Handbook for Safe Processing of Nuts

4th Edition

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PTNPA

PEANUT AND TREE NUT PROCESSORS ASSOCIATION

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The Peanut and Tree Nut Processors Association (PTNPA) would like to acknowledge the 2022 Handbook Task Force and their affiliations at the time when the latest update was based. These industry professionals graciously volunteered countless hours to provide thoughtful, thorough, complex, informed and technically complicated contributions to this Handbook. They have provided the food industry and other interested parties with the latest industry insights, practices and information. Special thanks go to all Handbook Section Leads for guiding their various topic area development and with additional acknowledgement and thanks to Yvonne Masters/John B. Sanfilippo and Son, Erin Clem/Diamond Foods and Wendy Maduff/The Wonderful Company for their leadership and dedication to the completion of this Handbook. Future editions and versions of the Handbook will likely be updated, developed and distributed incrementally in a matter of months vs. years to keep industry as up to date as possible. (More details are provided in Appendix A)

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EXECUTIVE SUMMARY and BACKGROUND

Background: Foodborne illness due to *Salmonella* contamination of low-moisture foods including nuts is a constant concern for the food industry.

On a global level, outbreaks associated with low-moisture products including nuts have been documented in the last several decades. Foods implicated in these outbreaks have included chocolate, infant cereals, milk powder, powdered infant formula, peanut butter and other peanut-containing products, snacks, raw almonds, pistachios, and toasted oats cereal. In May 2007, the Grocery Manufacturers Association (GMA; now Consumer Brands Association, or Consumer Brands) formed a *Salmonella* Control Task Force, which developed a guidance document for the control of *Salmonella* when manufacturing low-moisture foods (GMA 2009). The guidance was applicable to various low-moisture foods products.

To specifically assist the nut industry, GMA launched a second initiative in April 2009, targeted at building upon the *Salmonella* guidance for low-moisture foods and developing a comprehensive handbook for peanut and tree nut shellers, hullers, processors and manufacturers. As the Food Safety Modernization Act (FSMA) Preventive Controls for Human Foods Rule (Preventive Controls rule) was taking shape, GMA decided to update the handbook to reflect current knowledge and the new regulations and collaborated with the Peanut and Tree Nut Processors Association (PTNPA). The comprehensive manual, *Industry Handbook for Safe Processing of Nuts* (Handbook), included nine chapters. It also included 17 appendices and three addenda: *Industry Handbook for the Safe Shelling of Peanuts* (also updated in 2015), *Good Agricultural Practices for California Pistachio Growers*, and *Good Agricultural Practices for Almond Growers.*

In 2019, following several years of implementing the FSMA, the Peanut and Tree Nut Processors Association (PTNPA) and Consumer Brands (CBA; formerly Grocery Manufacturers Association/GMA) agreed that it would be appropriate to update the Industry Handbook to reflect the many guidance documents, protocols and procedures, which the industry has implemented since the publishing of the 2016 edition of this handbook. Several topics and sections were added to the 3rd Edition to account for the new issues highlighted and clarified due to the introduction and implementation of FSMA. This was an opportunity for the industry to provide clarity and the best food safety practices and knowledge possible as of August 2020, released by the Peanut and Tree Nut Processors Association in December. Again, with changing regulatory priorities, interests and concerns, the Peanut and Tree Nut Processors Association determined that an updated 4th Edition would be appropriate for release in October 2022. The latest Edition includes updates to the Food Fraud Section as well as NEW Sections on the subject areas of Culture of Food Safety and Traceability in response to the pillars identified by the FDA in the New Era of Smarter Food Safety.

Each chapter in the Handbook is divided into a number of sections, providing detailed guidance in topics covering management responsibility, Food Safety Plans (FSPs), process validation, segregated hygiene area assessment and environmental monitoring, allergen control, other controls including prerequisite programs and principles of equipment design. This edition now includes sections on Culture of Food Safety and Traceability now regularly discussed and better understood.

Management Responsibility and Increased Access and Communication

Each company processing nuts in the United States should establish, document and maintain a Food Safety Management System as a means of assuring that all materials conform to recommendations in this Handbook and applicable regulatory requirements. Authorities and accountabilities for food safety should be clearly defined and communicated. Management reviews of the food safety system should be conducted at a defined frequency. Every organization should have documented procedures and designated, trained personnel in place for managing food regulatory agency inspections and contacts. Communication in the supply-chain is critical when events occur that could impact food safety and companies should notify their affected customer base in a timely manner. And, in the era of company-wide food safety, all food safety topics, educational materials and associated plans should be widely distributed, utilized and provided to all company personnel regardless of position in the company.

Food Safety Plan (FSP)

The finalization of the Preventive Controls rules necessitates a shift from the commonly used Hazard Analysis and Critical Control Point (HACCP) system to an (FSP) that contains the elements required by U.S. Food and Drug Administration (FDA). The FSP encompasses the seven HACCP principles that should be applied as appropriate to address potential biological, chemical and physical hazards associated with peanuts and tree nuts. The seven principles include the following:

1. Conduct a hazard analysis
2. Determine the Critical Control Points (CCPs)
3. Establish critical limits
4. Establish monitoring procedures
5. Establish corrective actions
6. Establish verification procedures
7. Establish record-keeping and documentation procedures

The FSP expands upon HACCP by recognizing that, based on the hazard analysis, a risk may be best mitigated by a control, such as a supply-chain program, allergen control, or sanitation control.

Thus, the FSP elevates the status of programs that may formally have been considered prerequisite programs if those programs are necessary to control hazards identified in the FSP. The line between prerequisite programs and preventive controls becomes blurred in the new regulatory environment, and this guide seeks to provide clarity around the decision-making process.

A cross-functional team comprised of quality assurance, operations, and technical specialists familiar with food safety and the manufacturing operation should be formed to develop a Food Safety Plan (FSP). The plan must be developed, or the development must be overseen, by the Preventive Controls Qualified Individual (PCQI), which is described.

The guidelines described in this section are intended to help create common criteria for assessing hazards and identifying CCPs and other preventive controls across shelling and hulling, processing, handling, or manufacturing to assure the safety of nuts (including peanuts and tree nuts) and nut products.

Process Validation

Processors use various technologies to process tree nuts and peanuts including oil roasting, dry roasting, blanching, propylene oxide (PPO) and ethylene oxide (ETO) (approved for certain nuts), steam pasteurization, hot water pasteurization, and combinations of these. Associated with each process and production facility are minimum requirements that must be maintained to ensure product safety.

Processors should defer to legal requirements for the appropriate log reduction for *Salmonella* (if such requirements exist) or should determine the appropriate log reduction for *Salmonella* by scientific studies. To be effective, the process must consistently deliver a minimum degree of lethality that is appropriate for the target organism, typically

Experiments should be conducted to validate the log kill in each piece of equipment for each nut type. Two types of validation studies exist: 1. An inoculation challenge study of the process with the appropriate *Salmonella* strains or an appropriate surrogate organism, and
2. measurement of the physical delivery of the process in operation.

This section provides guidelines and examples for minimum elements of a validation study, including description of the process, data collection, validation guidelines, lethality computation, study report requirements, and scientific basis. Included is a critical factors worksheet in which to capture information related to validation shellers/hullers providing raw nuts as a non-ready-to-eat (non-RTE) ingredient may not have a CCP to eliminate *Salmonella* in their process.

