial carrot beverage, and several consumers developed botulism after drinking the juice after it was stored without refrigeration	Sheth et al. (2008)

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Environmental Monitoring to Prevent Facility-Related Hazards

9.1 Introduction

Potential ingredient-related biological hazards (discussed in [Chapter 3](#)) that become “resident” in a facility have been and continue to be the root cause of serious multistate foodborne disease outbreaks and significant food recalls. Incoming ingredients that contain potential hazards that are not controlled initially by one supplier can become established in multiple food processing facilities along the supply chain. This lack of control early in the supply chain can impact multiple products when a recall is required (or worse, when the product leads to a foodborne disease outbreak).

One such example of an ingredient-related hazard that can become a process and facility-related hazard is *L. monocytogenes*, which led to a multistate foodborne disease outbreak attributed to contaminated ice cream that lasted for half a decade (from 2010 to 2015). The exceptionally long time frame for the 10 cases and 3 deaths that occurred in this outbreak ([Fig. 9.1](#); [Centers for Disease Control and Prevention, 2015](#)) made the epidemiological investigation more challenging. In 2015, the South Carolina Department of Health and Environmental Control isolated *Listeria* as part of a routine sampling of two Blue Bell brand single-serving ice cream products collected from a distribution center. When informed of these test results, the Texas Department of State Health Services (where the facility that manufactured these products was located) tested and also isolated *Listeria* from samples of these two products and an additional product all made on the same production line in the Texas Blue Bell facility. Subsequent investigations by the FDA and CDC showed the root cause of the product contamination was the environmental persistence of *L. monocytogenes* in at least two different facilities located in two different states. These findings resulted in the recall of all linked products made in these facilities, which had been distributed nationwide ([Fig. 9.2](#)). *L. monocytogenes* was also isolated by the FDA from a company facility in Alabama that was not linked to the outbreak.

In 2016, Blue Bell initiated a similar public recall of all of its products that contained cookie dough. The cookie dough had been obtained as an ingredient for its ice cream products from a supplier, Aspen Hills Inc. After the FDA had found *L. monocytogenes* in a facility in Iowa run by Aspen Hills Inc., Blue Bell issued a press release stating boldly “BLUE BELL ICE

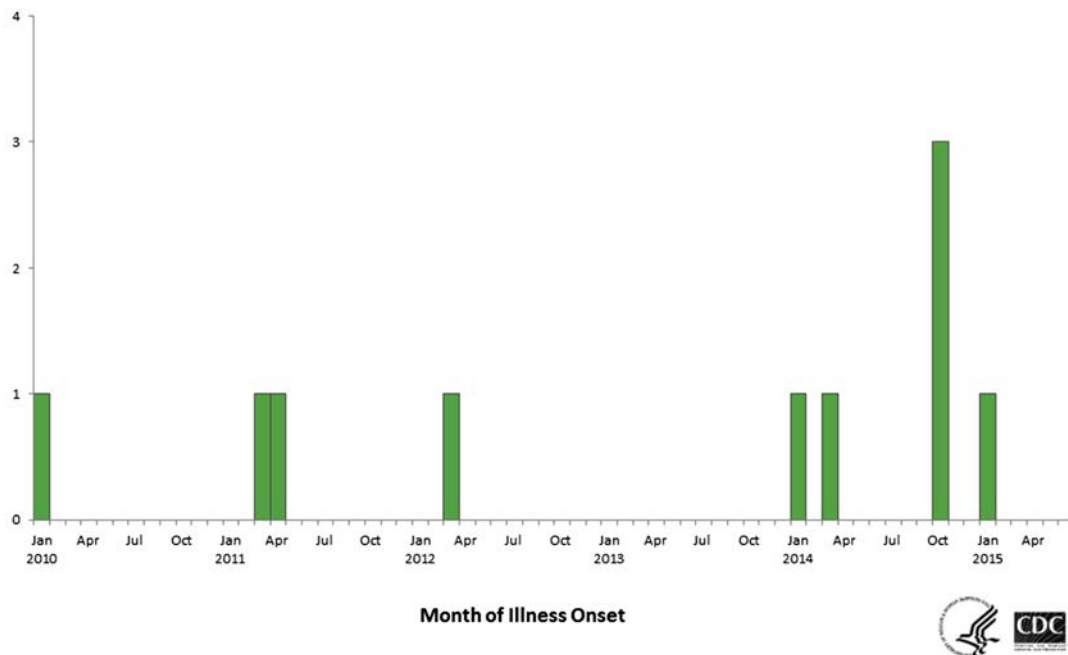


Figure 9.1

Epi curve of disease onset dates for Blue Bell ice cream *Listeria monocytogenes* outbreak cases. From Centers for Disease Control and Prevention, 2015. Multistate Outbreak of Listeriosis Linked to Blue Bell Creameries Products (Final Update). <https://www.cdc.gov/listeria/outbreaks/ice-cream-03-15/>.

CREAM RECALLS SELECT PRODUCTS CONTAINING CHOCOLATE CHIP COOKIE DOUGH PIECES PURCHASED FROM OUTSIDE SUPPLIER ASPEN HILLS DUE TO POSSIBLE HEALTH RISK” (Blue Bell Press Release, 2016). Environmental isolates of *L. monocytogenes* found in the cookie dough manufacturing facility matched those found in the Blue Bell product. A cookie dough recall notice by Aspen Hills Inc. was not made public. In addition to the Blue Bell Facilities, Aspen Hills Inc. shipped this same cookie dough product to more than 25 other food manufacturing facilities, all of which also initiated voluntary public recalls of all food products made with the Aspen Hill’s cookie dough ingredient produced during the time frame implicated in the recall.

The complex series of events leading to the 2015 outbreak and food product recalls by Blue Bell and the 2016 food ingredient and product recalls (Fig. 9.3) by both Aspen Hills and Blue Bell discussed above were all caused by the contamination of food products from the facility environments, as facility *L. monocytogenes* matched those found in product. Both businesses were also performing environmental monitoring of their facilities for *Listeria* before and at the time of the events. No link between *L. monocytogenes* strains was discovered between isolates found during the 2015 listeriosis outbreak and the 2016 recall related to contaminated cookie dough. However, in the 2016 recalls by both Aspen Hills and Blue



Figure 9.2

Listeria monocytogenes found in three Blue Bell ice cream manufacturing facilities. From Centers for Disease Control and Prevention, 2015. Multistate Outbreak of Listeriosis Linked to Blue Bell Creameries Products (Final Update). <https://www.cdc.gov/listeria/outbreaks/ice-cream-03-15/>.

Bell businesses, there was a direct link between the *L. monocytogenes* strains found in the Aspen Hills facility and its products with those found in the Blue Bell ice cream products.

The Aspen Hills company closed its business in 2017 (Fortune, 2017), suggesting to these authors that the cost to ensure removal of all environmental contamination was too high to remain in business. Although the financial impacts of the 2015 Blue Bell Ice Cream foodborne disease outbreak and 2015 and 2016 recall events caused by *L. monocytogenes*

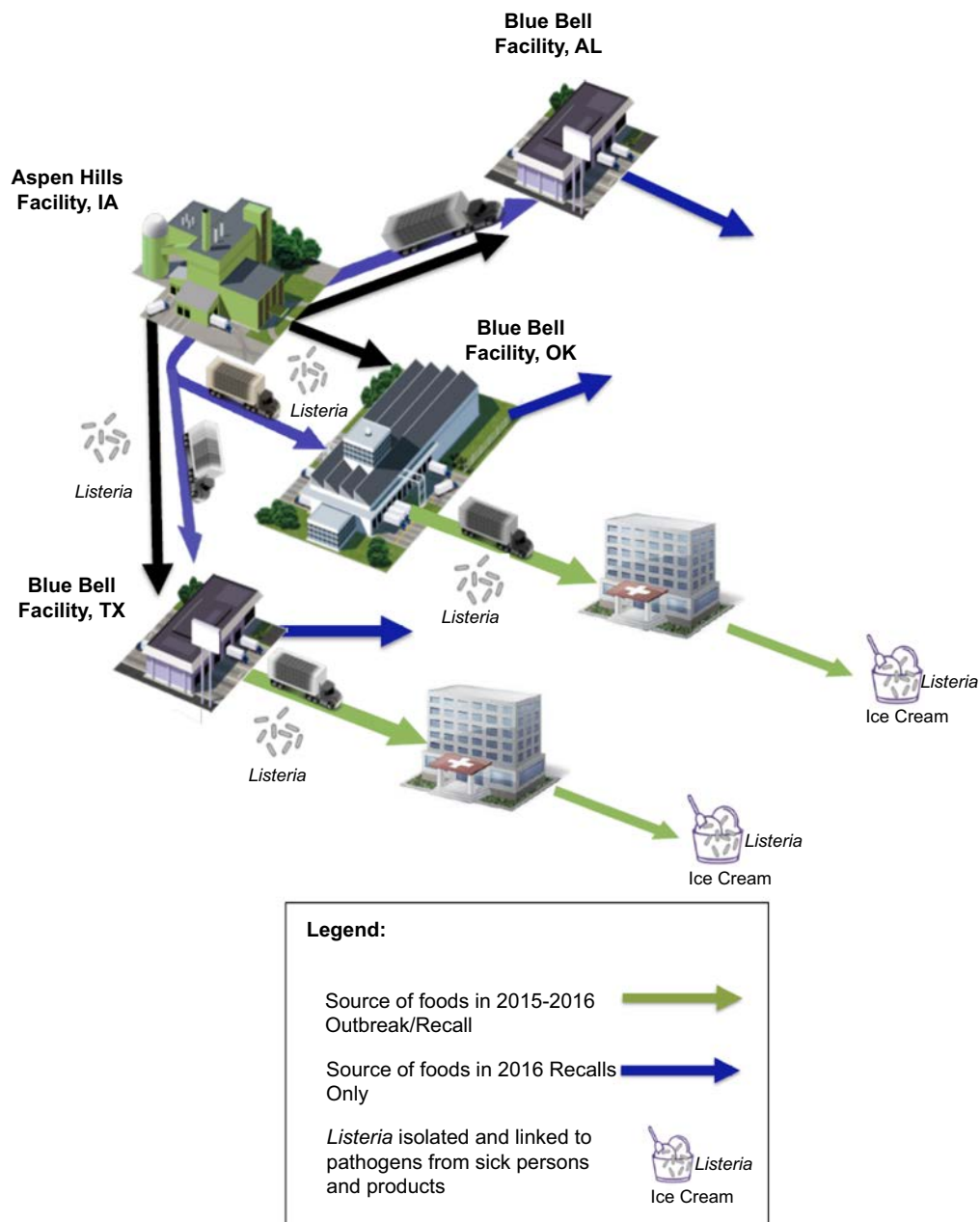


Figure 9.3
Summary of Blue Bell and Aspen Hills recalls, 2015 and 2016.

will likely not be known, the losses resulting from illnesses and deaths due to the likely contamination of food products from the facility environments are immeasurable (and preventable), and must be the focus of prevention in food manufacturing facilities where these potential hazards exist. This is especially critical with the knowledge that these same pathogens can persist in food manufacturing environments (with the risk of contamination of foods) for long periods of time. For example, *L. monocytogenes* can be highly persistent “resident pathogen”; one study showed the same strain of *L. monocytogenes* remained in an ice cream facility for over 7 years (Miettinen et al., 1999) and at two different fish processing facilities sampled 6 years apart (Holch et al., 2013). In the Blue Bell outbreak discussed above, the same strain of *L. monocytogenes* caused 10 known illnesses and 3 deaths over the course of 5 years (suggesting this strain persisted in a facility for at least 5 years). If this strain had been eliminated in 2010, three lives might not have been lost.

The CDC and FDA can confidently link pathogens from environmental sources in a food manufacturing facility to food products and to human illnesses/deaths by DNA sequence-based methods. Each pathogen has a unique DNA sequence, which is a linear sequence of chemical compounds called “bases.” There are four types of bases, each designed by a letter (A, T, C, and G). The linear order of these bases in a DNA molecule is called its sequence (e.g., TGCCATTGATCGGGGAATTTGA). Determining the order of bases is called DNA sequencing.

In the past, DNA sequencing was an expensive and time-consuming enterprise, so other techniques were used to compare DNA molecules. One of the most successful methods used by CDC, FDA, and many local agencies to analyze DNA samples collected from clinical, environmental, and food samples was pulsed field gel electrophoresis (PFGE). PFGE uses enzymes to cut the DNA at very defined sequences within the genome. The resulting DNA fragments will be different sizes based on the original genomic sequence. These fragments can be separated by size using PFGE, allowing a “bar code”-like comparison of different DNA samples. DNA that comes from isolates that are very similar in sequence will generate fragments that are similar in length. A similar pattern of lengths (“fingerprints” or “bar code”) on a gel (a laboratory assay used to analyze DNA fragments) from an environmental sample and a clinical sample might suggest a relationship between the two samples, while disparate patterns usually mean less closely related organisms.

PulseNet was founded 20 years ago to connect national, state, and local laboratories across the United States so they could easily share and compare PFGE analysis patterns. The ability to match DNA samples from different sources has proven invaluable in epidemiological investigations.

In more recent years, whole genome sequencing (WGS) has revolutionized DNA analysis, allowing analysis of the entire DNA sequence to be performed faster and less expensive than

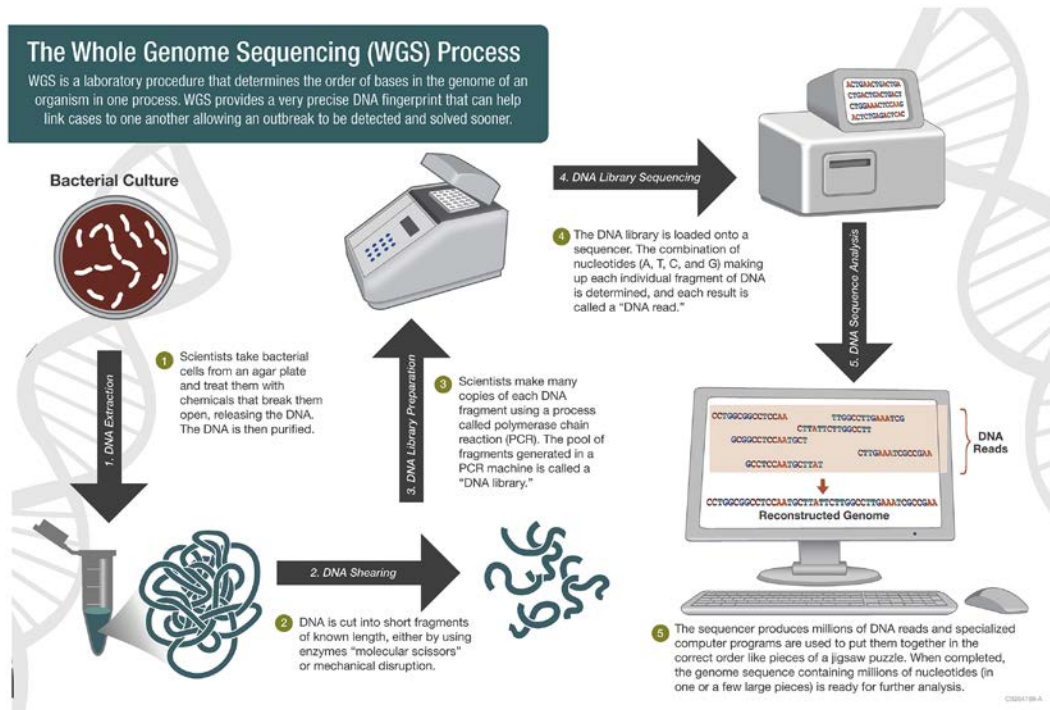


Figure 9.4

Overview of whole genome sequencing process. From Centers for Disease Control and Prevention, 2016. Whole Genome Sequencing (WGS). <https://www.cdc.gov/pulsenet/pathogens/wgs.html>.

ever before (Fig. 9.4). According to the CDC (Centers for Disease Control and Prevention, 2016), "Whole genome sequencing provides more detailed and precise data for identifying outbreaks than the current standard technique that PulseNet uses, pulsed-field gel electrophoresis (PFGE). Instead of only having the ability to compare bacterial genomes using 15–30 bands that appear in a PFGE pattern, we now have millions of bases to compare. That is like comparing all of the words in a book (WGS), instead of just the number of chapters (PFGE) to see if the books are the same or different."

Using WGS, CDC has found that some bacteria that appeared to be different using PFGE methods were actually the same strains and thus linked to the same source. This has helped the CDC discover the links to contaminated foods during outbreak investigations sooner. CDC began using WGS in 2013 to detect outbreaks caused by the *L. monocytogenes*. WGS proved instrumental in linking the pathogens from the environment and human illnesses/deaths in the outbreak discussed above (Centers for Disease Control and Prevention, 2015). The use of WGS is relevant to the food industry because the source of foodborne disease outbreaks will be identified much faster and with more precision in the near future.

Regulatory agencies can now match environmental pathogens found in food manufacturing facilities with outbreak-associated pathogens, including pathogen isolates from illnesses that may have occurred years before. However, WGS technology also represents a significant opportunity for the food industry as this technology can lead to better preventive controls and environmental monitoring processes to prevent these outbreaks from ever occurring.

The Blue Bell ice cream listeriosis outbreak, along with other high-profile listeriosis outbreaks in recent years arising from ready-to-eat (RTE) foods has made control of environmental pathogens within the food manufacturing environment a hot topic. In response, the FDA has issued a revised draft guidance on the control of *L. monocytogenes* in RTE foods during food manufacturing (Food and Drug Administration, 2017). This post-PCHF rule release guidance document provides many examples of the use of preventive controls to prevent pathogen contamination of RTE foods. Although the draft guidance focuses on *L. monocytogenes* control, many of the principles outlined in the guidance can be applied to other environmental pathogens. This chapter will also highlight some of the key recommendations from this new draft guidance document to provide retail food industry buyers with an understanding of how environmental contamination can occur, how it lead to food contamination, and how it can be prevented.

9.2 Reviewing Hazards and Environments That May Contribute to Contamination of Food Products

Environmental pathogens are becoming a serious problem in a food manufacturing facility because they can contaminate food products, including RTE foods, as described in this chapter and in more detail in the case study found in Appendix C of this book. A large number of biological hazards (including bacterial, viral, parasitic, and fungal pathogens, as well as the toxins they can produce) can persist in the environment. Some of these pathogens can not only survive harsh conditions in the environment (wide ranges of pH, temperature, and water activity) and resist chemical sanitation (Møretrø et al., 2017), but also can even grow under such conditions. This hardiness increases their probability of persisting in the environment of a manufacturing facility, potentially contaminating food products, and therefore increasing the risk of causing disease to consumers.

Because the environments found within most food manufacturing facilities (e.g., high moisture, food and biofilms, waste) are hospitable to these pathogens, these organisms can become hazards when they are transiently introduced into the facility via ingredients, packaging, pests, or people (Chapter 3). Once introduced into the environment, pathogens can persist within a food facility in niches and on equipment, potentially leading to contamination of RTE foods if those foods are exposed to the manufacturing environment prior to packaging (Fig. 9.5).