However, if companies are FDA-registered facilities, they will still need to develop a FSP, identify and evaluate hazards and have prerequisite programs and/or preventive controls in place to prevent *Salmonella* growth and minimize contamination, based on the outcome of the hazard evaluation.

Allergen Management

All facilities should have an effective program in place to evaluate, identify and control food allergens to assure that specific allergens are not inadvertently incorporated as an undeclared component of any product. The likelihood of the presence of undeclared allergens should be part of a hazard analysis. Depending on the hazard evaluation, a facility may manage allergens as a preventive control or

as part of prerequisite programs. A robust, thorough and comprehensive allergen management program has three main components: avoiding allergens, having allergen controls to minimize the potential for inadvertent cross- contact by undeclared allergens, and label controls.

Nut processors should have an allergen control program to ensure no allergens are in a specific finished product other than those declared on the label. Additionally, processors should have controls to ensure allergens contained in ancillary ingredients are managed to prevent cross-contact with products that do not declare these allergens on their labels.
Various individual programs, when brought together, make up an allergen control program. These programs represent a variety of ways to help manage allergens and reduce risk to the product and consumers.

Minimizing cross-contact during product changeover from an allergen-containing product to one containing a different allergen profile is dependent on effective sanitation practices to deliver a safe and properly labeled consumer product. Effective sanitation practices are

important in preventing cross-contact issues. Cleaning methods should take into consideration the form and amount of the target allergen, the equipment, the plant structure and other risks. Sanitation can be accomplished either by wet cleaning, dry cleaning, flushing, or a combination of methods.

Supply-chain Programs

In recognition of the complexity of the supply-chain and the execution of preventive controls at varying points in the supply-chain, the FDA introduced the concept of a supply-chain program serving as a preventive control. If a facility receives an ingredient from a supplier that has controlled a hazard (e.g., the supplier roasted nuts to reduce or significantly minimize the presence of *Salmonella*) and the receiving facility will use those nuts without the application of additional controls (e.g., in a confection, snack bar, cereal), then the FSP will likely recognize the need for a supply-chain program.

The identification of a supply-chain program as a preventive control prompts numerous responsibilities, including consideration of specific criteria to evaluate and approve the supplier and the selection of one or more verification tools to ensure the supplier is adequately controlling the hazard.

Like other preventive controls, corrective actions are required if the program reveals that the hazards are not being controlled as expected.

Other Preventive Controls Including Prerequisite Programs

Prerequisite programs can be utilized and fully functioning for a food safety system to perform effectively. The Handbook includes a list of key prerequisite programs, besides the preventive controls described in the sections above, which should be considered for peanut and tree nut operations. These prerequisite programs provide operating conditions conducive to the implementation of a FSP. They are

intended to keep low-risk potential hazards from becoming serious enough to adversely impact the safety of the product.

Shellers, hullers, processors and manufacturers of different nut commodities may have different processes and unique features in their operations. However, they have similar concerns regarding such topics as facility design, personnel practices, sanitation, pest control, control of extraneous matter and training issues.

The Handbook provides detailed guidelines to address these topics as well as other programs, including maintenance controls, raw material and product controls, corrective and preventive actions and laboratory operations. Even though not all aspects for every topic are applicable to all segments of the nut industry, each operation may evaluate the recommendations in this section and use them in a manner where they can choose those aspects that will best serve their individual operations.

Collectively, well-functioning prerequisite programs provide a broad and firm foundation to help ensure hygienic practices throughout a facility.

Environmental Monitoring and Segregated Hygiene Area Assessment

As the scientific understanding of *Salmonella* in dry environments has improved and as investigations of outbreaks and recalls have documented, post-process contamination of nuts and nut products is a valid concern in many instances. The Preventive Controls rule requires that facilities consider the potential for post-process contamination in ready-to-eat (RTE) foods that have some exposure to the environment after processing. This includes many nuts and nut products.

A hygiene area risk assessment is done to determine risk and necessary control measures to prevent or minimize the spread of contamination from raw areas and other potential sources to process areas located after the lethality step. The processor should identify and segregate areas within the facility based on an assessment of where products, traffic (including personnel and equipment), or the environment could be a potential source of microbial contamination. The Primary Pathogen Control Area (PPCA) in a nut handling facility is the area where handling of ingredients and product requires the highest level of hygiene control. Various control measures should be implemented to minimize or prevent PPCA cross contamination, which may include structural separation and other barriers, optimized traffic patterns, adequate filtration of the air handling system and effective (dry) sanitation. Evaluate and verify segregated area programs periodically to assure effectiveness and compliance to hygiene requirements.

A comprehensive Pathogen Environmental Monitoring Program (PEMP) is designed to verify the effectiveness of pathogen control programs (e.g.,*Salmonella, Listeria monocytogenes*). Routine environmental monitoring for *Salmonella* and *Listeria* spp. Is conducted on non- product contact surfaces, with samples taken primarily in the PPCA under normal operating conditions. Testing of product contact surfaces may be done under certain circumstances, such as commissioning of new equipment upon installation and as part of corrective actions for an environmental positive. Pathogen monitoring sites are categorized into four sampling zones based

on proximity to process equipment. Risk levels inherent to the product and process determine the sampling frequency and locations within a facility. An official or validated method should be used for testing. This section provides detailed guidelines for sampling procedures and methods consistent with standard industry practices and provides examples of corrective action procedures in response to positive pathogens findings in the plant environment.

Principles of Equipment Design and Installation

To ensure adequate cleaning and sanitizing, equipment used for nut processing should meet basic sanitary design principles. This section provides guidance on 10 principles of sanitary equipment design and installation for low-moisture foods, including peanuts and tree nuts.
Equipment should be constructed to be cleanable, including the use of materials compatible with the product, the facility environment and sanitation methods. All parts of the equipment should be readily accessible. There should be no stagnant product or liquid build-ups. Hollow areas of equipment should be avoided or permanently sealed. All parts of equipment should be free of niches.

During normal operations, the equipment should perform so it does not contribute to unsanitary conditions or the harborage of bacteria. Human and machine interfaces should be designed to ensure product and other residues do not penetrate or accumulate in or on the enclosures or interfaces. Equipment design should ensure hygienic compatibility with other equipment and factory systems. Equipment for raw and processed products should be separated wherever possible. Equipment and personnel at installation should meet hygiene and sanitation requirements.

Food Defense

The handbook includes a chapter on Food Defense. In May 2016, the FDA finalized a rule aimed at preventing the intentional adulteration of foods. Companies with more than $10M annual sales have needed to comply with this rule and have developed and implemented a Food Defense Plan beginning in May 2019.

Given this rule is now in place, the Food Defense chapter incorporates guidelines from regulatory agencies such as FDA, USDA, FSIS, AMS, and Global Standards (i.e.,GFSI). Some of the elements covered in this chapter are:

- Inside Security
- Outside Security
- Processing Security
- Utilities Security
- Shipping and Receiving
- Personnel Security, etc.

The goal of this chapter is to assist the industry to create a robust Food Defense Plan by also adding required elements in the FDA FSMA final rule on Mitigation Strategies to Protect Food Against International Adulteration. Some of the key components required under this rule are:

- Vulnerability Assessment
- Mitigation Strategies

- Monitoring Procedures
- Corrective Action
- Verification
- Training

UPDATED: Food Fraud Prevention

The topics of food fraud prevention is of increasing interest and concern, with today's complex global supply-chain realities, wide-spread and sophisticated fraud act, and global economic pressures and geopolitical complexities. The Handbook section on food fraud prevention has been updated to further assist companies in establishing best practices for the nut industry based on current day considerations.

It is important to note that over time, the intentional adulteration term has evolved to primarily refer to Food Defense.

In this section of the manual, we will attempt to clarify the different ways the term is used.

- Food fraud – including the sub-category of economically motivated adulteration (EMA) – is intentional deception for economic gain using food including ingredients through finished goods.

- Food Authenticity, citing the Elliott Review "is about ensuring that food offered for sale or sold is of the nature, substance and quality expected by the purchaser."

- Food Integrity, citing the Elliott Review "can be seen as ensuring that food which is offered for sale or sold is not only safe and of the nature, substance and quality expected by the purchaser but also captures other aspects of food production, such as the way it has been sourced, procured and distributed and being honest about those elements to consumers."
- Intentional Adulteration – especially when referring to FDA related compliance such as to the FSMA Intentional Adulteration rule (FSMA-IA)– applies to intentional acts with the intent to harm or Food Defense.
- Economically motivated adulteration -- especially when referring to FDA related compliance such as to the FSMA Preventive Controls rule (FSMA-PC) and FDA's working definition – is a "substance" added or excluded "for economic gain" that has a "health hazard." EMA is a sub-category of food fraud.

Fortunately, there are many interdisciplinary resources that provide insight, guidance and methods to conduct incident reviews, vulnerability assessments, prevention strategies, and management systems.

NEW: Culture of Food Safety

Food Safety Culture is a new initiative undertaken by the Global Food Safety Initiative (GFSI) and the Food and Drug Administration as part of the FDA New Era of Smarter Food Safety. Facilities that have a strong Food Safety Culture is one where food safety and quality are a shared responsibility between all employees and is not deemed just a function of one department. These facilities have

empowered and encouraged employees to act when they see any deficiencies and have a management team that supports addressing concerns or potential issues as they arise. Company plans and practices are individualized, authentic and customized. While the FDA does not yet have specific metrics or measurements to "regulate" a Culture of Food Safety, the evidence of programs, training, participation, meetings and a commitment to food safety is demonstrated in various ways as outlined in the Handbook.

NEW: Traceability

Traceability is an essential component of every Food Safety Plan (FSP). An effective traceability system enables manufacturers to quickly locate and recall/withdraw unsafe food from market before consumption by consumers. This system is necessary for regulatory compliance and ensures food safety and quality assurance of food. Historically, food manufacturers were only expected to trace product one step forward and one step back; this practice is no longer acceptable. Major recalls in the years leading up the Food Safety Modernization Act (FSMA) led to requirements for more effective traceability of food products.

Currently the Food and Drug Administration (FDA) includes food traceability as one of four key components that make up the New Era of Smarter Food Safety Blueprint which falls under the FSMA. Under the proposed rule, FDA defines food traceability as "…the ability to follow the movement of a food product and its ingredients through all steps in the supply chain, both backward and forward. Traceability involves documenting and linking the production, processing, and distribution chain of food products and ingredients."

Handbook Summary

This Handbook has been designed as a comprehensive resource of current guidance material for the nut industry to utilize in developing stronger food safety measures and programs relevant to its sector of the business. A cross-section of the nut growing, shelling and processing industry has been involved in development of the Handbook, which promotes understanding of the role of each segment plays in nut safety.

This Handbook is an evolving document and, therefore, can only benefit from further comment and input from shellers, hullers, processors, manufacturers and other interested stakeholders who use it as an operational resource, onboarding and training tool – and countless other applications.

The 4th Edition of the Handbook reflects the most current regulations, common practices and industry insights as of October 2022.

Chapter 1

INTRODUCTION

Today's nut industry increasingly relies on a robust network of inter-company relationships. Successful implementation of preventive Food Safety Plans (FSPs) and supporting prerequisite programs are required at shellers, processors and manufacturers to ensure effective food safety management. Preventing the production and shipment of contaminated or adulterated food is heavily favored over reliance on interventions once contaminated goods have entered distribution channels and, subsequently, the food supply.

1.1 Background

To aid the nut industry in the development of a preventive food safety scheme, in 2009, the Grocery Manufacturers Association (GMA; now the Consumer Brands Association), the American Peanut Council (APC), the Peanut and Tree Nut Processors Association (PTNPA), the American Food Safety Council, the American Peanut Shellers Association, the National Pecan Shellers Association, the Administrative Committee for Pistachios, the California Pistachio Research Board, the Western Pistachio Association, the California Walnut Board and the Almond Board of California (ABC) developed the *Industry Handbook for Safe Processing of Nuts,* and the addenda or references: *Industry Handbook for the Safe Shelling of Peanuts*, *Good Agricultural Practices for California Pistachio Growers* and *Good Agricultural Practices for Almond Growers.*

In 2016, the GMA and the PTNPA, supported by other industry associations, updated the *Industry Handbook for Safe Processing of Nuts.* The American Peanut Shellers Association updated the addenda, *Industry Handbook for the Safe Shelling of Peanuts*. These reference manuals represent a "tool chest" for nut industry members seeking successful food safety practices.

The Peanut and Tree Nut Processors Association (PTNPA) and Consumer Brands Association (CBA) convened industry again in 2019 to develop the 2020 version of the Handbook. This version now includes topics related to current food safety requirements along with issues of importance and relevance to the Nut Industry which has resulted in several new Sections in the 2020 Handbook. Once again, this Handbook should be considered guidance for nut processors to develop their Food Safety Plans (FSP), and other similar programs and best practices, which will enable safe processing of nuts. It is intended to have broad application for nut processing, including peanuts and tree nuts. Depending on a risk evaluation of the nut product and process, all or selected sections in this guidance may be applied.

Nothing in this document should be construed as limiting the ability of a processor to implement more stringent practices or requirements for its suppliers.

The term “processor” refers to a processor, manufacturer and handler. The term “customer” refers to one who buys product from a processor to distribute and sell for further processing or consumption. The term “sheller” is used in the peanut and pecan industries to denote the entity that removes the hard outer shell from the peanut or pecan. Peanut shellers clean, shell and sort peanuts, generally for further processing by manufacturers; pecan shellers clean, size, pasteurize, shell, sort and grade pecans prior to packaging.

The term “huller/sheller” is used by the almond industry to denote the entity that removes the outer hull and, possibly, outer hard shell and provides almond kernels (meats) to almond handlers or processors. The huller/sheller can be part of the handler operation or may deliver almonds to a handler. The handler cleans, grades, sorts, packs into cartons and fiber bins, and sells to processors and manufacturers. The almond handler may also pasteurize nuts and package them for direct sale to customers. “Huller/dehydrator” is the term used by the walnut industry to denote the entity that removes the hull and dries the walnuts to a stable moisture level. The walnut handler then cracks the shell and removes the hard outer shell before sorting and packing. The pistachio industry uses the term “processor” for those who remove the hull, dry in the shell, sort, shell and package pistachios.