BIOFILMS

In food processing environments, bacteria first attach to organic or inorganic matter from food residues on surfaces. As the bacteria grow on the surface, a matrix of live, damaged, and dead bacterial cells attaches to this matrix, initiating a “colonization” of the surface. Many different types of bacteria can initiate a biofilm, including *Listeria* spp. and *Listeria monocytogenes* (both of which can inhabit a single biofilm on a surface). Other bacteria, including nonpathogenic spoilage and pathogenic organisms, can attach to these biofilms. If not removed, a biofilm traps more food debris, which provides nutrients to the bacteria for further growth. As the colony of bacteria grow, it produces extracellular polysaccharides which aid the further attachment of more bacteria to the surface and protect the bacterial layer against cleaners and sanitizers.

Generally, food processing follows a processing stream where raw ingredients such as flour, sugar, eggs, etc. are mixed/cooked. The process flows from a raw to RTE final product as it moves between processing steps/equipment. The simplified diagram in Fig. 9.5 illustrates how transient pathogens present in raw ingredients or in the raw food processing area can enter the RTE-processing area. As these raw ingredients move from one area or equipment to another, they may spill or be extruded, for example, depositing food residue and any associated hazards (e.g., *L. monocytogenes*) onto environmental surfaces. Normally, these pathogens entering a new environment are only transient inhabitants which are eliminated from the environment following routine cleaning and sanitation. However, if these transient pathogens are not eliminated (e.g., if they are deposited onto surfaces that are difficult to clean or parts of equipment that are not regularly disassembled for cleaning), they may survive, potentially forming biofilms and becoming resident in the environment. Resident pathogens can persist for many years in a facility, potentially contaminating foods made in the facility, which can lead to foodborne disease outbreaks.

The following table (Table 9.1) discusses some of the key differences between transient and persistent pathogens within a food manufacturing environment.

Preventing transient pathogens from becoming permanent residents within a food manufacturing environment is an important goal of sanitation programs and of sanitation preventive controls.

9.3 Conditions That Favor Introduction of Biological Hazards Into Food Products

Some environments and foods processed within a food manufacturing facility are not normally conducive to survival and persistence of pathogens. As discussed in Chapters 6 and 7, a food product’s formulation (e.g., high acidity) and/or validated process controls (such as cooking to required time and temperature) can eliminate many of these pathogens.

If an RTE product is packaged before and therefore not exposed to the environment after these preventive controls are applied, then there is very little risk of contamination of the

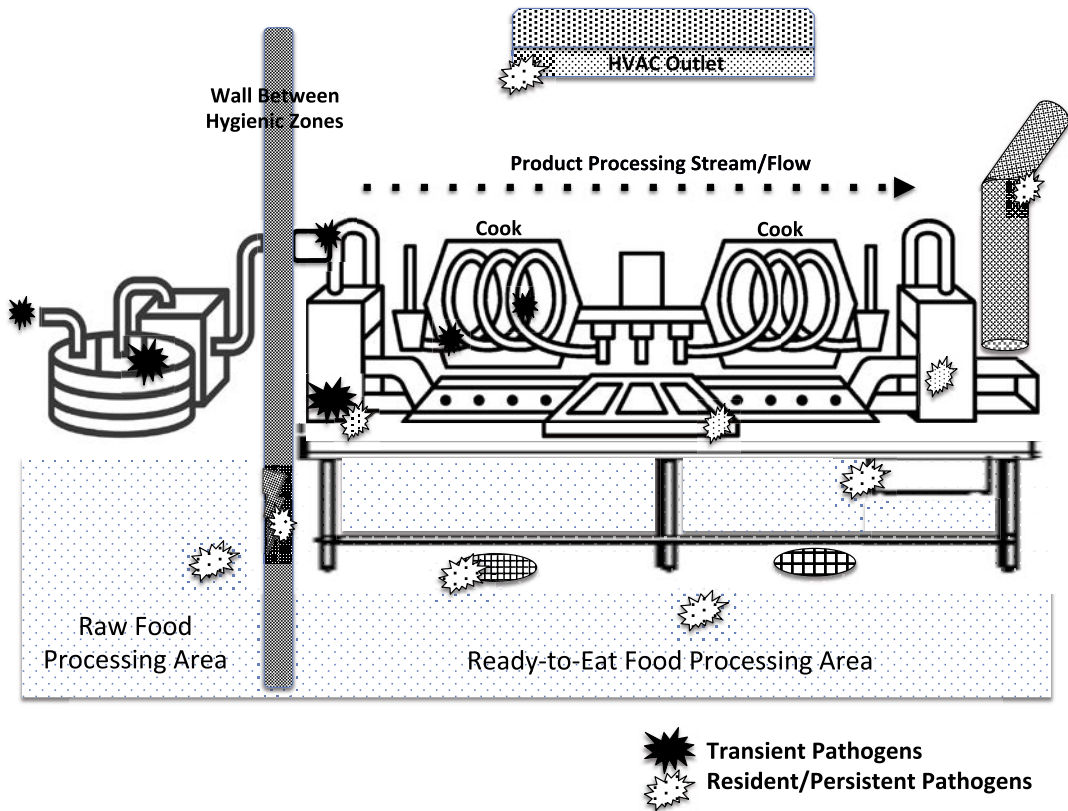


Figure 9.5
Locations of resident and transient pathogens in a food processing facility.

Table 9.1: Differences in resident versus transient pathogens in a food manufacturing facility.

Transient Pathogens	Resident (Persistent) Pathogens
<ul style="list-style-type: none"> Normally come into a food processing facility via raw ingredients, packaging, personnel, pests, and outside environments (leaking roofs) When associated with ingredients (potential hazards), product processing stream and environment is expected to sometimes test positive Normally removed and eliminated via cleaning and sanitation, pest control, facilities maintenance, personal hygiene Typically do not become established in the food processing environment 	<ul style="list-style-type: none"> Transient pathogens that become established and persist/survive in the environment Can persist for long periods of time and may provide source (biofilms) of additional strains of resident pathogens when left undisturbed Normally species (e.g., <i>Listeria monocytogenes</i>) specific but can include groups of strains of a species that change over time Normal cleaning and sanitation may not eliminate More likely to contaminate ready-to-eat foods during food processing

foods. However, in many food processing facilities, the contamination of foods with pathogens is a risk, such as under the following conditions:

- Product formulation supports the survival and growth of pathogens even at refrigeration temperatures
- Ingredients used to make the food products are associated with known pathogens (discussed in [Chapter 3](#))
- Food product formulations have a history of pathogen contamination
- Food products are made with RTE ingredients into an RTE product (e.g., mixing dried fruit, nuts, and honey into food bars) with no further processing or “kill” steps
- The food products are exposed to the environment in their RTE state before packaging

9.4 How Resident Pathogens Contaminate Food During Processing

Once transient pathogens become resident pathogens ([Table 9.1](#)), the locations of their environmental presence, the number of organisms present, and the time the pathogens are allowed to persist can determine the risk of RTE food contamination. The pathogen *Salmonella* can persist and survive (become resident) in dry environments and may not be a high risk for contamination of foods. However, a change in moisture and food source (food particles or film) can trigger growth and increase the potential for contamination of other environments, eventually leading to food contamination. Both pathogenic *Salmonella* spp. and *L. monocytogenes* can form biofilms in niches or surfaces within food facility environments (including on stainless steel) that lead to increased pathogen resistance to elimination by cleaning and sanitation.

Although many of the different bacterial pathogens associated with food ingredients can become resident pathogens in food facilities (because many are ubiquitous outside the food facility environments), *L. monocytogenes* causes higher mortality (20% vs. 1%) after infection in humans than does *Salmonella* and *E. coli* ([Crerar et al., 1996](#); [de Valk et al., 2005](#); [Scallan et al., 2011](#)). In addition, unlike these other vegetative bacterial pathogens, *L. monocytogenes* can grow in moist, cold environments that normally are effective preventive controls for the growth of *Salmonella* and other similar pathogens. *L. monocytogenes* can also survive high salt formulations, acid conditions, freezing temperatures, and is more resistant to heat ([Ferreira et al., 2014](#)). Because of these attributes, the FDA considers this pathogen as an adulterant in human foods and has provided guidance to the industry on the best means to prevent *L. monocytogenes* contamination of RTE foods in 2008 and in a revised form in 2017 ([Food and Drug Administration, 2017](#)), as discussed earlier in [Section 9.1](#).

It can be helpful to know where *L. monocytogenes* can contaminate food processing environments and how this pathogen can contaminate RTE foods in these environments to design methods to verify that preventive controls are working on a regular basis. The FDA’s new *L. monocytogenes* guidance document includes two helpful tables to help investigate *L. monocytogenes* contamination problems ([Food and Drug Administration, 2017](#)) that are reproduced here ([Tables 9.2 and 9.3](#)).

Table 9.2: Potential sources of *Listeria monocytogenes* in food facilities.

Description of Category	Potential Sources of <i>L. monocytogenes</i>
Ingredients	<ul style="list-style-type: none"> • Raw foods, such as: <ul style="list-style-type: none"> • Raw meat, poultry, and seafood • Raw milk • Raw produce
Processing materials	<ul style="list-style-type: none"> • Compressed air • Ice • Brine solutions used in chilling refrigerated RTE foods
Contact surfaces for ready-to-eat (RTE) foods	<ul style="list-style-type: none"> • Fibrous and porous-type conveyor belts • Filling and packaging equipment • Belts, peelers, and collators • Containers, bins, tubs and baskets • Slicers, dicers, shredders, and blenders • Utensils • Gloves
Surfaces that generally do not contact RTE foods	<ul style="list-style-type: none"> • In-floor weighing equipment • Cracked hoses • Hollow rollers for conveyances • Equipment framework • Wet, rusting, or hollow framework • Open bearings within equipment • Poorly maintained compressed air filters • Condensate drip pans • Motor housings • Maintenance tools (e.g., wrenches and screwdrivers) • Forklifts, hand trucks, trolleys, and racks • On/off switches • Vacuum cleaners and floor scrubbers • Trash cans and other such ancillary items • Tools for cleaning equipment (e.g., brushes and scouring pads) • Spiral freezers/blast freezers • Ice makers • Aprons

Continued

Table 9.2: Potential sources of *Listeria monocytogenes* in food facilities.—cont'd

Description of Category	Potential Sources of <i>L. monocytogenes</i>
Plant environment	<ul style="list-style-type: none"> Floors, especially cracks and crevices Walls Drains Ceilings, overhead structures, and catwalks Wash areas (e.g., sinks), condensate, and standing water Wet insulation in walls or around pipes and cooling units Rubber seals around doors, especially in coolers Metal joints, especially welds and bolts Contents of vacuum cleaners

From Food and Drug Administration, 2017. *Control of Listeria monocytogenes in Ready-to-Eat Foods: Guidance for Industry. Draft Guidance.* <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm>.

9.5 Facility Design and Operations to Reduce Resident Pathogens and Undeclared Allergen Exposure to Food Products

As discussed in Chapter 4, process and facility-related hazards can occur anywhere within a food manufacturing facility. Such hazards become more likely if facility areas are not well defined to segregate storage, movement of employees, and processing of the foods.

One of the best means to prevent process/facility hazards is to design the facility according to specific areas where each potential process/facility hazard can be more easily assessed and controlled. These areas have been described by others (FSPCA, 2016; Food and Drug Administration, 2017) as hygienic areas and are defined as follows:

- **Nonmanufacturing areas**—include maintenance areas, offices, and employee break areas
- **Transition areas**—include entry doors, locker rooms, and storage areas that open into a Good Manufacturing Practice (GMP) area, and small utensil/equipment washing/sanitation/storage areas
- **Basic GMP areas**—include raw ingredient receiving and storage areas, general food processing areas using raw ingredients, other food production processing locations
- **Primary pathogen control areas** (controlled access, often referred to as a **Zone 1** area)—include areas where cooked, pasteurized, or RTE products are produced and exposed to the processing environment
- **Sensitive/high hygiene areas** if used (restricted access)—include areas that produce cooked, pasteurized, or RTE products for sensitive populations such as infants and foods provided during health care

Table 9.3: Examples of scenarios that could lead to contamination of ready-to-eat (RTE) foods with *Listeria monocytogenes*.

<ul style="list-style-type: none"> • A packaging line is moved or modified significantly. • Used equipment is brought from storage or another plant and installed into the process flow. • An equipment breakdown occurs. • Construction or major modifications are made to an area where RTE foods are processed or exposed (e.g., replacing refrigeration units or floors, replacing or building walls, modifications to sewer lines). • A new employee, unfamiliar with the operation and <i>L. monocytogenes</i> controls, has been hired to work in, or to clean equipment in, the area where RTE foods are processed or exposed. • Personnel who handle RTE foods touch surfaces or equipment likely to be contaminated (e.g., floor, trash cans) and do not change gloves or follow other required procedures before handling the food. • Periods of heavy production make it difficult to clean the floors of holding coolers as scheduled. • A drain backs up. • Product is caught or hung-up on equipment. (Stagnant product in a system can be a major site of microbial growth during production.) • Raw or underprocessed foods are placed in an area designated for cooked foods. • Frequent product changes on a packaging line cause you to change packaging film, labels, forming pockets or molds, line speeds, etc. • Personnel are used interchangeably for packaging raw and cooked foods. • Increased production causes you to perform wet cleaning of lines that have been taken down from production in the same room as lines that are running product. • Heat exchangers have become compromised (e.g., with pinholes). • Equipment parts, tubs, screens, etc. are cleaned on the floor. • Waste bins in the RTE area are not properly maintained, cleaned, and sanitized. • Personnel handling RTE foods come into contact with these items and then contaminate the foods and/or food contact surfaces. • Recirculating pumps and lines are not cleaned and sanitized. • Indiscriminate use of high-pressure hoses in cleaning. • Inappropriate use of footbaths in a dry processing area. • Water is sprayed on wheels on transport cars when in-process product is stored near the wheels.

Adapted from Food and Drug Administration, 2017. Control of *Listeria monocytogenes* in Ready-to-Eat Foods: Guidance for Industry. Draft Guidance. <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm>.

Although the primary pathogen control area is most important (and described by the FDA as such) to preventing **biological** process hazards from being introduced into most foods, proper coordination and segregation of ingredient use in this area can also be important in the prevention of **chemical** hazards such as undeclared allergens.

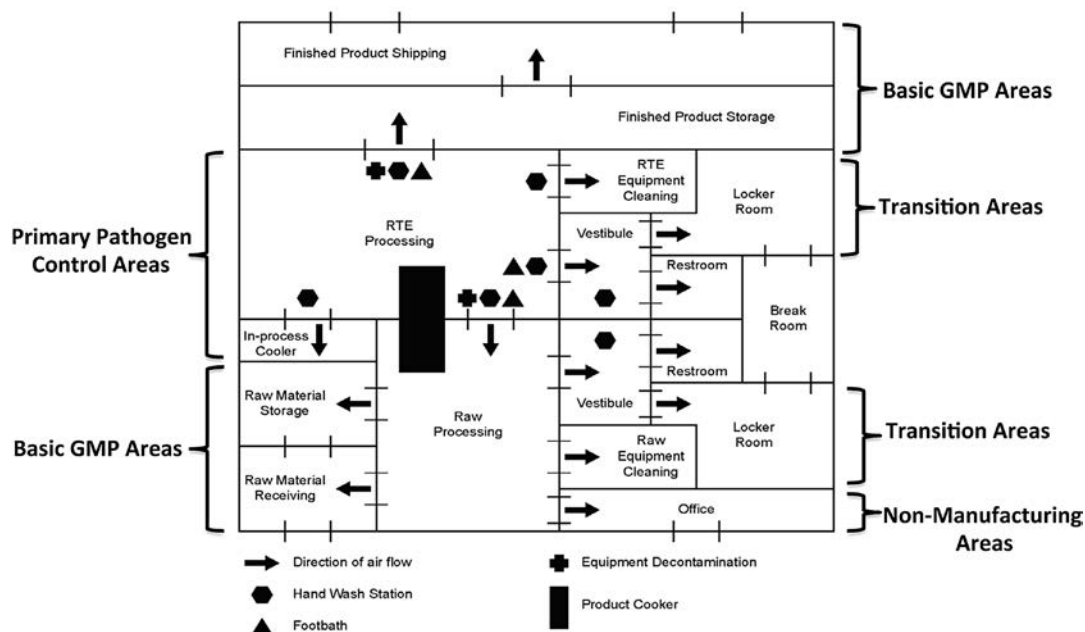


Figure 9.6

Example of optimized airflow direction within a food manufacturing facility and designated hygienic areas (in brackets). From Food and Drug Administration, 2017. *Control of Listeria monocytogenes in Ready-to-Eat Foods: Guidance for Industry. Draft Guidance.* <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm>.

Airflow is equally important and should be designed to push air out of the primary pathogen control areas where RTE foods are exposed to the environment by using heating, ventilation, and air conditioning systems that can achieve and maintain proper airflow (Fig. 9.6).

A useful way to identify which process and areas in the facility are most likely to harbor a hazard is to consider the root cause of prior food contamination events in processing facility areas that have led to recalls and/or outbreaks of foodborne diseases (as described in Tables 9.2 and 9.3 and discussed in earlier chapters of this book). The following questions should also be considered:

- What processes occur in each area according to designated work (e.g., employee uniform requirements in GMP and primary pathogen control areas vs. transition areas, which employees are trained to work in each area)?
- What food ingredient related-hazards (as incoming hazards into that area of the facility) that will be stored and/or used to process foods (both yours and other buyers)?
- What chemicals (lubricants, floor cleaners, petroleum-based equipment cleaners, etc.) are being stored and used in each area that could pose a process hazard in foods?
- What cleaning and sanitation standard operating procedures (SOPs) will be used in each area, and what chemicals will be used in those procedures?

Testing *Listeria* spp. versus *Listeria* *monocytogenes* (*L.* *monocytogenes*)

*The FDA states that “Your written environmental monitoring procedures should identify whether you are testing for *Listeria* spp. or *L. monocytogenes*. We recommend that you test for *Listeria* spp. because doing so will detect both *L. monocytogenes* as well as species of *Listeria* that are more common than *L. monocytogenes* and allow you to correct situations that could potentially lead to contamination with *L. monocytogenes*.”*

*A positive test result for the presence of *Listeria* spp. on a Food Contact Surface (FCS) or non-FCS indicates the potential for contamination of an FCS or non-FCS with *L. monocytogenes* and suggests that conditions are suitable for survival and/or growth of *L. monocytogenes*. A positive test result for the presence of *Listeria* spp. on an FCS or a non-FCS does not establish the presence of *L. monocytogenes* on an FCS or non-FCS.”*

*Sources: Food and Drug Administration, 2017. Control of *Listeria monocytogenes* in Ready-to-Eat Foods: Guidance for Industry. Draft Guidance. <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm>.*

- What pest control, disinfectant, and deep equipment/floor cleaning chemicals will be used in each area?
- What utensils, tools, transport carts, and equipment will be used in each area, and what maintenance of the equipment is required that could introduce process hazards into the food product?
- Are closed systems (e.g., conductive pipes) used when possible to transport ingredients (e.g., liquids, dry mixes)?

Food processing facilities should ensure both equipment used and flow of food processes are designed to enable proper and timely equipment disassembly to fully clean/sanitize all exposed as well as hidden surfaces. This is especially critical on food contact surfaces to ensure no resident pathogens become established at any time. The sanitary standards published by 3-A Sanitary Standards, Inc. and NSF International, Inc. may be helpful in the design of food processing equipment. Because resident pathogens can be difficult to eliminate using standard cleaning and sanitizing SOPs and chemicals, additional sanitation processes may be needed such as more abrasive cleaning tools to physically remove biofilms or special chemicals shown to kill the more resistant resident pathogens. For example, in one study that compared the best means to clean and sanitize *Salmonella*-contaminated peanut butter processing equipment, hot oil at 190°F did not completely remove all *Salmonella* from equipment surfaces; an additional 1-h treatment with 60% isopropanol and quaternary ammonium was required to completely eliminate the pathogen (Grasso et al., 2015). In addition to FDA’s new draft guidance on *L. monocytogenes* (Food and Drug Administration, 2017), there are numerous peer-reviewed scientific publications that specifically address the efficacy of different processes and chemicals for all resident pathogens, food ingredients, and surface types.

9.6 Monitoring Facility Processing Environments to Prevent Resident Pathogen Hazards in Food Products

The FDA has many excellent scientifically based resources to help set up an effective environmental monitoring program (EMP) to prevent resident pathogens in food manufacturing facilities. Other resources from trade associations may also be helpful such as The Association of Food, Beverage, and Consumer Products Companies' *L. monocytogenes* guidance document on an EMP for at-risk foods ([Grocery Manufacturers Association, 2014](#)). It may be useful to also contract a microbial ecologist expert on the detection and the elimination of pathogens in food processing facilities to set up the EMP and help validate it over time.

In its new draft *L. monocytogenes* guidance ([Food and Drug Administration, 2017](#)), the FDA recommends that food manufacturing businesses characterize areas according to the potential for product contamination in the process of setting up an EMP, and suggest defining each of these by four zones ([Table 9.4](#)). This type of zoning will work equally well to control and monitor other pathogens and for allergen control and monitoring as well. The FDA also recommends that the EMP follow these guidelines:

- Be written and documented
- Be scientifically valid
- Specify whether you are testing for *Listeria* spp. or *L. monocytogenes* (or *Salmonella* or *E. coli* if testing for these pathogens)

Table 9.4: Example of designated zones within hygienic areas based on probability for food contamination.

Zones	Description	Examples
Zone 1	Food contact surfaces (FCSs)	Utensils, table surfaces, slicers, pipe interiors, tank interiors, filler bowls, packaging and conveyors, hoppers
Zone 2	Nonfood contact surfaces in close proximity to food and food contact surfaces	Equipment housing or framework, and some walls, floors, or drains in the immediate vicinity of FCSs carts
Zone 3	More remote nonfood contact surfaces that are in or near the processing areas and could lead to contamination of zones 1 and 2	Forklifts, hand trucks, and carts that move within the plant and some walls, floors or drains not in the immediate vicinity of FCSs
Zone 4	Nonfood contact surfaces, remote areas outside of the processing area, from which environmental pathogens can be introduced into the processing environment	Locker rooms, cafeterias, and hallways outside the production area or outside areas where raw materials or finished foods are stored or transported

From Food and Drug Administration, 2017. *Control of Listeria monocytogenes in Ready-to-Eat Foods: Guidance for Industry. Draft Guidance.* <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm>.

- Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites should be adequate to determine whether *Listeria* and other pathogen control measures are effective
 - Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples should be adequate to determine whether *Listeria* and other pathogen control measures are effective
 - Identify the test(s) conducted, including the analytical method(s) used to test for *Listeria* spp. or *L. monocytogenes* or other pathogens
 - Identify the laboratory you are using for conducting the testing. Ensure the laboratory is accredited to perform pathogen testing and will prevent false positive and negative results by using proper aseptic methods and controls
 - Specify corrective actions (consistent with the 2017 FDA guidance document) you will use when *Listeria* spp., *L. monocytogenes* or other pathogens are found
 - Include allergen testing where appropriate using in-house sampling and testing or laboratory-assisted testing
- Source: [Food and Drug Administration \(2017\)](#).

An effective EMP should include well-defined sampling locations in each hygienic area (Fig. 9.7). The plan should also specify a means to track these locations according to test results. Documenting sampling sites and testing results will be critical to target the proper corrective actions to eliminate resident pathogens and also ensure appropriate regulatory compliance including holding products before distribution or recalling a product if pathogen contamination of a product is likely (e.g., Zone 1 test positive for *L. monocytogenes*). Pathogen testing results may not be available for up to 24–48 hours, although in-house laboratories may provide faster results. It is important to note that if a Zone 2 sample tests positive for a pathogen, then it is more probable that a Zone 1 area will be contaminated with this pathogen also. This is also true between the other zones. Therefore your EMP should focus on retesting positive zones as well as the next lower zone after corrective actions are made.

9.7 Follow-Up Sampling and Corrective Activities When an Environmental Sample Test Positive for Pathogens or Allergens

The most important function of the EMP is to identify resident pathogen harborage locations and specify corrective actions to ensure food products that contain contaminating pathogens or allergens are not distributed. A key part of the EMP corrective action process is the proper determination of what is done with any food product that has been processed in a facility where a Zone 1 sample has tested positive for a resident pathogen, especially if that pathogen is *L. monocytogenes*. The FDA prescribes ([Food and Drug Administration, 2017](#)) specific steps for follow-up activities when Zone 1 (Fig. 9.8) and

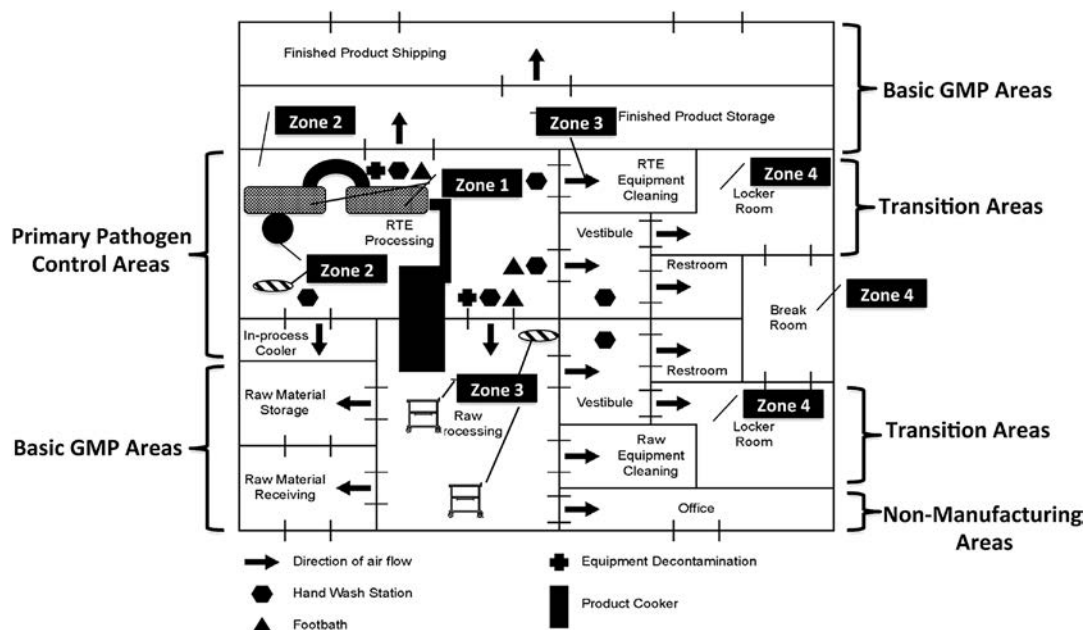


Figure 9.7

Hygienic zoning map in hygienic areas (brackets) for a food manufacturing facility. From *Food and Drug Administration*, 2017. *Control of Listeria monocytogenes in Ready-to-Eat Foods: Guidance for Industry. Draft Guidance*. <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm>.

Zone 2 (Fig. 9.9) sampling sites test positive for *L. monocytogenes*. These methods can also be applied when environmental testing shows the presence of *Salmonella* or *E. coli*. These are activities that should be performed alongside the corrective actions (cleaning and sanitation and root-cause investigations) necessary before resampling/testing is performed.

Corrective actions will normally always include additional or more robust cleaning and sanitation of the positive sampling site and adjacent areas even though it is recommended that sampling sites are recleaned and sanitized immediately after samples are taken. Again, the best resource for corrective actions to perform when a sample test positive for a pathogen is the FDA guidance documents on the control of *L. monocytogenes* (Food and Drug Administration, 2017). This is because these procedures are appropriate risk-based SOPs for any pathogen and include proper methods to ensure products adulterated with pathogens are not released to commercial distribution.

The FDA recommends that if you detect *Listeria* spp. on a Zone 1 surface that you follow predefined and documented risk-based corrective action procedures that describe the

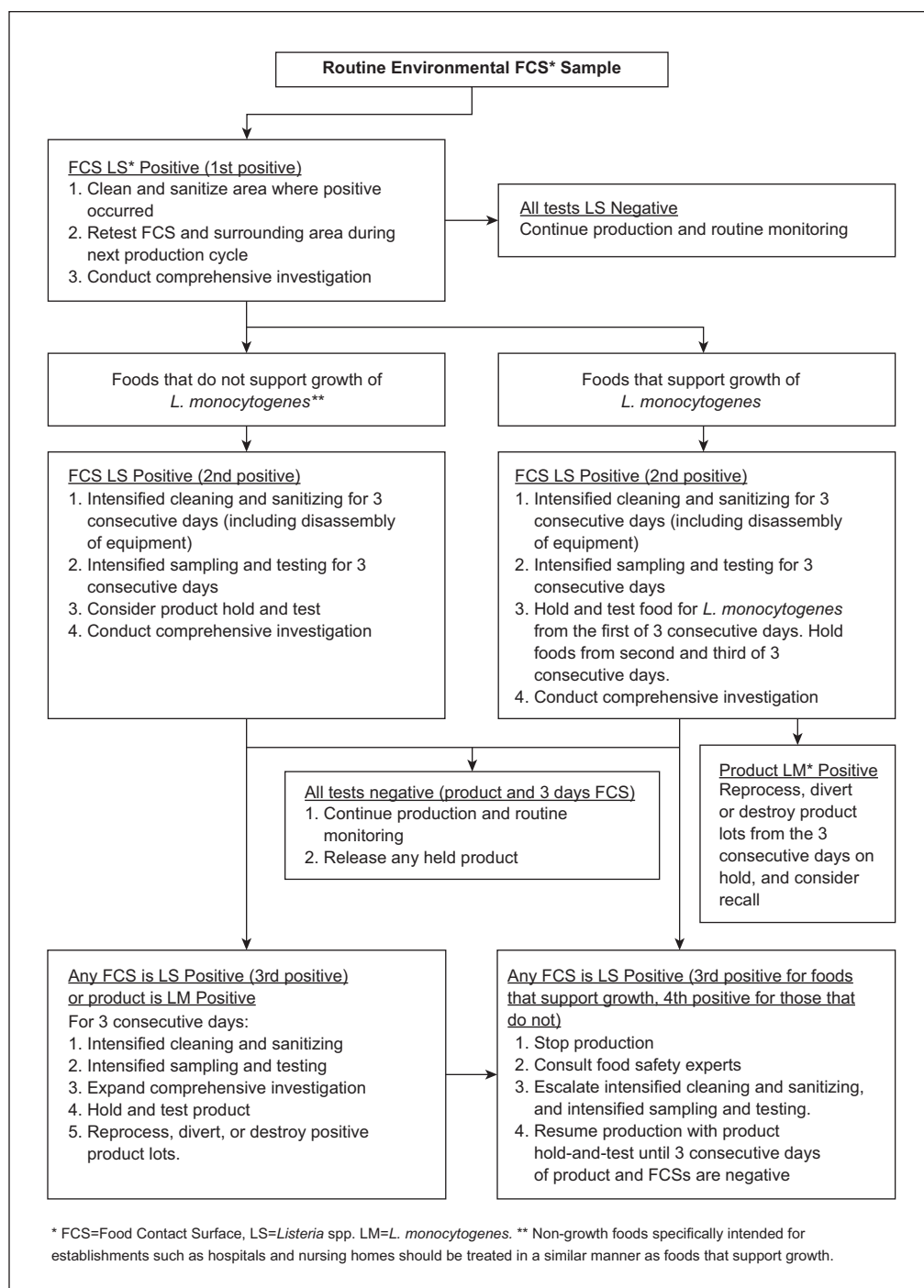


Figure 9.8

Example of food contact surface (zone 1) testing and follow-up activities. From Food and Drug Administration, 2017. *Control of Listeria monocytogenes in Ready-to-Eat Foods: Guidance for Industry*. Draft Guidance. <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm>.

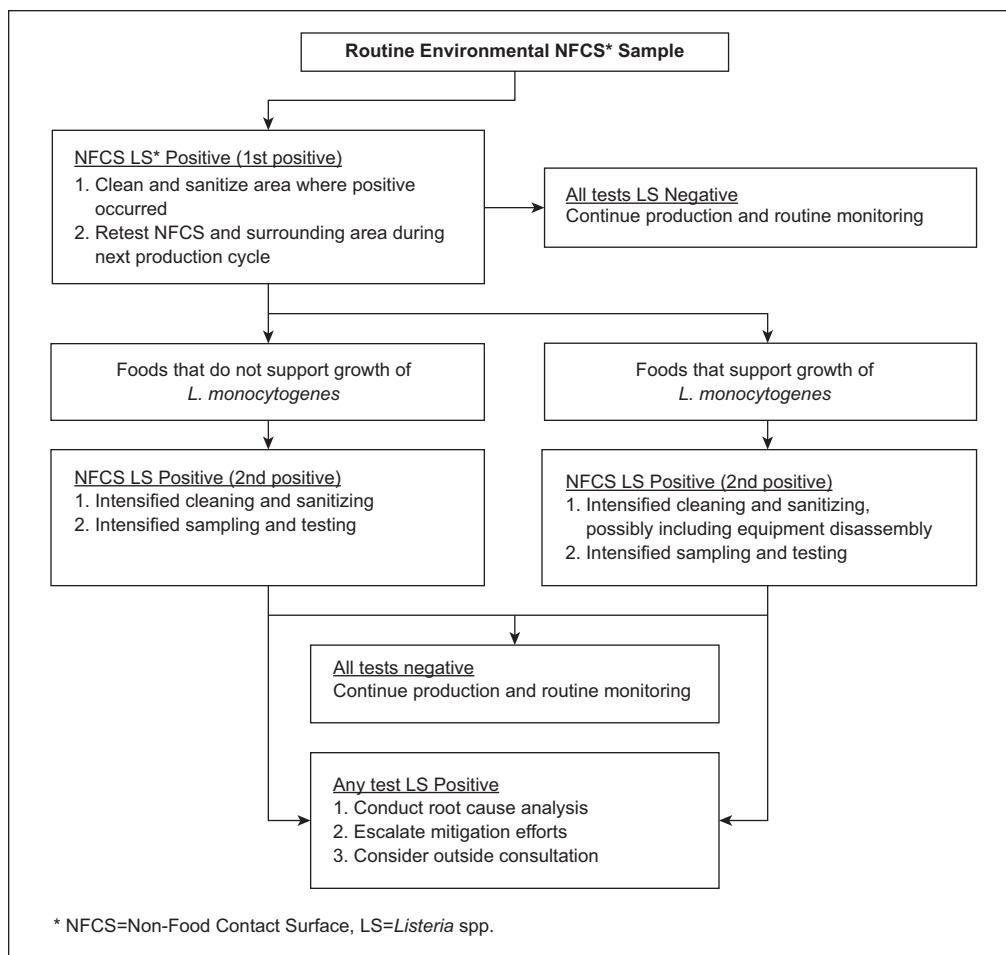


Figure 9.9

Example of non-FCS testing and follow-up activities for zone 2. From Food and Drug Administration, 2017. *Control of Listeria monocytogenes in Ready-to-Eat Foods: Guidance for Industry. Draft Guidance.* <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm>.

steps to be taken and assigns responsibility for taking those steps to ensure that the cause of the contamination is identified and corrected (following a root-cause investigation, Table 9.5). This is recommended to reduce the potential for release of RTE food that is contaminated with *L. monocytogenes* but is an effective strategy that can be applied for most other bacterial pathogens as well. The FDA describes corrective action procedures for *L. monocytogenes* positive sampling of Zone 1 (food contact surface) areas that differ based on whether a food supports growth of the pathogen or not (Fig. 9.8) but recommends that for a food that does not support growth but that is specifically intended for

Table 9.5: Recommended corrective actions if *Listeria* spp. is detected on a zone 1 food-contact surface site.

- Examine the equipment that yielded the positive finding and the area surrounding the positive site in all directions for potential sources of *Listeria* spp. or *Listeria monocytogenes* as described in Table 9.2 (bottom three rows). Pay particular attention to possible niches that allow harborage of *L. monocytogenes*.
- Review your hazard analysis and critical control point or Food Safety Plan, if any, and its implementation to determine if there are any design or execution flaws and modifying your plan as necessary.
- Conduct intensified sampling and testing of sites that represent a potential source of *L. monocytogenes* identified in the earlier examination, collecting samples several times during production to identify the source of contamination (the number of samples collected during production depends on the product and the production process).
- Test upstream from the positive FCS in the production area to help identify a source of contamination.
- Check maintenance records for modifications or repairs to major equipment.
- Interview and observe sanitation, maintenance, and production personnel to determine whether appropriate procedures are being followed.
- Review production, maintenance, and sanitation procedures to determine whether to modify the procedures to prevent contamination, and then make those modifications identified by the review.
- Review the scenarios that we provide in Table 9.3 as an aid to identifying causes of contamination.
- Review traffic patterns, equipment layout, and adherence to personnel hygiene procedures.
- Take appropriate actions based on findings of the above activities.

Adapted from Food and Drug Administration, 2017. Control of *Listeria monocytogenes* in Ready-to-Eat Foods: Guidance for Industry. Draft Guidance. <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm>.

establishments such as hospitals and nursing homes (where the food would be consumed by populations at high risk for listeriosis), you take corrective actions in a similar manner as for foods that support the growth of *L. monocytogenes*.

It is not the purpose of this book to provide comprehensive instructions on developing an EMP, especially when the FDA provides the most comprehensive and useful guidance in this area of *L. monocytogenes* control (Food and Drug Administration, 2017). However, we outline these processes and their value in the production of safe food here because these procedures are risk-based and scientifically sound strategies, which can also prevent the contamination of foods by other resident pathogens and allergens. We recommend you use the FDA guidance documents and other resources cited below and check the FDA website for updated materials, especially those FDA releases following regulatory actions it takes at food manufacturing facilities.