For the purpose of this Industry Handbook, the term “nuts” refers to peanuts and tree nuts. However, each nut commodity may choose to edit the nomenclature of this Handbook to make it consistent with the language commonly used within that industry segment. For example, “sheller”, used in the peanut and pecan industries may be most equivalent to a “huller/sheller” in the almond, pistachio and walnut industries. The term “handler” may be substituted for processor in some cases.

Furthermore, each nut commodity or industry segment may evaluate the recommendations in this Handbook and tailor its FSP to its unique operations. All aspects of the guidance document may not apply to each type of operation. For example, the scope of a shelling operation differs from that of a retail product manufacturing operation. The food safety team in each company should be responsible when applying relevant aspects of the Handbook.

1.2 Scope

The Handbook was developed for shellers, processors, and manufacturers in the United States. The addendum, *Industry Handbook for the Safe Shelling of Peanuts*, was developed for peanut shellers in the United States and references food safety guidelines for peanut shellers as well as current Good Manufacturing Practice (cGMP) guidelines for peanut buying points and Good Agricultural Practices (GAPs) guidelines for growers and farmer stock warehouses. These practices could be applied internationally, but the focus of this information resource is on meeting U.S. regulatory requirements. Industry members may want to consider the food safety programs referenced in this document as the foundation for a successful system designed to minimize the potential for product adulteration and contamination.

The impetus for the update is the recognition that many nut processing facilities will be subject to the FDA Preventive Controls for Human Food rule (FDA 2015). Growing some nuts may require implementation of the Produce Safety rule (FDA 2015). The requirements of the Produce Safety rule are outside the scope of this document although the industry should be familiar with the exemption for produce considered to be rarely consumed raw (§112.2(a)(I)). This list includes cashews, hazelnuts, peanuts and pecans.

The remainder of this document is devoted to the safe manufacturing and handling of peanuts and tree nuts.

1.3 Management Responsibility

1.3.1 General Requirements

The processor should establish, document, and maintain a Food Safety Management System as a means of assuring that all materials conform to specified requirements listed in this document and to applicable regulatory requirements. Authorities and accountabilities for food safety should be clearly defined and communicated. Management reviews of the food safety system should be conducted at a defined frequency.

1.3.2 Documentation Requirements

Records should be established and maintained to provide evidence of conformity to requirements of the effective operation of the Food Safety Management System. Records should be legible, readily identifiable and retrievable. A documented procedure should be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

1.3.3 Regulatory Inspections and Contacts

The processor should have documented procedures and designated, trained personnel in place for the management of food regulatory agency inspections and contacts.

Procedures should address the process for follow-up and closure of any issues arising from food regulatory agency inspections and contacts.

Records of all food regulatory agency inspections and contacts should be documented and maintained at the facility. All reports issued by inspectors and the corresponding facility responses and/or actions should form part of the inspection record.

The processor should immediately notify its customer base when any material produced is directly or indirectly the subject of regulatory contact, investigation, or action. This may include regulatory actions or product sampling by a regulatory body. This does not include routine inspections made on a regular basis.

In any case where material produced by the processor is sampled by a regulatory agency, all product represented by that sample still under control of the processor should be placed on hold. The processor should consider obtaining and

maintaining a duplicate sample of the lot examined by the external regulatory bodies, in consultation with legal counsel.

The processor should immediately notify its affected customers of any voluntary or involuntary retrieval of their product.

1.3.4 Communications with Customers

Communication in the supply-chain is critical when events occur that could impact product safety. Processors should notify their affected customer base immediately but no later than 24 hours after the following types of events occur:

- Systematic product quality defect or process control deviation that could lead to a recall or withdrawal.
- Discovery of potentially defective or adulterated ingredient or packaging material associated with product in distribution.
- Non-routine regulatory agency inquiry/investigation, testing, sampling, reporting, activity, or involvement.
- Highly suspicious event or substance threatening product security.
- Product tampering or threat of tampering.
- Notification by law enforcement or other authority of potential or actual product security event.

Effective September 2009, the FDA opened the Reportable Food Registry (RFR) electronic portal and required that “facilities that manufacture, process, or hold food for consumption in the United States now must tell the FDA within 24 hours if they find a reasonable probability that an article of food will cause severe health problems or death to a person or an animal.” Processors should notify customers and potentially affected suppliers in conjunction with notification to the FDA. More information is available at Reportable Food Registry (FDA 2016).

Chapter 2

FOOD SAFETY PLAN (FSP)

2.1 Introduction to Food Safety Plans

Facilities that manufacture, process, pack, or hold human food are required to register with the FDA and are covered under many of the rules related to the FSMA. The FSMA impacts domestic and imported food. This chapter will address "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (21 CFR Part 117), which is also known as the Preventive Control rule. The final rule was promulgated by the FDA in September 2015. In addition to setting forth new requirements for Food Safety Plans (FSPs), this rule also updated current Good Manufacturing Practices (cGMPs). In this chapter the term "FSP" is used to denote the requirements in 21 CFR Part 117 Subpart C. Similar requirements apply to the producers of animal food (21 CFR 507.31(c)).

Like other registered facilities, nut facilities subject to the Preventive Controls rule must have a written FSP. Though some exemptions and modifications exist, the rule generally applies to facilities registered with the FDA. Facilities storing unexposed packaged food (for example, some warehouses) are exempt from the requirements for hazard analysis and risk-based preventive controls. This handbook contains recommendations for facilities that would be subject to the rule.

The HACCP system has been used by companies for many years as the foundation of their Food Safety Management Systems. Nut processors may continue to use HACCP as a building block to their FSP but must update and expand upon these plans to meet the provisions set forth in the FSMA rules. The Preventive Controls rule and HACCP requirements may be integrated into a single FSP.

Within the Preventive Controls rules, updated cGMPs include protection against allergen cross- contact and requirements for handing human food byproducts destined for use as animal food. Certain provisions containing recommendations have been deleted. Previously nonbinding provisions, such as training and education, are now binding. Additionally, individuals in covered facilities must have the education, training, and experience necessary to manufacture, process, pack, or hold clean food as appropriate to their assigned duties. They must receive training in the principles of food hygiene and food safety, as appropriate to the food, the facility and the individual's assigned duties.

The main impact of the Preventive Controls rule is the requirement for an FSP. This chapter will outline the key requirements of the regulation and will discuss how to adapt a HACCP plan to build an FSP.

2.1.1 Key Elements of the Preventive Controls Rule

A key element to the Preventive Controls rule is the requirement that facilities develop and implement an FSP, which is prepared by a Preventive Controls Qualified Individual (PCQI) (discussed later in this chapter). The company's FSP must consist of six written forms:

1. Written hazard analysis, and if it identifies one or more hazards requiring preventive controls, then as appropriate:
2. Written preventive controls that address the hazard(s) identified in the hazard analysis as needing a preventive control
3. Written recall plan
4. Written procedures for monitoring
5. Written corrective action procedures
6. Written verification procedures

Many of the components of an FSP may also be part of HACCP plans and will be described in more detail later in this section. As with an HACCP, companies required to develop an FSP must conduct a hazard analysis to identify and evaluate known or reasonably foreseeable biological, chemical (including radiological) and physical hazards to determine whether any hazards require a preventive control. FSP hazard analysis must also consider economically motivated hazards as well as environmental pathogens if the food is ready-to-eat (RTE) and exposed to the environment before final packaging.