A food manufacturing facility can also use its EMP to control the risk of undeclared allergens in food products. Many of the same processes described above can be used to sample, test, document, and perform corrective actions, including cleaning and sanitation of the sample

area and retesting. It may also be useful to follow similar product hold procedures and to consider product testing as a verification method for the preventive controls used to prevent undeclared allergens in food products.

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Further Reading

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Regulatory Knowledge and Interactions for Retail Buyers in the FSMA Era

10.1 Overview

Imagine this scenario: you are the head of food safety for a retail quick-serve restaurant chain that sells, among other products, a breakfast sandwich. This sandwich is made at your retail locations from liquid egg product that you purchase from regional suppliers, biscuits that are shipped along with cookies and other baked goods from a US supplier, and fresh avocados that you import from Mexico. How do the Food Safety Modernization Act (FSMA) and the Preventive Controls for Human Foods (PCHF) regulations impact the way your suppliers interact with FDA? How will it also change your interactions with your suppliers?

It is important for manufacturers who must comply with FSMA and PCHF as well as anyone who depends on those producers (such as retail buyers in the retail sales and service industry) to understand the regulations. It is also useful to be aware of regulatory interactions that occur between manufacturers and regulators and how FSMA affects that interface. The relationship that a manufacturer has with the FDA and state and local regulators is important not only to that company itself but also to those to whom it supplies products. As a buyer, being aware of your supplier's history and relationship with the FDA and others can put you in a better position to evaluate your supplier, which in some cases can save you time and money. For example, when selecting vendors, you may be able to quickly eliminate potentially problematic vendors if you see that they have been the subject of FDA import alerts. Also, because regulatory inspections and on-site audits share many similarities, you may be able to draw on FDA inspection history to reduce the frequency (or improve the specificity) of on-site audits of your suppliers.

In some cases, FSMA is making it essential that retail food businesses take on new responsibilities when purchasing from suppliers (Table 10.1).

For example, your supplier may identify a potential hazard (such as *Salmonella* in a liquid egg product) that they specify in their Food Safety Plan will be controlled by the buyer. What are your responsibilities as a retail customer when you use that liquid egg product in a breakfast sandwich? As specified in the preventive controls regulation, you must provide your supplier with annual written assurance and documentation that you are controlling the hazard.

Table 10.1: Examples of Food Safety Modernization Act requirements that may directly impact retail food businesses.

Requirement	Example	Retail Food Business Responsibility	Regulatory Citation
Preventive controls	The supplier specifies in their Food Safety Plan that a potential hazard will be controlled by the buyer, who is a retail food business	You must provide your supplier with annual written assurance that you are controlling the hazard	21 CFR Part 117.136 (a)(4)
Foreign Supplier Verification Programs (FSVPs)	A large retail food business directly imports an ingredient or food product (very small importers or those importing from countries with equivalent food safety systems (Canada, New Zealand as of 2016) are subject to modified requirements)	You must establish and maintain an FSVP for each food that is imported to ensure that the imported food provides the same level of safety as domestic food produced with preventive controls, and ensure that the food is not adulterated or misbranded	21 CFR Part 1.502

As another example, if you are directly purchasing food products from outside of the United States for use in your products, you may be subject to the Foreign Supplier Verification Programs (FSVP) rule, which is another part of FSMA ([U.S. Food and Drug Administration, 2015b](#)). The importer, even if it is a restaurant owner not normally subject to FSMA, must establish and maintain an FSVP for each food that is imported to ensure that the imported food provides the same level of safety as domestic food produced with preventive controls and to ensure that the food is not adulterated or misbranded ([U.S. Food and Drug Administration, 2016e](#)). Essentially, this means that the importer must perform their own hazard analysis on any food that they import and conduct verification activities on the supplier to ensure any identified risks are being minimized.

In the case of baked goods such as the biscuits in the example, retail food facilities will be able to obtain a waiver and will likely not be required to follow FSMA's Final Rule on Sanitary Transportation of Human and Animal Food ([U.S. Food and Drug Administration, 2016j](#)); however, the shipper of the biscuits will need to comply with the rule. Perhaps you are receiving gluten-free chocolate peanut butter cookies in the same shipments that you receive the biscuits. FSMA and the sanitary transport rule may impact how you audit this supplier, even if you as a buyer are already assessing risks for cross-contact during shipment by this supplier.

This chapter will provide additional information to help retail buyers (who may not themselves be directly subject to FSMA and PCHF) understand what their suppliers need to be doing in the era of FSMA. In many cases, FSMA will not directly require buyers to do anything, but it should impact the way buyers evaluate their suppliers and ensure the safety of the products they source from these suppliers. Likewise, FSMA and PCHF will put in place

regulatory and documentation requirements for activities and controls specific to every ingredient and product that you source from them.

Although this book focuses on preventive controls and does not specifically cover FSVP or sanitary transport components of FSMA, this chapter will also provide you with some tools to help you find additional FSMA-related regulatory information to inform your supplier evaluations and audits. An overview of the interactions that manufacturers typically have with FDA and other regulators will be provided, and strategies for gathering regulatory information about your suppliers will be suggested.

Additionally, this chapter will provide a brief review of what happens during a regulatory inspection and how FSMA and PCHF are expected to affect the inspection process. This knowledge should aid in planning supplier evaluation and audit activities. This knowledge will also help you evaluate how well your suppliers work with regulatory authorities and whether your suppliers are compliant with PCHF, which should improve the integrity of your supply chain and the safety of ingredients and products that you source and sell as well.

As a final introductory note to this chapter, it may be helpful to realize that new federal and state inspectors and regulators will always be learning FSMA and PCHF too. While many of these individuals will have experience with hazard analysis and critical control point (HACCP), implementation of PCHF will greatly increase the number and diversity of establishments that will need to be inspected for their preventive strategies.

10.2 Regulatory Information Sources

To understand how well your suppliers are complying with rules and regulations, you need to have at least a rudimentary knowledge of them yourself. This section reviews how rules and regulations are made, lists key sources for FDA regulatory information, and provides suggestions for you to stay informed of changes to regulations as they occur.

10.2.1 By the Book: Rules, Regulations, Guidance Documents

Actually reading FDA's rules, regulations, and guidances (as referenced many times in this book) is the ultimate way to gain an understanding of requirements and recommendations that FDA has made. Reading FDA's words can be difficult, however, particularly if you do not know some of the basic jargon. For example, what exactly is a regulation, and how is it different (or not) from a law, a rule, or a guidance? If the FDA states that you "should" do something, does that mean it is required?

Fig. 10.1 provides a flowchart of the process by which laws are created and turned into regulations and guidance documents. Laws (which can be "acts" or "statutes") are written and enacted by Congress. Once a law is passed, "rules" or "regulations" are promulgated by federal agencies such as the FDA to explain how laws will be carried out. They are usually issued in

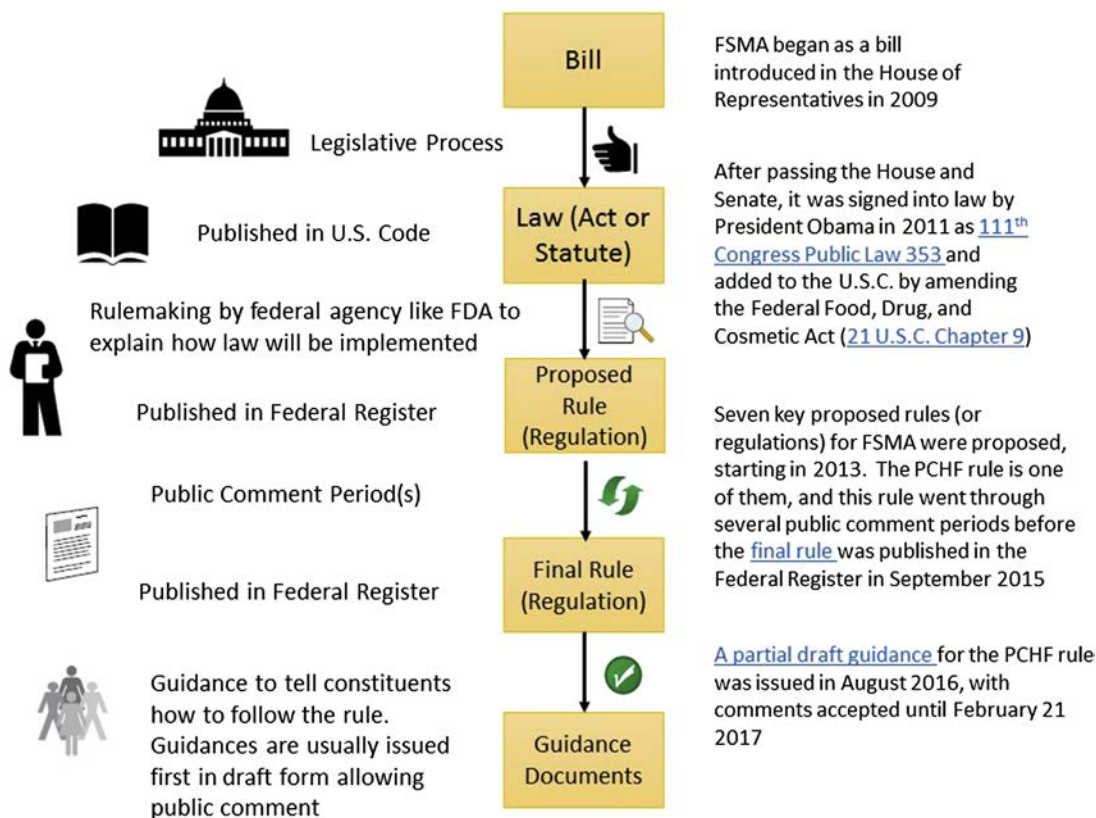


Figure 10.1
Overview of US Regulatory Process.

draft form in the Federal Register, providing the public and other stakeholders an opportunity to comment on the proposed regulations. Once the “Final Rule” has been published (again, in the Federal Register), the same agency who wrote the rule may issue guidance documents. The availability of guidance documents is announced in the Federal Register. Guidance documents provide assistance to regulated industry as to how to comply with rules and regulations. Guidance documents are also often first released in draft form, allowing for comments, and may be revised by the agency at any time.

FDA is careful to remind the public that guidance documents are not requirements. Most guidances include the following wording “Guidance documents for industry do not establish legally enforceable rights or responsibilities and are not legally binding on the public or the agency. Rather, they explain how the agency believes the statutes and regulations apply to certain regulated activities.” However, even so, it is a good idea to understand regulatory jargon: FDA will use language such as “shall, must, required, or requirement” when discussing a statutory or regulatory requirement, and will use other language such as “recommend,” “prefer,” and “suggest” to communicate advice.

Guidance documents can be found on the FDA website (www.fda.gov). You can also sign up to be automatically notified by email whenever a new guidance document (or other regulatory information) is released by FDA's Center for Food Safety and Applied Nutrition ([U.S. Food and Drug Administration, 2016b](#)).

10.2.2 Beyond the Book: Interpretation

It is not enough to require your suppliers to be in compliance with FSMA rules simply via legal contracts. Even though formal FDA inspection of some suppliers' facilities may only occur once every 7 years ([U.S. Food and Drug Administration, 2015c](#)), the safety of the products that a retail buyer sells to customers is critically dependent on how well its suppliers follow preventive safety measures that are built into FSMA. If your suppliers are in compliance at all times, the products they sell to you will have much less chance of causing a food safety crisis.

For you to be able to properly evaluate and audit your suppliers, you need to have an understanding of the regulations, the rationale behind them, and also, importantly, how they are being interpreted. Even after reading the regulations and guidance documents, it may not be immediately clear how the regulations surrounding FSMA and preventive controls should best be followed. As of 2016, the rules are still new and the interpretation is not yet complete. Interpretation of FSMA and PCHF is still evolving and will continue to evolve. How can you learn more about current thinking?

10.2.2.1 Food Safety Preventive Controls Alliance Training

The Food Safety Preventive Controls Alliance (FSPCA) represents a very new way of educating industry. Recognizing that FSMA and preventive controls, in particular, were going to be a significant change for many food companies, FDA worked to develop a coalition of government, industry, and academic experts to develop training for industry. FSPCA is, therefore, a public-private partnership, which was initially funded by FDA but has become self-supporting.

Attending (FSPCA) training may be very useful, even if you are only evaluating suppliers or are already familiar with HACCP or other risk-based preventive controls systems. The standardized FSPCA training, which lasts 2.5 days, is available at many locations throughout the United States and internationally. Some courses are being offered in languages other than English, and the training materials themselves are in the process of being translated into Spanish, Chinese, and Japanese ([Brckett, 2016](#)). A blended course that will be taught partially online is being launched ([Swanson, 2016](#)). Up-to-date course dates and other information can be found on the FSPCA website ([Food Safety Preventive Controls Alliance, 2016a](#)), which is operated by the Institute for Food Safety and Health at Illinois Institute of Technology.

The course is being continuously updated, with the current course manual available by free download ([Food Safety Preventive Controls Alliance, Undated](#)). This manual itself is a very

practical resource that contains a model Food Safety Plan and templates of many forms (many demonstrated in this book) that a company can use to help comply with PCHF.

To meet the needs of certain industries or groups for which the existing curriculum may not be ideal, alternative training on preventive controls are also being developed under cooperative agreements with FDA. FDA has allocated funds for development of such programs targeted toward local food producers (including those engaged in direct marketing) and tribal communities. These courses are expected to be recognized by FDA and will allow individuals who take them to act as preventive controls qualified individuals within an organization.

10.2.2.2 Attend Food Safety Meetings

In the words of FDA's current Deputy Commissioner for Foods and Veterinary Medicine, Stephen Ostroff, the publication of the foundational rules of FSMA is "not the beginning of the end, but the end of the beginning" in terms of implementation ([Ostroff, 2016](#)). This suggests that FSMA and PCHF will continue to be discussed at food safety meetings for many years. Attending meetings of organizations with food safety interests is a great way to hear current thinking from regulators, industry, and others. FDA also holds public meetings on new regulations and guidance documents and often releases presentations and records webinars for the public ([U.S. Food and Drug Administration, 2017a](#)). Annual meetings of organizations such as International Association of Food Protection, Institute for Food Safety and Health, Food Research Institute, International Life Sciences Institute, or other meetings such as the Food Safety Summit often feature regulators as speakers or attendees, providing opportunities to hear their current thinking and also ask questions directly. Presentations and informal discussions with others from industry may provide additional insights into effective strategies other organizations are using to implement Hazard Analysis and Risk-based Preventive Controls and thus comply with PCHF and FSMA.

10.2.2.3 Read Journals and Trade Magazines

Journals and trade magazines are also excellent ways to find out how regulators and other organizations are interpreting the new requirements of PCHF and FSMA. Regulators often serve as editors, reviewers, or even authors of these publications, which ensures that the information provided is consistent with their policies and approaches. Blogs, including the FDA's blog ([U.S. Food and Drug Administration, 2017b](#)) are another source of current thinking on regulatory topics related to PCHF, as are published meeting summaries.

10.2.2.4 Use FDA, CDC, and Other Governmental Resources

Become familiar with the resources that these organizations offer, some of which are listed in [Section 10.7](#). Online databases related to foodborne disease outbreaks, food recalls, import alerts, and more can help retail buyers understand which of their suppliers might be subject to increased regulatory scrutiny.

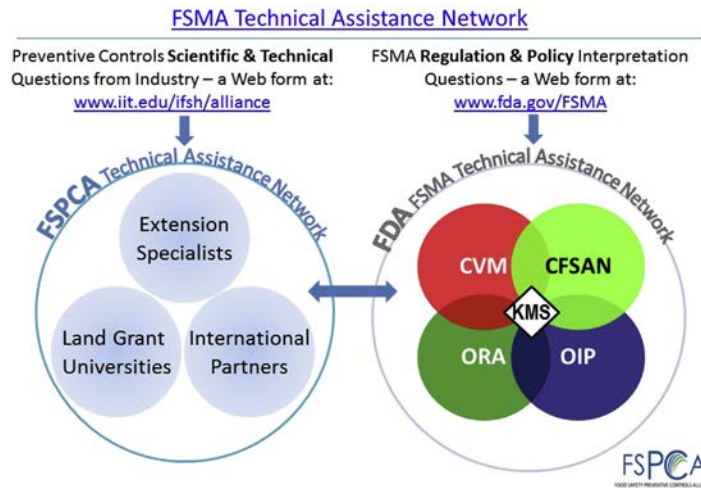


Figure 10.2

Food Safety Modernization Act Technical Assistance Network. From *Food Safety Preventive Controls Alliance, 2016c. Preventive Controls for Human Foods Participant Manual (Online)*. Available from: http://www.iit.edu/ifsh/alliance/pdfs/FSPCA_PC_Human_Food_Course_Participant_Manual_V1.2_Watermark.pdf.

10.2.2.5 Ask Questions

Recognizing that the changes associated with FSMA will trigger many questions, a two-component FSMA Technical Assistance Network (TAN) has been formed to answer questions from stakeholders (Fig. 10.2). One component of the TAN, the FSPCA TAN, draws on knowledge and experience of extension specialists, land-grant universities, and international partners to answer questions with scientific and technical content (for example, identifying appropriate supporting documentation for validations). The other component, the FDA FSMA TAN utilizes resources within FDA to answer questions related to regulation and policy.

Questions for either network can be submitted online and will be tracked to create FAQ documents.

Another way to ask questions or receive clarification regarding new regulations and guidances is to participate during comment periods when new guidance documents or draft rules are posted in the Federal Register. The FDA website includes detailed information on how to submit comments (U.S. Food and Drug Administration, 2014a). You can sign up for automated notifications from the Federal Register to ensure you know immediately when a new draft or final resource is available (Federal Register, Undated). Reading the comments from others in published Final Rules can also help you gain insight into regulatory thinking.

10.3 How FDA Knows Who Your Suppliers Are: Food Facility Registration

The year 2001 brought not only the terrorist attacks on 9/11 but also a wave of anthrax attacks that killed five people and sickened 17 others ([National Public Radio, 2011](#)). In response to these events, the possibility of future bioterrorist events was thoughtfully considered and the 2002 Public Health Security and Bioterrorism Preparedness and Response Act was created. The food supply fell under scrutiny during this time, and as a result, the law required food facilities for the first time to register with the FDA to assist them in protecting the public in the event of a food-related emergency such as a terrorist-associated intentional contamination of the food supply ([U.S. Food and Drug Administration, 2016i](#)). Previously, the FDA depended on information from states to provide them with records of food processing, packing, and holding facilities ([Redhead et al., 2002](#)).

FDA also uses food facility registration to identify the location of food facilities and put them on their “radar screen” for inspections. FSMA updated the system of food facility registration, as described in the 2016 publication of the Final Rule to Update Food Facility Registration ([U.S. Food and Drug Administration, 2016a](#)). Additional information on FDA’s current registration process for food facilities can be found on their FSMA Frequently Asked Questions page ([U.S. Food and Drug Administration, 2016e](#)).

Food facilities (but not restaurants or retail food establishments, which also are not subject to preventive controls rules) are required to register their establishment with the FDA ([U.S. Food and Drug Administration, 2016e](#)). FSMA has expanded the types of food facilities that are considered “retail food establishments,” which are not required to register with FDA.

As can be seen in [Table 10.2](#), most facilities that need to follow PCHF (shown in dark gray) also need to register with FDA, while most facilities that do not need to register with FDA (shown in light gray) are not subject to PCHF. Food manufacturing facilities must be registered before operations begin at a facility. Registrations are specific to a facility, not an organization.

Several changes to facility registration are occurring with FSMA, including a requirement for the registration to cite the type of activity conducted at a facility for each food product category, and some changes to the food product categories that are used on the registration form ([U.S. Food and Drug Administration, 2016a,g](#)). As a result, all food facilities (even those previously registered) must renew their registration in each even-numbered year. Registrations must also be updated within 60 calendar days of any change to the required information for registration, or within 30 calendar days if canceling a registration. Registration can be done on paper (via the 10-page FDA Form 3537) or online (and with FSMA, registration and renewals will be required to be done online rather than by paper by January 4, 2020). No fees are associated with food facility registration.

Qualified facilities (defined by PCHF as certain facilities associated with small businesses in 21 CFR Part 117.3) still need to register, but they are also required to submit a document attesting that they meet the definition of a qualified facility by completing and submitting Form FDA

Table 10.2: Facility registration requirements following Food Safety Modernization Act.

Must Register With FDA	Do Not Need to Register With FDA
Domestic food facilities engaged in manufacturing, processing, packing, or holding foods for human (or animal) consumption in the United States	Foreign facilities do not need to register if the food undergoes further manufacturing/packaging outside of the United States (unless the further activity is limited to labeling or other minimal activity). The last foreign food facility that handles the food prior to export to the United States must register, however, including a facility that simply attaches a label or performs another minimal activity.
Domestic food facilities involved in manufacturing, processing, packing, or holding foods subject to	
<ul style="list-style-type: none"> • Seafood or juice hazard analysis and critical control point regulations • Low-acid canned food regulations (but must follow preventive controls for hazards other than microbiological hazards) • Dietary supplements (but dietary ingredients must follow preventive controls) • Food subject to the produce safety requirements • Alcoholic beverages 	
Foreign food facilities engaged in manufacturing, processing, packing, or holding foods for human (or animal) consumption in the United States	Farms
Food facilities that only distribute within a state	Retail food establishments (grocery stores, convenience stores, vending machines)
Each facility of a company if that facility is engaged in manufacturing, processing, packing, or holding foods for human consumption	Roadside stands, farmer's market, community-supported agriculture programs, etc. that sell food products directly to consumers
Small and very small facilities/qualified facilities*	Restaurants
Distribution centers that store unexposed product not subject to refrigeration*, or storage facilities such as grain elevators or warehouses that only store raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing	Nonprofit food facilities such as central food banks, soup kitchens, nonprofit delivery systems where food is prepared for, and directly served to, the customer
	Fishing vessels not engaged in processing
	Facilities regulated exclusively and throughout the entire facility by USDA
	Private residences also used to make food that is sold at farmers' markets and to other consumers
	Municipal water systems
	Transport systems that only hold food
	Facilities that only manufacture, pack, or hold a food contact substance or pesticide

Dark gray, must follow full preventive controls requirements; *light gray*, do not need to follow preventive controls, or *can follow modified requirements.

Based on U.S. Food and Drug Administration, September 17, 2015a. *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods. Final Rule. 80 Fed. Reg. 55908*; U.S. Food and Drug Administration, July 14, 2016a. *Amendments to Registration of Food Facilities. Final Rule. 81 Fed. Reg. 45911*; U.S. Food and Drug Administration, 2012. *Guidance for Industry: What You Need to Know About Registration of Food Facilities; Small Entity Compliance Guide*.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Center for Food Safety and Applied Nutrition Qualified Facility Attestation for Human Food Facility		Form Approved: OMB No. xxxx-xxxx Expiration Date: XXXXXX xx, 201x See PRA Statement on page 3.
<i>If entering by hand, use blue or black ink only.</i>		
Section 1 – FACILITY INFORMATION		
Facility Registration Number		
Facility Name		
Facility Address		
Address 1 (Street address, P.O. box, etc.)		
Address 2 (If applicable; apartment, suite, unit, building, floor, etc.)		
City	State/Province/Territory	
Country	ZIP or Postal Code	
Telephone Number (Include area code)		FAX Number (Include area code)
E-mail Address		
Section 2 – TYPE OF NOTIFICATION		
a. <input type="checkbox"/> Initial Submission (21 CFR 117.201(c)(2)(i)) – Complete Sections 4, 5 and 6 only. b. <input type="checkbox"/> Biennial Submission (21 CFR 117.201(c)(2)(ii)) – Complete Sections 4, 5 and 6 only. c. <input type="checkbox"/> Status Change (21 CFR 117.201(c)(3)) – Complete Section 3 only.		
Section 3 – STATUS CHANGE (If applicable; if not, skip and continue to Section 4.)		
<i>Human food facilities that have changed status from a "qualified facility" to "not a qualified facility" must notify FDA of that change in status by July 31 of the applicable calendar year. Check the box below to indicate a status change.</i>		
<input type="checkbox"/> The above-named facility is no longer a "qualified facility" as defined in 21 CFR 117.3 based on the annual determination.		
Signature		Date
Printed Name and Title:		
Please check one option below that best describes your relationship to the facility.		
<input type="checkbox"/> Owner <input type="checkbox"/> Operator <input type="checkbox"/> Agent in Charge		

Section 3 continued, next page

Figure 10.3

First page of draft FDA form for Qualified Facility Attestation. *Reproduced from Food Safety Preventive Controls Alliance, 2016c. Preventive Controls for Human Foods Participant Manual (Online). Available from: http://www.iit.edu/ifsh/alliance/pdfs/FSPCA_PC_Human_Food_Course_Participant_Manual_V1.2_Watermark.pdf.*

3942a. The FDA has issued a draft guidance document ([U.S. Food and Drug Administration, 2016c](#)) explaining how to use this form (see [Fig. 10.3](#) for the first page of the draft three-page form). A retail buyer should consider obtaining a copy of this form from each supplier, which is a qualified facility to ensure their qualified facility status has been appropriately documented.

Registration notifies the FDA that a food facility is ready for all future inspections. All food facility registrations are required to contain an assurance that they will allow the FDA to inspect their facility at any time.

10.4 Inspections/Audits

10.4.1 Overview

Both FDA inspections and retail buyer audits of a food supplier will largely focus on the safety of the products that the food supplier is producing ([Fig. 10.4](#)).

Although retail buyers of foods are not themselves subject to FDA inspection, the products that they purchase will come from inspected facilities, and most state food codes require retail food businesses to show evidence of a safe supply of ingredients and products they purchase for retail sales. In addition, retail food establishments are inspected by state and local inspectors. Regulatory inspections and audits conducted by purchasers (either directly or by a third party) also share many similarities ([Table 10.3](#)), with an audit serving as a kind of “preinspection” in many cases. Knowing what happens when your supplier is inspected by the FDA and their state partners can help you plan what you evaluate and audit when you are assessing current or potential suppliers.

FDA conducts both routine inspections and “for cause” inspections (or investigations). The latter type of inspection may occur if there is an outbreak associated with a food produced at a certain manufacturing facility or if a previous inspection has suggested some kind of problem.



Figure 10.4

Overlap between FDA's and retail buyer's concerns when inspecting/auditing a supplier.

Table 10.3: Similarities and differences between regulatory inspections and audits.

Similarities	Differences
Both audits and inspections look for how well a supplier meets regulatory requirements	Audits are usually scheduled, while inspections may occur at any time. A manufacturer cannot refuse a regulatory inspection, although it could refuse an audit (and potentially lose that buyer's business)
Regulatory inspectors and auditors should be treated courteously, with appropriate questions answered honestly and consistently	Inspections may have administrative and legal repercussions in the event of noncompliance with requirements, while audit results may only impact a supplier's business with one buyer
A supplier should have both an audit and an inspection plan in place and should practice conducting mock audits and mock inspections	Inspections results may be made public, while audit results are usually private
Do not allow an inspector or an auditor to wander unaccompanied in your facility. Do not allow them freely access any documents in your facility	An audit may only cover part of a manufacturing facility pertaining to one product, while an inspection may look at more of the facility (and potentially take more time)
	When audited, you will likely be asked to produce regulatory inspection reports. When inspected by a regulatory agency, you should not be asked to provide audit reports
	Audits may be performed by third parties (neither the supplier nor the retail buyer). Inspections are usually performed by the regulatory agency themselves

The Food, Drug, and Cosmetics Act (21 U.S.C §374(a)) gives FDA inspectors the right to inspect at any time (and the facility registration document requires facilities to acknowledge this right), so although sometimes advance notice of an inspection is given, a food facility should be prepared for inspection at all times.

During an FDA inspection, the food company's representative will first be presented with the inspector's credentials and an official "Notice of Inspection" form. The inspector will likely visit production facilities where they may collect samples. They will likely also review manufacturing records, including the Food Safety Plans and associated supporting documentation. When the inspection is complete, the inspector will discuss any findings and concerns and will present a list of observations to company management. The observations may be summarized in an FDA Form 483 (or in serious situations, an FDA Warning Letter), which may be received soon after the inspection from the local FDA district office and will list any objectionable conditions or practices. There will be opportunity to discuss findings and possible corrective actions with the inspector. Following the visit, the company will need to respond in writing to a Form 483 (or Warning Letter) with details as to corrective actions. The FDA will maintain the Form 483 (or Warning Letter) and all responses in the Establishment Inspection Report, which may be made available publicly (following redaction of proprietary information) under

Table 10.4: FDA compliance tools.

Administrative Compliance Tools	Judicial Enforcement Tools
Voluntary correction of problems at the facility level that occurs immediately during an inspection	Seizure actions
Voluntary correction of problems through deficiency letters and additional inspections	Injunction actions
Administrative detention of product	Criminal prosecution for falsifying records, lying to FDA, knowingly putting consumers at risk, or other appropriate causes
Voluntary and mandatory recalls of potentially hazardous food	
Administrative suspension of registration	

Based on U.S. Food and Drug Administration, 2014d. *Operational Strategy for Implementing the FDA Food Safety Modernization Act* (Online). Available from: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm395105.htm>.

the Freedom of Information Act. Warning Letters are typically posted on the FDA website (for example, see [Appendix A](#)).

It may be helpful to review the inspection guides that the FDA uses for its inspectors. The current general Investigations Operations Manual and specific inspection guides for food and other regulated products are available online (U.S. Food and Drug Administration, 2014c, 2016f).

FSMA allows FDA inspectors expanded access to records. Not only can they ask for records related to foods suspected of being adulterated but can also now examine records related to any food that they may reasonably expect to also be affected or will cause serious adverse health consequences to humans or animals. Retail buyers can also ask for those records specific to their own products. Under FSMA, FDA now also has enhanced administrative compliance tools and judicial enforcement tools that it may use in the event of inspection findings or lack of appropriate corrective actions following inspections ([Table 10.4](#)).

10.4.2 When Do Inspections Occur?

Under FSMA, food facilities are expected to be inspected with greater frequency than they were previously. For the first time, FSMA created risk-based inspection frequency mandates: Domestic facilities deemed “high risk” will be inspected at least once every 3 years, while those considered “low risk” will be inspected at least once every 7 years. Foreign facilities will also be inspected, but mandated inspection frequencies for nondomestic facilities have not been established at the time of this publication. Because of the increased numbers of inspections, FDA is expected to rely on other federal, state, and local inspectors to conduct inspections.

FDA has not issued a final definition for “high-risk facility,” but it will include consideration of the safety risks of the foods produced or stored at the facility, the compliance history of the facility, the quality of the facilities hazard analysis and preventive controls, and other criteria (U.S. Food and Drug Administration, 2015c). The FDA originally published the domestic facility risk category determination process that is shown in [Fig. 10.5](#), although it is expected to be refined in the future.

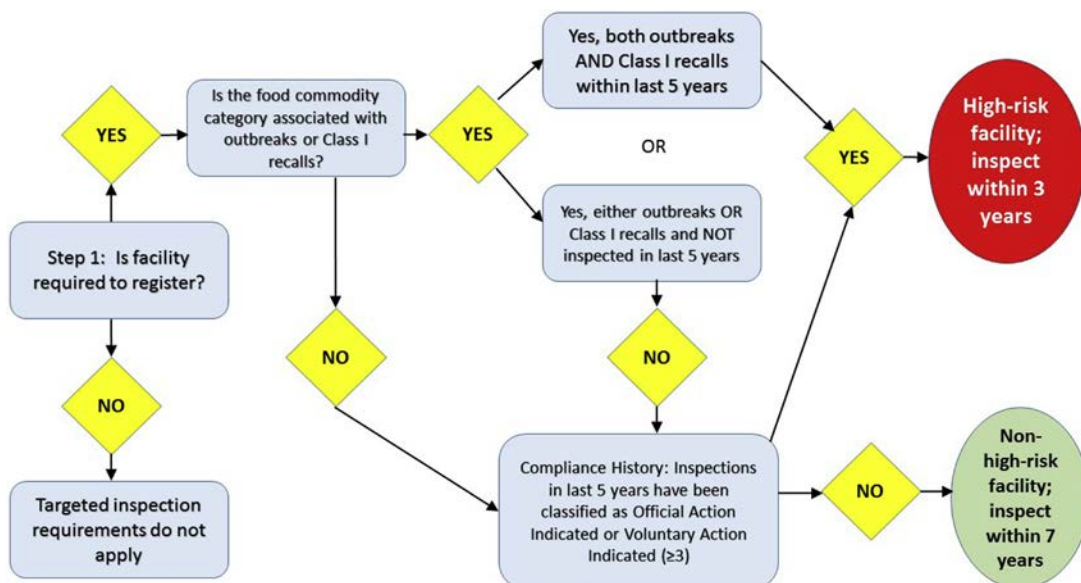


Figure 10.5

Food Safety Modernization Act domestic facility risk category determination process. *Adapted from U.S. Food and Drug Administration, 2015c. FSMA Domestic Facility Risk Categorization (FY 2012) (Online). Available from: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm295345.htm>.*

As discussed in [Chapter 1](#), FDA has plans to designate certain foods as “high-risk foods” ([U.S. Food and Drug Administration, 2014b](#)). Additional recordkeeping requirements for these foods will be specified, and it is likely that designation of a product as a “high-risk food” will mean increased inspection frequency.

FDA has indicated that they will provide incentives for compliance through “reduced scrutiny of firms with records of demonstrated good performance” ([U.S. Food and Drug Administration, 2014d](#)). It is in your suppliers’ best interests, both current, and future, to be compliant. Having Global Food Safety Initiative (GFSI) certification or other third-party audits will not replace the need for FDA inspections (although it could possibly reduce inspection frequency) (Food Safety Preventive Controls Alliance, 2016b).

With FSMA, FDA can now charge fees (\$224 per hour for US inspections) for reinspection of facilities to determine that compliance has been achieved when an initial inspection (for which no fee is required) identifies a problem ([U.S. Food and Drug Administration, 2011](#)).

10.4.3 Who Will Conduct Inspections?

The FDA estimates the number of domestic facilities that they will need to inspect at 82,300 ([U.S. Food and Drug Administration, 2015c](#)). This does not include the 130,000 foreign facilities in 200 countries that will also require inspection at some undefined frequency.

Together, this indicates that more individuals will need to be involved in conducting inspections (U.S. Food and Drug Administration, 2016h).

FDA will use several approaches to meet new inspection demands. First, it will increase the number of its own inspectors, particularly for foreign inspections (U.S. Food and Drug Administration, 2016h). Increased sharing of inspection duties with state and other agencies is also planned. Finally, FDA will be using certified third-party auditors to assess foreign food facilities for food safety. These audits will be required for participation in the Voluntary Qualified Importer Program, which will expedite entry of imports into the United States (U.S. Food and Drug Administration, 2016d). It is not clear if these third-party audits will in any way replace FDA inspections, but it is possible that FDA will deprioritize inspections of foreign facilities that have third-party audit certifications.

Separate from FSMA, FDA began a Program Alignment initiative in 2013 that will have a significant impact on field investigations. This initiative is expected to result in a reorganization of the agency's district offices and inspectors (Schwartz, 2016). Instead of each office and each inspector being responsible for many types of regulated products, district offices and inspectors will likely specialize in one category of product (such as foods or pharmaceuticals). Given the increasing complexity of the universe of FDA-regulated products, this should improve the efficiency and utility of inspections.

10.4.4 Auditing and Assessing How Prepared Your Supplier Is for Preventive Controls for Human Foods Inspections

The audit of a supplier by a retail buyer shares many similarities to an FDA or other regulatory inspection. The audit will want to ensure that the supplier is producing safe food and will assess many of the same things that the regulator would inspect. A company's regulatory history can identify specific areas that could be important to a buyer that could be investigated during an audit.

It is important for the retail buyer to ensure that the supplier is meeting regulatory requirements to ensure continuity in the supply chain. How prepared a supplier is for an audit is a good way of assessing how they will respond during a regulatory inspection. A prepared supplier will not be scrambling at the last minute to sign documents, organize files, and clean facilities (although some of this invariably will occur). The following outlines what you might look for when auditing a supplier to gauge how well prepared they are for a regulatory inspection.

- Does the supplier have a communication strategy for audits/inspections?
 - Is there a designated point(s) of contact and backup? Is there a preventive controls qualified individual involved?
 - Do they document all regulatory interactions and inspections? What has the FDA noted at previous inspections?

- Do they have an inspection plan that includes audits and/or mock inspections?
 - Do all personnel understand what they need to do (or not do) during an inspection?
 - Do they have a designated room for the auditor or inspector during their visit?
 - How does the company notify other personnel that an FDA inspector or auditor is in the facility?
- Do they have a carefully designed Food Safety Plan and well-organized supporting records?
 - Do they follow templates that minimize reviewer effort? Are records organized and easy to navigate, with tables of contents, indexes, etc.?
 - How quickly can they produce requested records?
 - FDA allows either paper or electronic records (21 CFR Part 117.305(a), but if they use electronic records, are they controlled in a way to allow you access to only the requested records?
 - Are they keeping records for the required time periods ([U.S. Food and Drug Administration, 2012](#))?

[Appendix D](#) of this book contains a Supplier Approval Checklist that might also be useful for a retail business when selecting and auditing a supplier.