If hazards requiring a preventive control are identified, facilities must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented (SMOP).

The five preventive controls below include, as appropriate based on the hazard analysis, the following:

1. Process controls (essentially HACCP CCPs, as discussed later in this section)
2. Food allergen controls (to prevent allergen cross contact and ensure correct allergen labelling)
3. Sanitation controls
4. Supply-chain program
5. Other controls as determined to be appropriate by the preventive controls qualified individual

As mentioned previously, a written recall plan is required in an FSP when the hazard analysis identifies a hazard requiring a preventive control. However, if a preventive control is not identified in the FSP, a written recall plan may be useful in an event of a recall (class I, class II, class III, market withdrawal) and can minimize consumer/ and customer product issues.

When a hazard is controlled by another entity later in the distribution chain (e.g., commercial customer), the facility must disclose that the food is for further processing (e.g., label the food as “not processed to control *Salmonella*”) and obtain annual written assurances the hazard will be controlled, including identification of the procedures.

Facilities must have written procedures for monitoring and verification of preventive controls as well as corrective actions. All these activities must be documented in records. The regulations expressly allow for exception records for monitoring activities, i.e., records demonstrating loss of control, rather than affirmative records demonstrating control. Verification activities are similar to those conducted in the HACCP but may also include environmental monitoring and/or product testing, depending on the outcome of the hazard analysis.

Verification must include, as appropriate to the facility, food and nature of the preventive control, the following:

- Validation of process preventive controls
- Verification of monitoring and corrective actions
- Calibration of process monitoring and verification instruments
- Product testing and environmental monitoring as appropriate
- Records review

Written verification procedures are required for calibration, product testing and environmental monitoring if appropriate.

Validation is not required for allergen, sanitation and supply-chain preventive controls but maybe useful in some cases. Also, a validation is not required for the recall plan, but a mock recall exercise may be useful for training purposes.

Corrective action procedures are required. They outline the steps to be taken in the event preventive controls are not properly implemented. If testing, such as product testing and/or environmental testing is conducted, correction action procedures must address positive test results. Corrective action procedures should be tailored to the nature of the preventive control and the nature of the hazard.

Review of monitoring and corrective action records must be performed within seven working days from the time of creation and must be performed or overseen by a PCQI. When issues are identified during the review, corrective action is required.

Corrections are defined as an action to correct a problem that does not directly impact product safety. For example, corrections can be applied to sanitation and food allergen controls. Corrections can be taken without the documentation associated with corrective action procedures.

Re-analysis of the FSP is required at least every three years or whenever there is a significant change or new information that creates a potential for a new or changed hazard. Re-analysis should be done if a preventive control has been determined to be ineffective.

2.1.2 Hazard Analysis and Critical Control Point

As previously mentioned, a commonly used framework for a Food Safety Management System is the HACCP system. Philosophically, the HACCP also involves a proactive, preventive approach to control food safety hazards. The HACCP provides a mechanism to prevent, eliminate, or reduce to an acceptable level, food safety risks. When utilizing the HACCP, potential hazards are identified, associated risks are assessed, Critical Control Points (CCPs) are identified, critical limits are defined, prerequisite programs (PPs) are specified, methods for control are identified and criteria for compliance are clearly defined. The key difference between the HACCP and the FSP plan is that the HACCP focuses on CCPs whereas an FSP requires a broader consideration of the ways that hazards can be significantly minimized or prevented (including allergen controls, supplier controls and sanitation controls).

HACCP principles and application guidelines are described in the United States by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1998) and internationally by the Codex Alimentarius Commission (the Codex) (CAC, 2003). According to the NACMCF (1998), the HACCP includes the following seven principles:

1. Conduct a hazard analysis
2. Determine the CCPs
3. Establish critical limits
4. Establish monitoring procedures
5. Establish corrective actions
6. Establish verification procedures
7. Establish record-keeping and documentation procedures

Principle 1 involves identifying potential food safety hazards associated with all process steps within an operation and involves determining what significant food safety hazards exist, i.e., hazards that are reasonably likely to cause significant illness or injury without their control.

Principle 2 involves identifying CCPs by determining the operational steps within the operation where identified significant food safety hazards can be prevented, eliminated, or reduced to an acceptable level.

Principle 3 involves establishing critical limit(s) (CL or CLs), which should be met to ensure the CCP is under control.

Principle 4 involves establishing a system to monitor adherence to the critical limits by scheduled measurements or observations.

Principle 5 involves establishing the corrective actions to be taken when monitoring indicates a deviation from a critical limit and that a CCP is not under control.

Principle 6 establishes verification procedures (including supplementary tests, where appropriate) to ensure the plan is working as designed. Verification activities confirm that the HACCP system is being implemented according to the HACCP plan and that it is working effectively.

Principle 7 involves establishing documentation concerning all procedures and records appropriate to these principles and their application.

2.2 Building a Food Safety Plan

Preliminary steps involve identifying the PCQI and assembling the food safety team.

Processors may choose to build upon their HACCP plan to develop the FSP that meets the Preventive Control rule requirements. The facility's HACCP plan should be consistent with the principles and application guidelines defined by the NACMCF or Codex.

Each company must have a PCQI 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 the FDA or is otherwise qualified through job experience to develop and apply a food safety system. Responsibilities of a PCQI include the following:

- Preparation of the FSP
- Validation of preventive controls
- Review of records
- Re-analysis

In preparation for conducting a hazard analysis, a cross-functional team, comprised of quality assurance, operations, and technical specialists familiar with food safety and the manufacturing operation, should be formed. The PCQI responsible for development of the FSP should be included as part of the hazard analysis team. It is helpful for each facility to have a preventive control and/or HACCP team leader who can take responsibility for the maintenance and upkeep of the plan documents.

In the HACCP, the team should take the following preliminary steps: describe the food and its distribution; describe the intended use and consumers of the food; develop a flow diagram that describes the process; and verify the flow diagram. These preliminary tasks will generate specific information used to focus the hazard analysis on the specific product and process under consideration, and these tasks are also a useful aid in developing a FSP, although they are not required by regulation.

2.3 Hazard Analysis and Risk Evaluation

During the hazard analysis, the food safety team should determine all potential biological, chemical and physical hazards that can be introduced, enhanced, or controlled in the raw materials and during processing. The hazard analysis is made up of two stages: hazard identification and hazard evaluation. The hazard analysis must be scientifically based and well documented because it is the foundation of the food safety system. Hazard analysis should include those hazards that may be

unintentionally introduced as well as those substances introduced for economic gain that may present a food safety hazard.

2.3.1 Hazard Definition

In HACCP, a “hazard” is defined as a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control (NACMCF, 1998). Under FSMA, “hazard” is similarly defined as any biological, chemical (including radiological), economically motivated adulteration, or physical agent with the potential to cause illness or injury.

2.3.2 Hazard Identification

To identify the potential hazards, the following considerations may be assessed and documented. The following information should be available to all developers and reviewers of HACCP or FSPs.

Although not required by the FDA, the food safety team should develop and verify a flow diagram for the product and process. Using the flow diagram, the team identifies potential biological, chemical and physical hazards that may be introduced, increased, or controlled at each step of the process.

The team creates a potential hazard list by reviewing the following information:

- Raw materials and ingredients, processing aids, rework, water, compressed gasses, byproducts (for animal food) etc.
- Packaging materials in direct contact with finished product
- Activities conducted at each process step, including handling, sampling and environmental conditions
- Equipment used to make the product

A HACCP hazard analysis and an FSP hazard analysis differ in several ways. Under an FSP, a facility producing RTE foods exposed to the environment *must* evaluate the potential hazard of post-processing contamination. For nuts, the relevant environmental pathogen is *Salmonella*; however, nuts have also been recalled for contamination with *Listeria monocytogenes* (*L. monocytogenes*). Environmental monitoring is discussed elsewhere. Also, in the hazard identification process, the team should review the potential for undeclared allergens due to allergen cross-contact, e.g., undeclared allergens being introduced into the product being assessed from other products currently run on the manufacturing line. Reviewing the plant layout is helpful to assess each area or room in the processing facility to determine the potential for microbiological cross-contamination and the potential for allergen cross-contact between areas. The FDA’s Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry (Chapter 3, Appendix 1) outlines potential biological, chemical (including radiological), physical and/or economically motivated hazards to consider in your hazard analysis (FDA, 2018).

Examples of potential hazards that a nut facility may consider in a hazard analysis include the following:

TABLE 1: Biological Hazards Identification:

Hazard(s)	Ingredient/Origin	References /Comments
Salmonella spp.	from incoming raw peanuts	Peanuts (Calhoun, 2013); Peanut butter (Scheil, 1998; Cavallaro, 2011; Sheth, 2011)
Salmonella spp. and pathogenic *E. coli*	from incoming raw tree nuts	Almonds (Isaacs, 2005); Coconut (Ward, 1999); Pistachios (CDC, 2009; CDC, 2016); Pine nuts (CDC, 2011); In-shell hazelnuts (Miller, 2012); Raw, shelled walnuts (Rothschild, 2011); Almond and pistachio shelf life study with *E. coli* O157:H7 (Kimber, 2012); Walnut study with *E. coli* O157:H7 (Blessington, 2012).
Bacillus cereus, Clostridium botulinum, Clostridium perfringens, pathogenic *E. coli, Salmonella* spp., *L. monocytogenes,* and/ or *Staphylococcus aureus*	from incoming raw ingredients (e.g., spices, dairy)	See FDA's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry (Chapter 3, Appendix 1) for specific pathogens of concern in various ingredients (FDA, 2018)
Clostridium botulinum	In rare cases due to process conditions, (e.g., canned peanuts, hazelnut yogurt, infants/immunocompromised persons in peanut butter)	Canned peanuts (Chou, 1988); hazelnut yogurt (O'Mahony, 1990; Brett,1999); Peanut butter (Sheppard, 2012)
Salmonella spp. and *L. monocytogenes*	Due to environmental re-contamination	-----
Enteric pathogens	From human handling	-----
Salmonella spp.	Contamination from dust	-----
Salmonella spp. and *L. monocytogenes*	Re-contamination from condensate or wet cleaning in the facility	-----
Pathogen growth	During storage (if applicable)	If water activity allows for growth

Table 2: Chemical Hazards Identification

Hazard(s)	Ingredient/Origin	References/Comments
Mycotoxin (Aflatoxin)	due to mold outgrowth on nuts	USDA, 2016; FDA, 2018; ICMSF, 2005; Wood, 1992.
Undeclared allergen(s)	• due to incorrect label application (e.g., walnut label on peanut product) • due to rework addition (e.g., peanut fines added to almond product) • due to cross-contact (e.g., peanut residue on equipment for almond product) • due to ingredients (e.g., milk allergen in seasonings	-----
Undeclared sulfites (> 10 ppm)	due to ingredients (e.g., sulfites in fruit for trail mixes)	-----
Unapproved colors and/or additives	due to ingredients (e.g., salted or seasoned nuts)	-----
Radiological hazards	due to contaminated soil, water, or air, ingredients with radionuclides, packaging materials	WHO, 2011

Table 3: Physical Hazards Identification:

Hazard(s)	Ingredient / Origin	Reference(s) / Comment(s)
Metal	due to metal-to-metal wear of equipment (e.g., sorters, sizers, screens, sifters, pumps, grinders, mills)	-----
Glass	from glass jars	-----
Plastic pieces	from equipment, tools, or raw product packaging material	-----
Rocks, stems, bones, or debris	from harvesting operations	-----

Salmonella

Although there is increasing recognition of the possible presence of *L. monocytogenes* or pathogenic *E. coli* on nuts, for nuts the organism of primary focus is *Salmonella.* This stems from the organism's potential presence in raw nuts due to the nature of nut cultivation and harvesting, the epidemiological history of *Salmonella* in nut products, survival of *Salmonella* in dry environments and products and heat resistance of *Salmonella* in dry products.

The presence of *Salmonella* in low-moisture products is a concern because low numbers of *Salmonella* in foods can cause illness. This is contrary to a common misconception that low numbers of *Salmonella* are not a problem in low-moisture foods because these products do not support *Salmonella* growth. *Salmonella* does not need to grow to cause illness; in some instances, infection has occurred from consuming low-moisture products contaminated with less than one organism per gram, depending on the host, the product, and the *Salmonella* strain. In the 2006–2007 outbreak associated with peanut butter, *Salmonella* was found at 1.5 organisms per gram (estimated) in an unopened jar, and a lower level was found in another product sample (Zink, 2008).

Salmonella is not eliminated during refrigeration, freezing, or drying. Its presence may be controlled in nuts and nut products by inactivation using a thermal treatment (e.g., oil roasting, dry roasting, steam or hot water treatment followed by drying), a non-thermal treatment, e.g., chemical processing using propylene oxide (PPO) (not approved for peanuts) or, ethylene oxide (ETO) (for black walnuts only) (FDA, 2018; ABC, 2008; 40 CFR 180.151). The other major control measure is to implement a program to prevent post-lethality recontamination prior to packaging (GMA, 2009).

Processors of RTE nut products may or may not have a Preventive Control/Critical Control Point (PC/CCP) to eliminate *Salmonella* in their process. If the processor uses a nut ingredient without a kill step in its product (i.e., the nut ingredient is considered a "sensitive ingredient"), its hazard analysis will likely indicate *Salmonella* as a hazard, with a supply-chain preventive control identified as the control measure. Additional information on compliance with the FDA requirements for a supply-chain program appear later in this handbook.

Hullers/shellers who provide raw nuts as a non-ready-to-eat ingredient may not have a CCP or preventive control to eliminate *Salmonella* in their process. However, they should have PPs in place to prevent *Salmonella* growth and minimize contamination. They are also required under the Preventive Controls rule to inform their customers in writing and on the product label that the nuts have not been processed to control *Salmonella* and are required to obtain annual written assurance from the customers that the hazard will be controlled, including identification of the procedures used.