10.5 Communications With Auditors and Inspectors

How a company's representatives treat an auditor will likely mirror how they treat a regulatory inspector. Here are some things to watch for when you are conducting an audit of a potential supplier:

- Are they knowledgeable, confident, positive, professional, responsive, and courteous?
- Do they argue or act defensively, evasively, or are they overly apologetic?
- Do they ask your opinion or treat you as a consultant? In the case of a supplier audit, this is acceptable in some cases, but they should know what they are doing without your help.
- Do they answer questions succinctly without volunteering more than what is asked? Do they attempt to fill silences with information that has not been requested?
- Do they allow you access to more information than you request? Are their files organized so that you only see what you need to see?
- Do they interrupt you? Do they listen carefully to questions, asking for clarification when needed?
- Are they honest, up-front, and consistent? Do they use facts rather than opinions or "I think..." or "usually we do it this way." Do they guess if they do not know an answer?
- Do they leave you alone in the facility at any time?
- Do they answer questions with the phrases "unofficial" or "off the record?"
- Do you overhear conversations in the facility while you are there that you should not be hearing?
- Are the personnel leading the audit courteous to other employees who are involved with the audit? Do they interrupt them, argue with them, or whisper to them?



Figure 10.6

What not to say during a regulatory inspection or audit. Adapted from *Compliance Insight*, 2013. FDA Inspection Do and Don't List (Online). Available from: <https://www.youtube.com/watch?v=maBU4UKx38>.

- Do they correct all miscommunications immediately?
- Do they say any of the phrases in Fig. 10.6?

10.6 Summary and Conclusions

Retail buyers may assume that being exempt from FSMA means they have no responsibilities under FSMA and they do not have to understand FSMA or preventive controls. However, there are some situations where a hazard may not be controlled by the supplier (either because the supplier's Food Safety Plan specifies that the buyer assumes the hazard, or the retail buyer is importing a product from a foreign supplier and needs to comply with FSMA's Foreign Supplier Verification Program) and the retail buyer assumes certain responsibilities.

Importantly, as well, a retail buyer should understand how hazards are being identified and how preventive controls are being used by their suppliers to make the products the retail buyer purchases safer. Purchasing safe ingredients is an important way for the retail buyer to help ensure the products they eventually sell to consumers are safe.

An understanding of the FDA regulatory requirements and food safety trends will help a retail buyer assess whether their supplier is in compliance during audits and other interactions with their suppliers. It will also help the retail buyer gather the most important information during audits related to food safety.

10.7 Selected Web Resources

This section (Table 10.5) lists some of the key resources you might want to access as you consider how PCHF and FSMA affect the ingredients and products that you source for your company.

Table 10.5: Selected web resources on Preventive Controls for Human Foods and Food Safety Modernization Act (FSMA).

Type of Resource		Name of Resource	Website
Laws, regulation, and guidance documents	Laws	Food, Drug, and Cosmetic Act	https://www.law.cornell.edu/uscode/text/21/chapter-9
		FSMA	https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247548.htm
	FSMA foundational rules and regulations	Current Good Manufacturing Practice, Hazard Analysis and Risk-based Preventive Controls for Human Foods; Final Rule	https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm
		Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; Final Rule	https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm
		Produce Safety Final Rule	https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm
		Accredited Third-Party Certification Final Rule	https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361903.htm
		Mitigation Strategies to Protect Food Against Intentional Adulteration	https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361903.htm
		Sanitary Transport Final Rule	https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm383763.htm
	FSMA-related guidances	Draft Guidance for Industry: Hazard Analysis and Risk-based Preventive Controls for Human Food	https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm
		Guidance for Industry: What you Need to Know about Registration of Food Facilities: Small Entity Compliance Guide	www.fda.gov/downloads/Food/GuidanceRegulation/UCM332657.pdf
		Guidance for Industry: What You Need to Know About Establishment and Maintenance of Records; Small Entity Compliance Guide	https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm391329.htm

Table 10.5: Selected web resources on Preventive Controls for Human Foods and Food Safety Modernization Act (FSMA).—cont'd

Type of Resource		Name of Resource	Website
Educational materials	Course material	Food Safety Preventive Controls Alliance (FSPCA) Training and Participant Manual	https://ifpti.absorbtraining.com/Files/Instructor%20Resource%20Portal/FSPCA%20PC%20Course%20Participant%20Manual_V1.2_2016.02.23.pdf or https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food
	FSMA Technical Assistance Network	Preventive Controls Scientific and Technical Questions from Industry	https://www.ifsh.iit.edu/fspca
		FSMA Regulation and Policy Interpretation	https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm
FDA inspection resources		FSPCA Community	https://fspca.force.com/FSPCA/s/?language=en_US
		Investigations Operations Manual	
		Partnership for Food Protection Best Practices: Model for Local Federal/State Planning and Coordination of Field Operations and Training	https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/UCM373333.pdf
FDA reportable food registry, recalls, import alerts, and warning letters		Reportable Food Registry	https://www.fda.gov/Food/ComplianceEnforcement/RFR/ucm200958.htm
		Food recalls	https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Recalls/default.htm
		Import alerts	https://www.accessdata.fda.gov/cms_ia/default.html
		FDA warning letters	https://www.fda.gov/Food/ComplianceEnforcement/WarningLetters/default.htm
Other sources of information		FSMA webinar on Final Rule under FSMA to Update Food Facility Registration	https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm510187.htm
		CDC Foodborne Outbreak Online Database (FOOD Tool)	https://wwwn.cdc.gov/foodborneoutbreaks/
		FDA presentations	https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247546.htm
		FDA Compliance Policy Guides	https://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/default.htm
		FSPCA website	https://www.ifsh.iit.edu/fspca
		FDA ombudsman	https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ucm482210.htm

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Appendix A: Example of an FDA Warning Letter

Aspen Hills, Inc. 1/10/17



Kansas City District Office
8050 Marshall Drive - Suite 205
Lenexa, Kansas 66214-1524
913-495-5100

WARNING LETTER

January 10, 2017

VIA UPS OVERNIGHT DELIVERY RETURN RECEIPT REQUESTED

Thomas S. Lundeen, President & Co-Owner
Nancy J. Lundeen, Secretary Treasurer & Co-Owner
Aspen Hills, Inc.
830 N. State St. Garner, IA 50438

Reference CMS Case# 509769

Dear Mr. and Mrs. Lundeen:

The U.S. Food & Drug Administration (FDA or we) inspected your frozen cookie dough (including ready-to-eat (RTE) cookie dough) manufacturing facility located at 830 N. State St., Garner, IA 50438, from September 27 through October 6, 2016. During our inspection, FDA collected environmental samples from various areas in your processing facility. FDA laboratory analyses of the environmental swabs found the presence of *Listeria monocytogenes* (*L. monocytogenes*), a human pathogen, in your facility. Additionally, FDA investigators observed serious violations of the Current Good Manufacturing Practice (CGMP) regulation for foods, Title 21, Code of Federal Regulations, Part 110 (21 CFR Part 110).¹ Based on FDA's analytical results for the environmental samples and inspectional findings documented during the inspection, we determined that your frozen cookie dough (including RTE cookie dough) products commonly called pucks, pellets, and pails are adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act and FDA's regulations through links in FDA's home page at <http://www.fda.gov>. (<http://www.fda.gov/>)

This inspection resulted in FDA's issuance of an FDA Form-483, Inspectional Observations (FDA-483), at the conclusion of the inspection. We acknowledge your firm's responses dated November 1, 2016, and December 19, 2016, to the FDA-483, which include a description of corrective actions taken by your firm. We address the adequacy of specific corrective actions below.

Presence of *L. monocytogenes*

L. monocytogenes is a pathogenic bacterium that is widespread in the environment. It can proliferate in food processing facilities without proper controls, where it may contaminate food. Consuming these contaminated foods can lead to a severe, sometimes life-threatening illness called listeriosis, a foodborne illness that is of major public health concern because of the severity of the disease, its high case-fatality rate, long incubation time, and tendency to affect individuals with underlying conditions or who are otherwise more susceptible to illness.

FDA laboratory analysis of the environmental samples collected on September 28, 2016, confirmed that four environmental swabs were positive for *L. monocytogenes*. The four positive environmental swabs were collected from the manufacturing area in the following locations:

- On the second stair/rung of the ladder well leading to the elevated control room. This ladder is adjacent to the (b)(4) used on the cookie dough (b)(4).
- On the wheels of the pallet jack used to move food products within the production room. The pallet jack was located in the (b)(4) of the production room adjacent to the (b)(4) at the time of sampling.
- On the basket located in the (b)(4), which is adjacent to the (b)(4) where the exposed cookie dough receives (b)(4).
- In the (b)(4), which is adjacent to the (b)(4) where the exposed cookie dough receives (b)(4).

Between September 18 and 26, 2016, your firm's environmental program detected *L. monocytogenes* in ten environmental swabs and in one finished product lot of cookie dough product, which was not distributed into commerce. The frequency of these environmental findings in conjunction with your finished product finding indicates that your firm is not taking aggressive action to identify harborage sites for *L. monocytogenes*, to deep clean your facility effectively, and to prevent finished product contamination.

Whole Genome Sequencing (WGS) analysis was conducted on the four previously mentioned *L. monocytogenes* isolates obtained from the FDA environmental samples collected on September 28 and the eleven previously mentioned *L. monocytogenes* isolates detected by your firm's environmental program (including one finished product sample). WGS analysis of bacterial human pathogens provides high-resolution data, enabling direct links to be established between clinical isolates and food or environmental sources of bacterial contamination and illness. WGS data can also be used to infer the evolutionary relationships (or phylogeny) within a given set of isolates as it measures each DNA position in a bacterial genome. The WGS phylogenetic analysis of these 15 isolates finds that they comprise a single strain of *L. monocytogenes*. Comparing this strain to the larger WGS database shows that it matches three other isolates: two isolates from finished ice cream products tested by a commercial laboratory, and one isolate from a cookie dough ingredient sample collected by the state of Texas in 2016.

The presence of *L. monocytogenes* in your facility is significant because it demonstrates your cleaning and sanitation practices are inadequate to effectively control pathogens in your facility to prevent contamination of food. Furthermore, *L. monocytogenes* found in the environment of your facility increases the risk of your finished product becoming contaminated. Once established in a production area, personnel or equipment can facilitate the pathogen's movement and contamination of food-contact surfaces and finished product. It is essential to identify the harborage sites in the food processing plant and equipment where this organism is able to grow and survive and to take such corrective actions as necessary to eradicate the organism by rendering these areas unable to support the growth and survival of the organism.

We acknowledge after our findings, your firm took extensive corrective actions. This included hiring a third-party laboratory and consultant group to conduct a comprehensive review of your operations and to make recommendations for changes in your policy and procedures. It also included revising your Standard Operating Procedures ("SOPs") in three critical areas: (1) environmental pathogen monitoring; (2) product sampling and testing; and (3) cleaning and sanitizing facilities. We will ascertain the adequacy of your corrective actions during our next inspection. Additionally FDA acknowledges your firm conducted a voluntary recall to include all lots of RTE cookie dough produced at your facility between June 8 and September 30, 2016, as a result of the Agency's inspectional findings, the detection of *L. monocytogenes* within your processing environment, and the results of the WGS analysis.

CGMP Violations

FDA investigators observed the following significant violations of the CGMP regulation for foods [21 CFR Part 110]:

1. Your firm failed to take all reasonable precautions to ensure that production procedures do not contribute contamination from any source, as required by 21 CFR 110.80. Examples of the lack of such precautions include the following:

a. On September 27, 2016, employees were observed conducting their **(b)(4)** cleaning process, which included spraying the floors using **(b)(4)** spray nozzles connected to hoses, while there were **(b)(4)** buggies containing uncovered, in-process White Chocolate Macadamia cookie dough on the production floor [see 21 CFR 110.80(b)(5)]. Standing water was observed on the floor surrounding the exposed products in the buggies [see 21 CFR 110.37(b)(4)].

Your firm's response indicates that you improved management oversight and provided additional training to ensure product is not exposed during the cleaning process. It also indicates that **(b)(4)** cleaning with water will not begin until after all products are in the process of being packaged and removed from the production floor, except that cleaning with water may begin on the opposite end of the production room from the packaging machines, approximately **(b)(4)**. We will ascertain the adequacy of your corrective action during our next inspection.

b. Residual flour, shortening, and liquid pasteurized egg ingredient were observed on the floor of your production room. Your employees, pallet jack, and forklift were observed entering and exiting the production room, passing through the product build-up on the floor and leaving defined imprint trails.

Your firm's response indicated that you have addressed appropriate cleaning of spills through retraining employees and ensuring stronger management over existing procedures. Your response also indicates that you have changed procedures to eliminate traffic through the production room. We will ascertain the adequacy of your corrective action during our next inspection.

c. Employees were observed to be moving in and out of the production room to take trash to a dumpster, located in an adjacent room, wearing rubber boots and aprons also used during production. An employee's apron brushed against the dumpster while throwing away the trash, and other employees were observed picking up empty raw material bags lying on the production room floor, carrying them against their aprons to the dumpster outside the production room to dispose of the empty bags in the dumpster. Each time the employees were observed re-entering the production room, they were wearing the same rubber boots and aprons without cleaning or sanitizing them.

Your firm's response indicates that you have changed procedures to limit employee movement from the production room to the warehouse, amended your procedures with respect to the use of overshoes in the production room, **(b)(4)** by the entrance to the production room, and improved training and management oversight. We will ascertain the adequacy of your corrective action during our next inspection.

d. On September 27, 2016, during the cleaning process, an employee was observed spraying the floor and drain of the production room. Overspray from the floor was observed splashing on the equipment parts, such as augers used to process cookie dough.

Your firm's response indicates that you have revised your cleaning procedures and taken steps to train employees in the proper techniques for cleaning and sanitizing equipment to ensure it is ready for production. Your response also indicates you **(b)(4)** to create an open area to prepare for cleaning without risking splatter to other areas of the production room. We will ascertain the adequacy of your corrective action during our next inspection.

2. Your firm failed to ensure that cleaning and sanitizing of utensils and equipment is conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials, as required by 21 CFR 110.35(a). Specifically, our investigators observed:

a. On September 27, 2016, employees were observed dispensing pasteurized liquid egg product from a tote into metal pails for the purpose of weighing them on a scale. The scale was observed to be covered in pasteurized liquid egg product throughout the production day.

Your firm's response indicates you are retraining employees and enforcing an existing policy to clean up spills as they occur. In addition, your response indicates that you plan to introduce disposable gloves and train employees on the proper use and replacement of gloves. Your response indicates the training will be ongoing. We will ascertain the adequacy of your corrective action during our next inspection.

3. Your firm failed to maintain equipment so as to facilitate cleaning of the equipment, as required by 21 CFR 110.40(a). Specifically our investigators observed:

- a. Apparent rust on the (b)(4) used to cut cookie dough as it leaves the (b)(4) on the (b)(4)
- b. Apparent rust and degradation of the bottom edges of the (b)(4) mixers in the production room used to mix all products manufactured by your firm.
- c. Missing bolts from the upper white plastic edge of the (b)(4) mixer. The missing bolt holes were observed to contain debris while mixing White Chocolate Macadamia puck dough.

Your firm's response indicates that you have adopted a new SOP which requires the replacement of the (b)(4) and that requires a (b)(4). Your response indicates that you plan to (b)(4) for a more cleanable surface. Your response indicates that you have cleaned and replaced the missing bolts. We will ascertain the adequacy of your corrective action during our next inspection.

Recall Classification

FDA acknowledges that your firm conducted a voluntary recall and considers the 19 RTE cookie dough products, all manufactured between June 8, 2016, and September 30, 2016, that your firm recalled beginning on September 20, 2016, and expanded on October 9, 2016, and on November 9, 2016, to have posed an acute, life-threatening hazard to health.

The FDA has designated your recall as Class I. This classification is based on findings of *L. monocytogenes* in your products and in the production environment. Information regarding your recall will be published in the weekly **FDA Enforcement Report**. FDA's policy regarding recalls is published in 21 CFR Part 7. Our Kansas City District Office Recall Coordinator will remain in contact with you until this matter is resolved.

This letter is not intended to be an all-inclusive list of the violations that exist in connection with your products. It is your responsibility to ensure that your products are in compliance with the Act and all applicable laws, including the Current Good Manufacturing Practice regulation for foods [21 CFR Part 110].²

You should take prompt action to correct these violations cited in this letter. Failure to do so may result in regulatory action without further notice, including without limitation, seizure and injunction.

Additionally, FDA has the following comments on your corrective action documentation:

- 1. Your firm's response indicates that you continue to maintain a (b)(4) procedure for you RTE products. However, you did not include details of this (b)(4) procedure such as the amount of product manufactured and (b)(4), the results of the analyses of the product, and the disposition of any affected lots of product.
- 2. Your firm's response referenced procedures that did not appear to contain a version number or an implementation date. Therefore, it is difficult to know when some of the procedures were implemented and may be difficult for your employees to know if the procedure is current. For example, your response indicates you were

enforcing and retraining employees on existing procedures; however, the training records supplied with your response show employees were trained on topics such as “Sanitation” (9/13/16) and “Highlighted Proper Sanitation, High APC counts and Importance of properly cleaned facility” (9/15/16). These trainings were just prior to the start of our inspection on September 27, 2016, and therefore cannot be considered to constitute corrective actions to issues identified during the inspection. It is your responsibility to ensure that training is effective and understood by your employees.

You should respond in writing within fifteen working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct violations, including an explanation of how your firm plans to prevent the recurrence of the violations described above or the occurrence of similar violations. More specifically, your response should include documentation of the corrections and/or corrective actions (which should address systemic problems) your firm has taken. If your firm’s planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Please include copies of any available documentation demonstrating corrections have been made.

Section 743 of the Act (21 U.S.C. 379j-31) authorizes FDA to assess and collect fees to cover FDA’s costs for certain activities, including reinspection-related costs. A reinspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the Act, specifically to determine whether compliance has been achieved. Reinspection-related costs means all expenses, including administrative expenses, incurred in connection with FDA’s arranging, conducting, and evaluating the results of the reinspection and assessing and collecting the reinspection fees [21 U.S.C. 379j-31(a)(2)(B)]. For a domestic facility, FDA will assess and collect fees for reinspection-related costs from the responsible party for the domestic facility. The inspection noted in this letter identified noncompliance materially related to a food safety requirement of the Act. Accordingly, FDA may assess fees to cover any reinspection-related costs.

Your response should be sent to Andrew A. Hoopes, Compliance Officer, U.S. Food and Drug Administration, 210 Walnut Street, Suite 369, Des Moines, IA 50309. If you have any questions about this letter, please contact Compliance Officer, Andrew A. Hoopes at 515-244-0480, ext. 1002 or andrew.hoopes@fda.hhs.gov.
[\(mailto:andrew.hoopes@fda.hhs.gov\)](mailto:andrew.hoopes@fda.hhs.gov)

Sincerely,
/S/
Cheryl A. Bigham
District Director
Kansas City District Office

¹ Part 110 was modernized and codified in Subpart B of Part 117 by the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR Part 117) (CGMP & PC rule). An establishment will continue to be subject to Part 110 until the Part 117 compliance date applicable to its business size. See http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm#Compliance_Dates (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm#Compliance_Dates) for PC rule compliance dates.

² See footnote 1 for further information about the recent modernization of Part 110 and the possible applicability of Part 117.

Appendix B: Unexpected Allergens in Food Ingredients

Food allergens can be present in many food ingredients and are not always obvious from their name. This list is a guide to assist industry to identify basic food ingredients and food additives that may contain or be derived from one or more of the allergens. This is not a comprehensive list and should only be used as a guide as many additives and ingredients can be produced from various sources, not always the allergen identified in the list.

Product/Ingredient Name	Details
Acidity regulator—lactate	What is it derived from (e.g., milk (lactic acid), pork, whey, etc.)?
Acidity regulator—lactic acid	What is it derived from (e.g., milk, tomatoes, molasses, potato, maize starch, wheat starch)?
Albumin/albumen	What is it derived from (e.g., egg, milk, etc.)?
Amylase (alpha and beta)	What is it derived from (e.g., pig, wheat, barley, soy, etc.)?
Antioxidants	What are they derived from (e.g., soy, egg)?
Baking powder	Does this contain any carriers or bases (e.g., wheat flour, rice flour, etc.)?
Banana chips	What oil was used in the preparation of this product? Peanut oil has been reported to have been used. Refer to section on fat/oil.
Beta-carotene	Does it contain tocopherols, and what are they derived from (e.g., soy)? Is it microencapsulated? If so, is the capsule derived from fish?
Beta-galactosidase	Does it contain milk?
Beverage whitener	Does it contain wheat, maize, casein, etc.?
Bran	Does it contain wheat, oats, rye, barley, spelt?
Breadcrumbs	Do they contain sesame seeds?
Brine	Check for allergens (e.g., casein—milk protein).
Caramel	What is it derived from (e.g., wheat, maize, sugar beet, cane sugar, etc.)?
Carotenoids/canthaxanthin	Check for allergens (e.g., fish, crustacea).
Cereal/gluten	Which cereal: wheat, oat, rye, barley, etc.?

Continued

Product/Ingredient Name	Details
Cheese	Does it contain rennet (refer to section on rennet), vinegar (refer to section on vinegar), gelatin (refer to section on gelatin), lysozymes (refer to section on lysozymes), starch (e.g., Edam and Gouda cheese)?
Cheese (grated)	Does it contain a free-flowing agent? If yes, what is it and what is it derived from (e.g., wheat starch, wheat flour, maize, etc.)? Refer to section on cheese.
Cheese powder	Does it contain a free flowing agent? If yes, what is it and what is it derived from (e.g., wheat starch, wheat flour, maize, etc.)? Refer to section on cheese.
Clarifying agents (used in wine, wine vinegar, fruit and vegetable juices, animal/vegetable stock/broth)	Clarifying agents include casein (milk protein), egg white, isinglass (fish collagen), gelatin (refer to section on gelatin), or chitosan (crustacean protein).
Cocoa powder	Does it contain soy lecithin or wheat flour?
Coconut milk/coconut milk powder	Does it contain casein (milk protein)?
Color—riboflavin	What is it derived from (e.g., yeast—refer to section on yeast)?
Color—carbon black or brilliant black	Does it contain glucose? Is the glucose from wheat?
Color—beta-carotene	Is it microencapsulated? If so, what is the encapsulating medium (e.g., fish gelatin)?
Color—xanthophylls	What is it derived from (e.g., animal, egg, egg yolk, crustacea, fish)?
Color(s)	Is there a carrier? If yes, what is the carrier derived from (e.g., maltodextrin (refer to section on maltodextrin), starch (refer to section on starch), yeast (refer to section on yeast), soy, gluten-containing substances)? Check for the addition of sulfites.
Corn	Does this refer to maize or wheat? (Some countries use the terms “corn” and “wheat” interchangeably.)
Corn flour	Is this derived from wheat or maize flour?
Cultures	Check for milk.
Curry paste	What are the component ingredients? Do they contain allergens?
Dates	Check if they are rolled in oat (powder).
Dehydrated/dried products	Do they contain oils (used as a processing aid)? Refer to section on fat/oil. Check for sulfites.
Dextrin/dextrose/maltodextrin	Is this derived from oats or wheat?
Emulsifier	What is it derived from (e.g., soy, egg, wheat)?
Emulsifier—calcium stearate/stearic acid	What is it derived from (e.g., peanuts)?
Emulsifier—sodium lactylates/calcium stearoyl lactylate	What is it derived from (e.g., peanuts, milk)?
Enzymes	Do they contain carriers? Is the carrier from a wheat source?
Ethanol	What is it derived from (wheat)?
Fat/oil	What is the fat/oil derived from (e.g., beef, soy, peanut, sesame, canola, olive, sunflower, etc.)? Does it contain antioxidants (refer to section on antioxidants)?
Fatty acids (mono- and diglycerides)	What are they derived from (e.g., soy)?
Flavor enhancers	What are they derived from (e.g., meat, sardines (fish), wheat, soy, maize)? If microbial synthesis, what is the source of the nitrogen and carbohydrate (e.g., wheat, soy, maize, etc.)?

Product/Ingredient Name	Details
Flavors	<p>Do they contain any bases, carriers, free-flowing agents (e.g., maltodextrin (refer to section on maltodextrin), casein, oleoresins (refer to section on oleoresins), emulsifiers (refer to section on emulsifiers), oils (refer to section on fat/oil)). If yes, what are they derived from (e.g., wheat, maize, soy, egg, peanut)?</p> <p>Do they contain hydrolyzed protein (refer to section on hydrolyzed proteins)?</p> <p>Do they contain fatty acids (e.g., mono-, di-, or tri-glycerides) (refer to section on fatty acids)?</p> <p>Have they been encapsulated with fish gelatin?</p>
Fruit	Check waxes applied to fruits for allergens.
Gelatin	What is the gelatin derived from (e.g., fish (isinglass), beef, pork, chicken, etc.)? Check for the addition of sulfites.
Gellan gum	What is the carbohydrate source used to grow the gum (e.g., wheat, maize, molasses, cane sugar)? What is the protein source used to grow the gum (e.g., soy, egg)?
Glucose/glucose syrup	What is it derived from (e.g., wheat, maize, rice, potato, oats, etc.)?
Glycerine	Check for peanuts.
Herb extract(s)/spice extract(s)	Does it contain any bases, carriers, free-flowing agents (e.g., maltodextrin, flour, oleoresins, emulsifiers). If yes, what are they derived from (e.g., wheat, maize, soy, egg, etc.)?
Herb(s)	Does it contain any bases, carriers, free-flowing agents (e.g., maltodextrin, flour, oleoresins, emulsifiers). If yes, what are they derived from (e.g., wheat, maize, soy, egg)?
Hydrolyzed animal protein	What is it derived from, or does it contain casein, whey, egg, fish?
Hydrolyzed vegetable protein	What is it derived from (e.g., soy, wheat, maize, peanut, sesame, etc.)?
Icing sugar	Is it 100% pure icing sugar? If not, what else is added (e.g., wheat)?
Isoflavones	Are they derived from soy?
Lecithin	What is it derived from (e.g., soy, egg, etc.)?
Lysozymes	Check for egg protein.
Malt/malt extract	Is this derived from gluten-containing cereals?
Maltodextrin	Check for wheat and added sulfites.
Mayonnaise	What are the component ingredients? Do they contain allergens (e.g., egg)?
Meat (manufactured—fish, meat, poultry)	Does it contain binders? If yes, do the binders contain milk and/or egg? Does this product contain fillers? If yes, do the fillers contain soy or gluten-containing cereals?
Milk powder	Does it contain soy lecithin?
Minerals	Are they microencapsulated with fish gelatin?
Mustard	Does it contain wheat?
Nondairy creamers	Milk derivatives have been reported in some nondairy creamers.

Continued

Product/Ingredient Name	Details
Oil (vegetable)	What is the source of the oil (e.g., soy, peanut, sesame, canola, olive, etc.)? Does it contain antioxidants? If so, what are they derived from (e.g., soy, egg)? Check for the addition of soy lecithin.
Oleoresins	Do they contain antioxidants/tocopherols or emulsifier? If yes, what are they derived from (e.g., soy, egg, sesame)?
Omega 3, 6	Are they derived from fish, linseed, etc.? Check for the addition of soy lecithin.
Polyols	What are they derived from (wheat, maize, etc.)?
Rennet	What is it derived from (e.g., bovine or synthetic)? If synthetic, what is the source (e.g., maize, wheat, soy, molasses, sugar beet)?
Soy sauce	Does it contain wheat (in addition to soy)?
Spices	Do they contain any bases, carriers, free-flowing agents (e.g., maltodextrin, flour, oleoresins, emulsifiers). If yes, what are they derived from (e.g., wheat, maize, soy, egg)?
Stabilizers	What are they derived from (e.g., soy, egg)?
Starch (modified—chemically or physically)	What is the starch derived from (maize, tapioca, potato, wheat)? Check for added sulfites.
Sterols (plant)	What are they derived from (soy)?
Suet	Check for gluten-containing cereals.
Sugar	What is it derived from (e.g., cane sugar, sugar beet, wheat)?
Sulfites—sulfur dioxide, bisulfite, metabisulfite	What is the level of addition (ppm or mg/100 g)?
Sultanas	Check for soy oil.
Sweeteners (artificial)—polyols, e.g., sorbitol (420)	Check for wheat starch used as a dusting to prevent sticking. What are they derived from, e.g., glucose (what is the glucose derived from, e.g., wheat, maize, cane sugar)?
Textured vegetable protein	Does it contain wheat, soy?
Thickener	What is the thickener derived from (maize, tapioca, potato, wheat), and what is the carrier material?
Tocopherols	What are the tocopherols derived from (wheat, soy)?
Vinegar	What is the vinegar derived from (e.g., wheat, barley, maize, malt)? Are clarifying/fining agents used in processing the vinegar/wine (e.g., casein (milk protein), egg white, isinglass (fish protein), gelatin (beef, fish, chicken, pork), or chitosan (crustacean protein))? If wine vinegar, what is the residual sulfite content? If balsamic, does it contain caramel (refer to section on caramel)?
Vitamin E	Check for soy.
Vitamins/vitamin premix	Are they microcapsulated with fish gelatin? Check for lactose (milk) carriers.
Whitener	Does it contain wheat, casein?
Worcestershire sauce	Check for the addition of anchovies (fish).

Product/Ingredient Name	Details
Xanthan gum	What is the carbohydrate source used to grow the gum (e.g., wheat, maize, molasses, cane sugar)? What is the protein source used to grow the gum (e.g., soy, egg)?
Yeast and yeast extract	What is the substrate the yeast is grown on (e.g., wheat, malt, barley, soy, etc.)? Are there any carriers—refer to section on flavors.

Modified from Allergen Bureau, 2011. *Unexpected Allergens in Food*. <http://allergenbureau.net/>.

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Appendix C: Case Study

This case study describes how a Food Safety Plan that includes a hazard analysis and risk-based preventive controls process will help a *fictitious* company called Completely Cookie Inc. prevent future *Listeria monocytogenes* contamination of its products, which previously resulted in a national recall.

Despite having a written hazard analysis and critical control point (HACCP) plan, appearing to be in compliance with all applicable government regulations, and achieving consistently excellent scores on third-party and Global Food Safety Initiative (GFSI) certification audits, one of Completely Cookie Inc.'s food products tested positive for *L. monocytogenes*, resulting in a recall of all products from that production lot. The company's owners believed that the written HACCP plan was implemented, monitored, and verified according to HACCP principles.

Completely Cookie Inc. is a small food processing establishment that began as a “guy with a truck” business delivering food products to restaurants in the 1960s. The company grew into a father–daughter business that baked food products for the same restaurants, eventually evolving into a larger business that invested in bigger machinery to provide several of their best-selling ready-to-eat (RTE) baked products, including USDA-inspected savory chicken pot pies and cookie products, to a wider audience. The company today employs between 50 and 60 people to make products that are sold by several grocery store chains and restaurants.

Completely Cookie Inc. owns an old building in a section of the city that has largely fallen into neglect. The brick walls are badly cracked on the outside, with only the sidewalk between the walls and the street. Heavy truck traffic causes the glass in the windows high up on the walls to rattle against the metal security bars, and the dock doors are locked anytime not in active use to prevent unauthorized people from getting inside the building. Employees enter the facility using electronic key cards into the security vestibule, which has a turnstile that only allows one person at a time through the second locked door. This second door opens into a tiny locker room, which has small, separate-gender restrooms located on either side. Employees put purses, coats, and personal belongings into their lockers before entering the southern end of the production area, next to the shipping office. Production employees do not change shoes or wear uniforms; only the quality assurance (QA) employees put a white smock over their street clothes.

The company business offices are located in a second-floor area that overlooks the production room. The brick walls of the large production area are painted white, and the floors are poured concrete (with cracks in many areas). The “mix area” is on the northern end wall of the open area, with large mixers and tables for hand preparation of items to go into the ovens. Dedicated mixers and other equipment are used for peanut- and tree nut-containing cookies. The belt ovens extend down the length of the large open area, with conveyers and cooling belts traveling toward the southern end of the building, where packing tables are located. Coolers and freezers are located along the northern end of the other long wall, while the loading docks are located along the southern end of the same wall.

The USDA-inspected savory chicken pot pies are produced in a “separate” area running down one side of the other operations (marked by painted lines on the floor). The USDA area includes a couple of large scraped-surface kettles for cooking the chicken and broth before a gravy is created in the kettles. Frozen vegetables are added to the mixture to start the cooling process before the filling is added to the pie tins. The pie top (crust) is made on a table in the USDA mix area and then added to the top of the filled tins before the pies are run through the belt oven for baking. After baking, the pot pies are cooled and then frozen before shipment to customers.

All production employees start their day in the mixing areas, preparing products for the bakery operation or the pot pie operation. (Employees working in the USDA production area generally only work in that area and do not participate in the other bakery production activities.) When the first products go into the ovens, some of the employees move down to the other end of the production room and start staging packaging materials while the first products are baking. When the first products have passed through the ovens to the cooling areas, additional employees move to the opposite end of the room and help to package the baked items into paper sleeves and then pack them into shipping cases.

Later in the day, after all the “daily delivery” items have been packed and the delivery trucks dispatched, the next shift of baked products are packaged and then case-packed and put into the freezers for grocery and restaurant store sales.

The mixing and baking processes continue for two shifts per day, with the third shift dedicated to sanitation, while the last of the items baked during the first two shifts are case-packed and go into the freezers. Sanitation activities for the bakery operation include cleaning of the mixers, utensils, conveyers, preparation, and pack-off tables; wiping off the outside of the ovens; and then cleaning of all the floors around the production equipment. Sanitation activities for the USDA production area include washing of the kettles and wet cleaning of the entire mix area, which includes dumping the wash water from kettles onto the floor and flooding the entire area with water meant to drain to the trench drains in the floor between the USDA area and the general bakery area.

The above described operation continued for many years with no problems found by regulatory personnel or auditors, and no serious food safety–related customer complaints or food poisoning incidents associated with their products. The USDA operation was required to have a USDA-approved HACCP plan for the chicken pot pies, but the other general bakery operations were not required by regulation to have HACCP plans. To meet the requirements of their retail buyer’s third-party audits, the company owner and QA technicians had attended HACCP training and had developed a written HACCP plan for the general bakery products with one critical control point (CCP), which involved metal detection. The HACCP team had decided that the mixers created a possibility of metal-on-metal contact that might generate metal shavings, and they had in the past had incidences of screws falling from equipment into the product, so now all of the products are run through a metal detector after packaging and prior to case-packing.

The largest grocery store chain customer of Completely Cookie asked for a line extension, requesting that the company supply them with double chocolate cookie dough that customers could take home and bake themselves. The owner of Completely Cookie was not initially happy to sell a product that was not fully cooked, but then reasoned that it would mean a big boost in sales which would not require any new equipment or investment to accomplish.

After more discussion, the customer decided to extend the product line to include a variety of raw cookie doughs, including a cranberry and ricotta cheese cookie to pay homage to the red and white school colors of a large regional university. The customer required that Completely Cookie purchase the new ingredients, dried cranberries and ricotta cheese, to immediately begin production of the new items.

The owner of Completely Cookie and the HACCP team wrote a new HACCP plan for the new items and again decided that the only CCP should involve the metal detector. Using the “likelihood versus severity” reasoning of HACCP, the team decided that potential biological hazards associated with the new ingredients were “not likely to happen” due to the fact that the raw cookie dough would go through a heating step before consumption by the end user.

Completely Cookie found new vendors for the ricotta cheese and dried cranberries and made the first order of new cookie dough products for the customer. A long-standing agreement with this grocery store chain customer was a requirement that all batches of product have samples sent to an outside microbiology laboratory for testing. Normally, the product was held at Completely Cookie until the micro lab results were obtained prior to shipping the product to the client. But for this first-time order, the client was in a rush to provide the new items in their stores prior to the start of college football season, so they demanded that the items be shipped before the micro lab results were returned. The owner of Completely Cookie had never had a problem with lab results before, so did not see a problem with complying with the customer’s request to ship the product immediately.

When the lab results came back, they indicated a positive finding for *L. monocytogenes* in several of the new product samples, including the cranberry and ricotta dough as well as the double chocolate chip dough. When the owner of Completely Cookie notified his client, he was told that all of the product was still in the grocery store chain's central storage freezers, so there was no problem to ship it back to Completely Cookie for proper disposal.

Unfortunately, that was not true, and the following week the owner of Completely Cookie was contacted by the FDA notifying him that they had a positive finding of *L. monocytogenes* in his raw cookie dough product when a state inspector tested product for sale in a grocery store in a nearby state. This finding resulted in a Class I Food Safety recall (see [Chapter 8](#)) and a shutdown of the Completely Cookie manufacturing plant for 10 weeks while the entire food processing area was renovated and all equipment was either cleaned and sanitized or replaced with new.

The cause of this recall was eventually attributed to a number of problems with the facility, product handling practices, faulty sanitation practices, and mistakes in decisions regarding the product shipment and testing. How could this situation have been avoided if Completely Cookie had implemented a Food Safety Plan using a hazard analysis and risk-based preventive controls?

If Completely Cookie had put together a more comprehensive Food Safety Plan, they might have considered more hazards of concern requiring more controls than just “metal detection.” Their first mistake was rushing to find vendors for new materials and taking delivery of those new ingredients without first determining if the new ingredients might have hazards that were not addressed by the current HACCP plan. A proper hazard assessment for all potential ingredients (see [Chapter 3](#)) and process/facility-related hazards (see [Chapter 4](#)) done prior to placing orders for the new items would have brought potential problems to light, and a hazard analysis (see [Chapter 5](#)) for the production of the final product in the facility would have identified all the hazards where preventive controls would be required.

For instance, Completely Cookie's owner would have become aware that raw cranberries sometimes carry *Salmonella* and could have specified to his purchasing agent that he only wanted to source cranberries that had been heat-treated and came with a Certificate of Analysis stating that they had been tested by a reputable microbiology lab and found free from *Salmonella* in each 25 g sample.

Unfortunately, the owner of Completely Cookie was NOT aware that the ricotta cheese he purchased for the product was made from raw milk or that the farm where it was produced had in the past been cited by their local health inspectors for unsanitary conditions. If Completely Cookie had done a more comprehensive background investigation of the ricotta cheese producer to verify that the hazard was under a preventive control, they would have found that this particular ricotta cheese was not pasteurized and had been recalled twice during previous years due to findings of *L. monocytogenes*.

The end result was a dried cranberry ingredient (that luckily did not have *Salmonella* in this case) blended into a ricotta cheese-based cookie dough that had low-level contamination with *L. monocytogenes*. Completely Cookie then increased the initial problem because they decided it was easier to dispense the dough (that was stiffer than other doughs they worked within the past) if it was left to sit at room temperature for “a while.” This period of time was not specified or recorded and may have been sufficient to allow contaminating *L. monocytogenes* to grow.

Because Completely Cookie failed to develop and follow a comprehensive Food Safety Plan with research of all the potential hazards coming in with the raw materials, they neglected to appreciate that the ingredients would not be going through a “bake-kill step” that was normal for their other RTE product lines. In this case, the low levels of contamination that came in with the raw ingredients needed to be tightly controlled during the handling of the product prior to packaging and low-temperature storage. The time periods when the dough was allowed to sit at room temperature allowed the low-level contamination to multiply extensively, which may have contributed to the positive *L. monocytogenes* results when samples were sent for testing.

If the company had done a better hazard analysis of the ingredients selected for the new items, they would have found a number of recalls in the past from ricotta cheese and other soft cheeses contaminated with *L. monocytogenes*. The new cookie dough product would NOT be fully cooked by Completely Cookie and thus would NOT go through a microbiological kill-step during their processing, therefore putting them into a category of “hazard likely to happen, not controlled in my process, must be controlled by my vendor” and thus requiring a **supply-chain preventive control** (see [Chapter 6](#)). Items in this category are only allowed to be purchased from a known vendor that complies with requirements for controlling the specified hazards, which in the case would have been “vegetative pathogens such as *L. monocytogenes* in the raw ingredients.” If Completely Cookie had conducted an on-site audit of the ricotta cheese facility they would likely have discovered the lack of good sanitation practices.

Another mistake made by Completely Cookie that likely contributed to the spread of the pathogen throughout their products was their failure to control the **sanitation of food contact surfaces** ([Chapter 6](#)). If they had implemented a comprehensive Food Safety Plan and included a section in their hazard analysis specifically looking at “sanitation” factors during the new product preparation process, they should have identified the potential for spread of pathogens on food contact surfaces (specifically the mixer and area where mixing and filling occurred). Because Completely Cookie normally sent all their products through a full “kill-step” by baking the cookie dough themselves, they had gotten away with some sloppy habits during the preparation steps. While making the two new types of raw cookie dough, the ingredients were mixed without wash-down or wipe-down of the food contact surfaces in between the two operations. Then, to make matters even worse, the dropped bits of cookie

dough sat on the tables in a very warm area of the bakery operation, sometimes for hours. This failure to wipe down or clean the tabletops between steps in the preparation of the finished product most likely led to the double chocolate cookie dough being cross-contaminated with raw materials from the cranberry and ricotta cheese cookie dough. The manager of the Completely Cookie decided it was a financial savings to produce the red-and-white cranberry and ricotta cookies first, then produce the double chocolate chip cookies on the same equipment and tables, due to the “color” of the dough. The bits of red-and-white dough left on equipment was not a “visual color” problem when mixed with the darker brown chocolate cookie dough, whereas it would have caused a visible problem to make the red-and-white cookies on the same equipment after the double chocolate chip dough was produced, unless there was a full clean-up between products. (Note here that an additional problem overlooked by Completely Cookie at this point could have been a cross-contact issue if different allergens were in the two types of cookie dough.)

An additional item that Completely Cookie failed to take into consideration that should have been addressed if they had implemented a comprehensive Food Safety Plan including a thorough hazard analysis was the sanitary condition of employee hands, gloves, and uniforms along with separation of raw operations from finished (baked) operations (see [Chapter 4](#)). As noted in the introduction of this example, Completely Cookie production employees entered the facility wearing street clothes and street shoes and worked the entire day in the same clothes and footwear, despite the fact that the same employees moved from areas of raw material preparation in the morning to handling of finished product later in the day. An observation of the employees identified that they had obvious smears of the new ingredients (pinkish ricotta cheese) on their clothing from early in the morning until later in the day when they worked to fill the finished products. This may have contributed to the spread of pathogens from the raw materials to employee clothing to the finished raw dough product.

Observation of the employees during the FDA investigation of the recall indicated that most employees wore gloves, but gloves were not changed and hands were not washed when handling the plastic tubs that had been stacked on the floors. It was also observed that employees did not consistently wear gloves when putting lids on the plastic tubs of raw dough. When questioned as to why they were not wearing gloves, they explained that the gloves sometimes became caught when trying to snap on the lids, so it was just easier and “cleaner” to not wear gloves. The company owner allowed this practice because he and the HACCP team reasoned that “the risk was low” for those employees to contaminate the product. A more in-depth look at prerequisite programs such as employee hygiene and sanitary handling of finished products from the perspective of a **preventive controls qualified individual (PCQI)** ([Chapter 2](#)) might have noted that employees sometimes touched the inside of the container lid (which could touch the raw dough within the plastic tubs) with a bare hand. A trained PCQI might have reasoned that all employees handling the finished product should be wearing clean disposable gloves.

Another failure of Completely Cookie's management, in this particular case, was not conducting a proper hazard analysis and planning the lay-out of operations in a sanitary manner before the new items were introduced to the processing floor. They rushed to fill a customer request without proper planning, which allowed far too much crossing back and forth of the dough back to the prep tables rather than following a more sanitary arrangement as was done for the fully baked cookies.

The management's logic was faulty in assuming that they did not have to worry about "sanitation" because the finished products were going to be baked by the end user. The stance that the FDA has taken is that certain pathogens such as *L. monocytogenes* are not allowed to exist in food products in the marketplace, regardless of whether they are being sold as "ready-to-eat" or "ready-to-bake." In this particular example, Completely Cookie expected that the consumer would completely bake the dough before eating it, as per cooking instructions printed on the package. However, some consumers may have eaten the dough raw, and others likely would NOT have taken the entire product up to a temperature high enough to kill the fairly high levels of *L. monocytogenes* present in the new items produced by Completely Cookie. If the regulatory inspection had not tested and found the pathogen in these items and stopped their production, it is possible that consumers would have been made ill or possibly even died from listeriosis.

After the FDA learned of the *L. monocytogenes* in the product and started their investigation, they found the pathogen was also harbored in cracks in the floors of the processing plant. The FDA strongly suggested that Completely Cookie repair and resurface the floors of the entire production facility before they were allowed to resume operations. The FDA investigation team also found *L. monocytogenes* to be harboring in cracks in the walls of the facility, which "sweat" water down the inside of the walls due to the temperature differential between inside and outside of the facility. Completely Cookie also needed to fix the walls. They chose to have the large cracks in the mortar of the brick walls repaired with concrete. All of the wall surfaces were then coated with the same polyurethane-type coating that they had applied to the newly repaired concrete floors to make them "impermeable surfaces" and better able to maintain a "sanitary condition" in the future.

Completely Cookie Inc. also hired a professional contract sanitation company to help train their sanitation employees during the period when the facility was shut down. On review of their "normal" cleaning practices, the sanitation contractor immediately identified some problems that were contributing to the proliferation of *L. monocytogenes* within the facility. The day-time employees dropped food materials and various types of debris onto the floors during the day and just left it there for the sanitation crew to remove. The sanitation crew only half-way picked up the large debris before bringing out the hoses and starting the wash-down activity. This behavior was mirrored in the USDA production area, where the kettles were not completely scraped clean before water was added and then dumped to the floors while still containing chunks of cooked chicken, gravy, and vegetables. The drains would quickly clog

from the solid materials. Backed up water from the drain pits would at times cover the floor of the entire production area, and the sanitation employees would slosh around in the water up to 6 in. deep as they cleaned the equipment and hosed down the walls. The last thing the sanitation employees did before leaving for the night was to pull up the drain baskets and remove solid material, leaving the water to slowly drain down through the mostly clogged pipes during the remainder of the third shift.

The sanitation contractor immediately identified that this flooding of all the production floors every evening was contributing to the spread of *L. monocytogenes* (and likely other pathogens) that harbored in the drain pits up onto all of the floors and undersides of all the production equipment. Leaving the standing water to drain after they left meant that those heavily contaminated floors were NOT rinsed with clean water or sanitized after the dirty water receded. Instead, they were left with *L. monocytogenes* sitting there in the puddles and underneath equipment and down in the drain pits to grow to even higher levels.

So again, if Completely Cookie had implemented a comprehensive Food Safety Plan and performed a good hazard analysis with specific consideration given to their sanitation programs and training of the sanitation employees, many of the problems that existed there would have been identified and corrected earlier.

Finally, the owner of Completely Cookie was questioned about how the FDA investigators were finding such high levels of contamination with *L. monocytogenes* existing throughout his facility when he claimed to have an environmental monitoring program (see [Chapter 9](#)) in place. His reply was that he had never found *L. monocytogenes* with any of the environmental swabs collected. A review of his environmental testing results found that “*Listeria* species” positive results were being reported every month; however, when the lab went on to type the species, *L. monocytogenes* was not identified. The company owner did not investigate further into sanitation activities or take any sort of “corrective actions” in regards to sanitation because “no pathogen was found.” This is a common problem in the food processing industry, especially in the small-to-medium sized companies that do not have a microbiologist on-staff and where none of the company personnel have sufficient training in the area of microbiology. If the owner of Completely Cookie had been more knowledgeable in the area of food microbiology, he would have understood that regular findings of “*Listeria* species” in the environment were an indication that his sanitation activities were not effective in preventing the conditions that could allow *L. monocytogenes* to survive in that environment. It would just be a matter of time before the pathogenic strain found its way into that environment along with all of the nonpathogenic cousins. A proper environmental monitoring program ([Chapter 9](#)) with defined corrective actions performed would have significantly reduced final product contamination, as the *Listeria* species would have been targeted for elimination and sanitation verified.

Donna F. Schaffner, M.S.

Authors' Note

In this case study, the cost to Completely Cookie Inc. of a recall (cost of obtaining all recalled product still in distribution, lost product sales, additional changes to facilities, new training requirements, change in labor, change in contract cleaning program, change in suppliers, harm to brand reputation in the marketplace, etc.) would likely have been prevented if the company had implemented a hazard analysis and risk-based preventive control process via a defined Food Safety Plan, even without a mandate by FDA to use this effective food safety management tool. If the products had caused a foodborne illness or outbreak of disease, the cost to the company would have been even higher. If a person had died from listeriosis after eating the product, the company would likely go out of business or require significant additional capital to recover the business (likely with much lower sales potential).

The cost to implement a hazard analysis and risk-based preventive control process via a defined Food Safety Plan in a food manufacturing business is less than the cost of even one recall, and these costs are certainly lower than all the other additional costs after a product causes a foodborne illness. Most importantly, it is the right thing to do to assure safety for consumers.

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Appendix D: Supplier Approval Checklist for Retail Businesses

- ☐ FDA compliance history (FDA warning letters, past FDA audit results) for the facility
 - ☐ All FDA Form 483s
 - ☐ Last FDA inspection results specific to your product type
 - ☐ Letter of Guarantee to meet all local, state, and federal laws under Code of Federal Regulations (CFR), Food Safety Modernization Act (FSMA), and the United States Federal Food, Drug, and Cosmetics (FD&C) Act
- ☐ Global Food Safety Initiative (GFSI) certificate
 - ☐ Copy of most recent audit based on food products produced in the facility (as prerequisite for capabilities in safe food production)
 - ☐ Full report with list of noncompliances and corrective actions taken
- ☐ Facility design diagram noting the following:
 - ☐ Flow of foods (receiving, storage, processing, packaging, shipping)
 - ☐ Identification of food processing zones (e.g., hygienic zone and food contact zone 1 for ready-to-eat (RTE) food processing)
 - ☐ Methods used to ensure proper hygienic zone use in the facility
- ☐ Facility information
 - ☐ All ingredients received and used in the facility that could contribute to facility- and process-related hazards for your product
 - ☐ Ingredients received and used in the facility that contain one of the major food allergens
 - ☐ Employee training on processing foods
 - ☐ Existing hazard analysis and critical control point (HACCP) plans for similar products
 - ☐ Cleaning and sanitation plans
 - ☐ Environmental monitoring plans
 - ☐ Pest management processes
 - ☐ Nonemployee/contractor management during work in the facility
 - ☐ Facility/equipment preventive maintenance program
 - ☐ Contact information for each facility QA/food safety manager

- ☐ Food Safety Plan (developed according to FSMA rules) for each product that will be made for you including the following:
 - ☐ The hazard analysis and risk-based preventive controls that have been identified
 - ☐ The name and contact information of the designated preventive controls qualified individual (PCQI(s)) who developed the plan
 - ☐ Supplier identifications for all ingredients used in your products and a list of any supply-chain preventive controls in place
 - ☐ The recall plan (and your company's contact information listed in the plan if they are currently your supplier), including the program that will be used to trace back all product lots
 - ☐ Validation, monitoring, and verification records
- ☐ Supplier management program
 - ☐ Suppliers audits and certificate of analysis (CoA) verifications
 - ☐ Ingredient country of origin information
 - ☐ Foreign supplier program
- ☐ Final product specifications for your products that will be made there
 - ☐ Testing performed after routine finished product runs (per lot/batch), including any microbiological and sensory testing
 - ☐ Final product specifications (pH, a_w , microbiological, shelf-life, and storage requirements)
 - ☐ Current label including all ingredients, allergens declared, nutritional data, and product storage and use requirements (RTE, store refrigerated, best-by-date on opening, etc.)
- ☐ Logistics plan
 - ☐ Distribution logistics (routes, warehouse staging/storage locations) for all out-bound product shipments
 - ☐ Storage and shelf-life protection before retail receiving (e.g., where will the products be and how will they be stored to protect temperature requirements especially, if temperature control is a preventive control in the Food Safety Plan)
 - ☐ Transportation program (sanitation) with in-bound and out-bound inspection process/records
- ☐ Facility visit during product production to do the following:
 - ☐ Verify flow of food and zone identification use in the facility during production
 - ☐ Observe Food Safety Plan in action (preventive controls) during production
- ☐ Process for your company to routinely receive data from preventive controls monitoring/verification and corrective actions
 - ☐ Information from each product run
 - ☐ Environmental sampling data performed in the facility relative to products being made (including microbial and/or allergen testing results)
- ☐ Process for holding retained samples of lot/batch product runs if required per best-by-date/expiration date of product

Glossary

AFIA American Feed Industry Association
 a_w Water activity (the water in food that is not bound to food molecules and can support growth of microbes)
BSE Bovine spongiform encephalopathy
BT Bioterrorism
CAST Council for Agricultural Science and Technology
CCP Critical control point
CDC Centers for Disease Control and Prevention
CFIA Canadian Food Inspection Agency
CFR Code of Federal Regulations
cGMP Current Good Manufacturing Practice
CIP Clean-in-place
CoA Certificate of analysis
COP Clean-out-of-place
CPG Compliance Policy Guide
EFSA European Food Safety Authority
EMP Environmental monitoring plan
EPA Environmental Protection Agency
FALCPA Food Allergen Labeling and Consumer Protection Act of 2004
FAQs Frequently asked questions
FCS Food contact surface
FD&C Act United States Federal Food, Drug, and Cosmetics Act
FDA United States Food and Drug Administration
FMEA Failure modes and effects analysis
FOOD Foodborne Outbreak Online Database
FRI Food Research Institute at the University of Wisconsin–Madison
FSIS Food Safety and Inspection Service
FSMA Food Safety Modernization Act
FSP Food Safety Plan
FSPCA Food Safety Preventive Controls Alliance
FSVP Foreign Supplier Verification Program
GFSI Global Food Safety Initiative
GMA Grocery Manufacturers Association
HACCP Hazard analysis and critical control point
HRF High-risk food
HVAC Heating, ventilation, and air conditioning
ISO International Organization for Standardization
LS *Listeria* species
MCL Maximum contaminant level
NACMCF National Advisory Committee on Microbiological Criteria for Foods
NASA National Aeronautics and Space Administration

NFCS	Nonfood contact surface
NLM	National Library of Medicine
OAI	Official Action Indicated
OTA	Ochratoxin A
PAL	Precautionary advisory labeling
PCB	Polychlorinated biphenyls
PCHF	Preventive Controls for Human Foods
pCi/L	Picocuries per liter
PCQI	Preventive controls qualified individual
PFGE	Pulsed field gel electrophoresis
ppm	Parts per million
QA	Quality assurance
QSR	Quick service restaurant
Ra	Radium
RFR	Reportable Food Registry
RTE	Ready-to-eat
SOP	Standard operating procedure
spp.	Species
SQF	Safe Quality Food Institute
STEC	Shiga toxin–producing <i>Escherichia coli</i>
TAN	Technical Assistance Network
US	United States
USC	United States Code
USDA	United States Department of Agriculture
VAI	Voluntary Action Indicated
WGS	Whole genome sequencing

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Zones 1–4 testing. *See* Environ-
mental pathogens and
monitoring

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Hazard Analysis and Risk-Based Preventive Controls

Improving Food Safety in Human Food Manufacturing for Food Businesses

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Hazard Analysis and Risk-Based Preventive Controls: Improving Food Safety Risk in Human Food Manufacturing for Food Businesses is a comprehensive, first-of-its-kind resource for the retail food industry on the Hazard Analysis and Risk-Based Preventive Controls for Human Foods (PCHF) regulations of the US Food Safety Modernization Act (FSMA). This book covers all aspects of PCHF, including the legislation's intent, applications to ensure safe food production, and resources to keep up-to-date on new food safety hazards and regulatory guidance. Written for food safety professionals and food business leaders, its emphasis on what the retail food industry needs to know about PCHF makes it an indispensable resource for organizations buying food from companies required to demonstrate PCHF compliance.

PCHF implementation is (or soon will be) required for human food companies along the supply chain in the United States, as well as all food companies that import ingredients and products for human consumption into the United States.

Key Features

- Explains what retail food industry professionals need to know about PCHF, and how they can leverage PCHF when working with suppliers
- Provides the most current "how to" information on implementing PCHF to prepare for new Food and Drug Administration (FDA) regulations in the food industry
- Identifies the right resources to perform hazard analysis and develop effective preventive controls
- Demonstrates step-by-step examples for continuous improvement in sustaining PCHF responsibilities and in keeping abreast of new food safety information

About the Authors

Dr. Hal King has an extensive background in the food safety management of supply chain, distribution, and restaurant operations. Dr. King now focuses on the design and development of food safety management systems and on the innovation of new food safety services and products that will help the food industry implement best-in-class food safety programs in their business.

Dr. Wendy Bedale has worked in a variety of scientific, clinical, regulatory, and project management roles in the pharmaceutical, medical device, and biotechnology industries before taking a position that fulfilled two of her passions (scientific writing and food) as part of the Food Research Institute (FRI) at the University of Wisconsin–Madison. Since then, she has written about many aspects of food safety for a variety of audiences.



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