Certificates of analysis (COAs) can be used as part of a facilities supplier verification program and to understand the microbial load entering a facility to address potential issues with environmental contamination. If a supplier is controlling the hazard in the ingredient (as opposed to the receiving facility), then the COA can be used by the

receiving facility as part of the supplier program (e.g.,as a verification activity). In this case, the COA shows that, according to the defined sampling plan and testing method, the pathogen(s) was/were not detected in a specific lot. In situations where a facility receives an ingredient that will be further processed with a kill step, COAs for those ingredients are not required as part of the FSP because a CCP will be applied. However, this information can be used in the management of potential environmental cross-contamination within a facility and should be managed as part of a PP with zoning and other controls. *Salmonella* contamination may occur and testing cannot guarantee the absence of a pathogen. See Appendix B for sampling plans, sampling techniques and results interpretation.

Chemical Hazards

Mycotoxins (including aflatoxin), antibiotics, pesticides, heavy metals, undeclared food allergens, radiological hazards and sulfites are potential chemical hazards. Many nut producers need to address the potential for undeclared allergens.

Food allergy is a complex subject, and the information included here should not be considered as comprehensive. During the development of an FSP, an individual with appropriate knowledge of food allergies should be included as a part of the cross-functional team. In appropriate circumstances, undeclared allergens should be addressed in the hazard analysis.

In most cases, due to the low likelihood of occurrence and/or the nature of the hazard, chemical hazards (including allergens) were often managed by PPs under HACCP. Some chemical hazards, especially allergens, may now need to be managed as a preventive control. Control measures and activities generally are part of a robust and thorough allergen control program and are described in more detail later in this handbook (Chapter 4).

Radiological hazards are considered rare occurrences in food. However, these hazards can pose a health risk when a person is exposed to radionuclides. Therefore, a hazard analysis for radiological hazards must be considered in the FSP risk assessment. The FSP may include a risk assessment of the distance of the food facility from a nuclear power plant and/or radionuclide contamination of water (e.g., from a private well).

Physical Hazards

In general, foreign objects are any object/material including extraneous matter that may become part of the product being produced that is not designed to be a part of such product. Extraneous matter does not usually present a significant risk of a severe adverse health effects; the matter may be aesthetically unpleasant but usually does not cause injuries.

Extraneous matter that does not cause injury is best managed by PPs, such as supplier selection and approval. A hazard analysis should determine if preventive controls are necessary.

In some cases, the characteristics (size, shape and type) of foreign objects may potentially cause serious harm. Typically, these objects will be hard or sharp, such

as glass, metal, and hard plastic. Hard or sharp foreign objects that can cause injury are potential physical hazards. The size of extraneous matter also dictates the severity of the hazard (e.g., if it is a choking hazard). Objects in the range of 7–25 mm are often considered choking hazards (FDA, 2005). If the hazard analysis determines that a potential physical hazard is likely to occur and have a potentially severe health consequence, it should be controlled by a PC/CCP.

The food safety team can use the Hazard Evaluation Flowchart to help determine if a potential physical hazard posed by extraneous matter needs to be controlled. The following control measures may be used as PCs/CCPs or PPs depending on the outcome of the hazard analysis.

- Density Detectors
- De-stoners
- Magnets
- Metal Detectors
- Filters
- Screens
- Sieves
- Strainers
- Vision Systems
- X-Rays
- Others

Economically Motivated Hazards

The official FSMA FSPCA training refers to a number of terms including "economically motivated hazards," "economically motivated adulteration," and "economically motivated food safety hazards." The core HACCP hazards are biological, chemical, and physical. Any hazard that occurs from an act that is motivated by economic gain would be because of from one of those three root causes. In reference to hazard analysis requirement in FSMA (21 CFR 507 and 117): ""The hazard analysis must be written regardless of its outcome" and this includes further clarification that "(iii) The hazard may be intentionally introduced for purposes of economic gain." These concepts more generally referred to as food fraud. The food fraud prevention vulnerability assessments and preventions, such as recommended by the Global Food Safety Initiative, are defined to include addressing these concepts. (For more detailed recommendations, please see the Food Fraud Prevention Section).

2.3.3 Hazard Evaluation

After listing potential biological, chemical and physical hazards, the team determines which of these potential hazards present a significant risk to consumers. The two factors used in this determination are severity (seriousness of illness or injury resulting from exposure to the hazard if it does occur) and likelihood of occurrence in the absence of the preventive control.

The nature of the identified hazard should be considered. For example, is the adverse effect of the hazard a result of a single acute exposure? If the level of a potential chemical contaminant is below a level that would cause illness, it may be better managed as a cGMPs/PP.

Pathogens, microbial toxins, some hard or sharp extraneous matters and undeclared allergens are examples of potential hazards that tend to be viewed as having the following characteristics:

- Acute illness/injury
- Response resulting from a single exposure

Therefore, if these hazards are assessed as likely to be present in the product (e.g., through raw materials, handling), then they will require strict and continuous control.

However, other concerns, such as residual sanitizers or trace levels of pesticides, do not generally cause serious, adverse health effects based on scientific evidence. These risks may be effectively managed by growers, using GAPs, and hullers/shellers, using cGMPs and PPS, prior to providing the product for manufacturing or handling a RTE product. COAs may be requested for pesticide residue and aflatoxin results on incoming lots.

Severity should be determined by considering the susceptibility of intended consumers to foodborne illness, possible impact of secondary problems and magnitude and duration of illness or injury. Scientific data are helpful in making this determination.

Likelihood of occurrence may be influenced by the following:

- Effectiveness of prerequisite programs (PP)
  - For an FSP, facilities will need to review the hazard analysis and re-evaluate hazards previously determined to be not reasonably likely to occur due to a PP. Under an FSP, the PP may be recategorized as a preventive control, requiring a written program, monitoring, etc.
- Frequency of association of potential hazard with the food or an ingredient
- Method of preparation within the processing facility or by consumer prior to consumption
- Storage and transportation conditions
- Historical experience within the processing facility
- Design of processing equipment
- How the likely occurrence is affected by normal adherence to cGMPs
- Food safety recalls, warning letters, and/or import alerts of similar ingredients or product type

In the determination of whether a hazard is reasonably foreseeable, the team may consider the likelihood of the hazard's presence at levels likely to cause illness or injury and whether the adverse effect of the hazard is a result of a single exposure (acute) or if exposure is at a level below which harm would occur. The long-term effect may also need to be considered due to chronic exposure (e.g.,liver cancer from aflatoxin) (Barrett, 2005; NIH; Wu, 2014). The team may also review applicable PPs or other preventive controls that may be used to manage potential hazards and ensure that the PPs are documented and implemented. Examples of applicable PPs, other preventive controls, and associated verification activities may include the following:

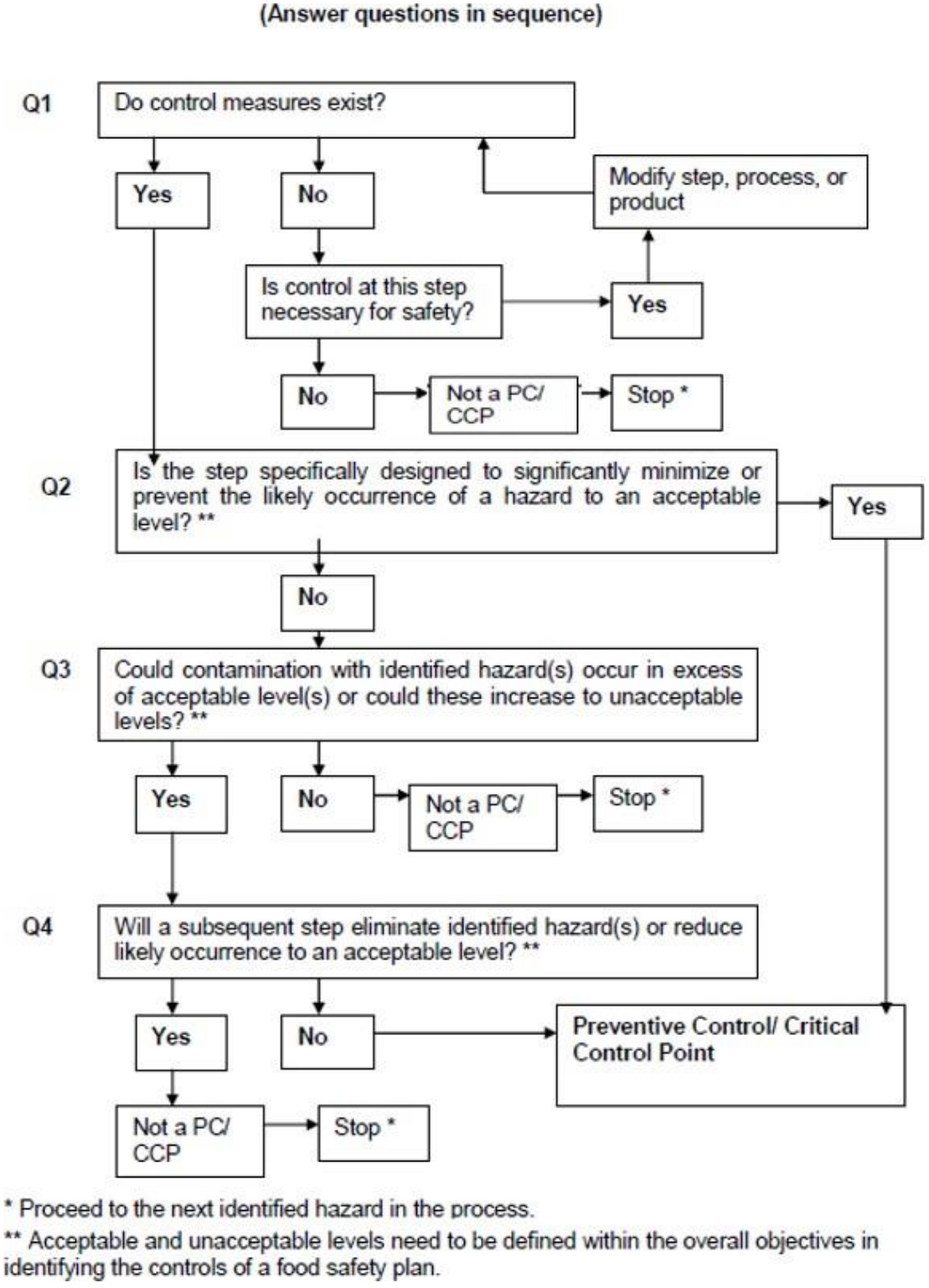
- Building structure/utility systems (e.g., walls, barriers, airflow)
- Employee hygiene/practices (e.g., traffic patterns)
- Effective sanitation
- Post-roast/cook recontamination (prevention of)
- Environmental monitoring for pathogens

Further elaboration of using the two-stage approach (i.e., hazard identification and hazard evaluation) to conduct a hazard analysis can be found in published technical papers (Bernard et al., 2006; Bernard and Scott, 2007; Scott and Chen, 2009).

2.4 Hazards and Hazard Management Criteria

Guidance for how to determine whether a process step or activity is a PC/CCP for a significant hazard identified in the hazard analysis is provided in the NACMCF HACCP document (NACMCF, 1998), the General Principles of Food Hygiene HACCP Annex (CAC, 2003), and the GMA HACCP manual (Barach and Hayman, 2014). The FDA has developed a draft guidance document on this topic to support implementation of the Preventive Controls rule (FDA, 2018). The team may use a decision tree, such as the adapted Decision Tree to Identify PC/CCPs in Diagram 2.1, to aid in the determination of whether a particular step on the process flow diagram is a PC/CCP.

Diagram 2.1. Example of Decision Tree to Identify PC/CCPs (Codex Decision Tree, Adapted)



* Proceed to the next identified hazard in the process.

** Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the controls of a food safety plan.

2.5 Critical Limits, Parameters and Validation

All facilities supplying processed tree nuts, peanuts and/or associated products (e.g., nut butters, nut pastes, marzipan, nut flours) should have effective processing

and handling conditions in place to control all significant hazards identified in the hazard analysis, whether by a PC/CCP or other preventive control.

As described in Chapter 3, the effectiveness of specific PC/CCPs must be established and scientifically validated. Critical limits are minimum or maximum values that need to be achieved to prevent, control, or eliminate the hazard; examples include time, temperature, flow through rate and humidity. A critical limit can also be a parameter rather than a numerical value, such as a metal detector is "on and functioning" or a screen is "present and intact".

A scientific validation study (Chapter 3) is used to determine the appropriate critical limits that achieve the desired reduction in the hazard.

Recognizing that some types of preventive controls, such as allergen and sanitation controls, may be managed by a set of parameters rather than a numerical value, the FDA has included the term "parameter" in the regulation.

2.6 Monitoring

Once the critical limits or parameters are set, it is important to show, through monitoring, that they are being attained (if values) or implemented (if programs). This is done through monitoring.

Monitoring activities should be conducted at a frequency to demonstrate control and to rapidly detect a deviation if one occurs.

Monitoring can be done with instruments, as is conventionally done for the monitoring of PC/CCPs. Monitoring can also be accomplished through observation that activities are occurring, such as sanitation. All monitoring activities must be documented and reviewed (see Section 2.7).

2.7 Verification

Verification activities are performed for each preventive control to verify that the monitoring activities are being conducted properly and that the plan is being implemented as intended. These activities should be performed at a frequency sufficient to demonstrate control.

Verification includes the review of records associated with monitoring activities. For compliance with the Preventive Controls rule, this must be done within seven working days although many facilities conduct a review of records daily. Verification can also include environmental monitoring or finished product testing.

Examples of verification activities include:

- Routine review of records (monitoring, corrective actions, calibrations)
- A designated plant employee review of records prior to release of product
- Calibration of measuring devices used to monitor critical parameters
- Independent checks such as a second person conducting the monitoring
- Periodic finished product sampling and testing where appropriate
- Environmental monitoring where appropriate

2.8 Corrective Actions

If monitoring or verification show that controls are not working as expected, a correction or corrective action must be taken. Corrections (as opposed to corrective actions) can be taken when no food safety risk exists, for example, when a pre-operational inspection shows that a production line is unclean. The correction would be to re-clean the surface prior to starting the line, and documentation of this action would not be required. In contrast, if a critical limit of a process control is not met, the safety of the product could be compromised.

If a deviation is noted during processing, post-processing, or after packaging, all the product since the last documented successful check should be placed on quarantine hold pending product review and determination of product disposition. The cause of the problem should be identified and corrected, and appropriate action should be taken to prevent it from reoccurring. All these activities must be documented. Hold and Release documentation should be available.

2.9 Record Location

All records should have a designated, secure location. Examples of records include temperature charts, thermometer calibration logs, Hold and Release records, corrective action records, verification records and traceability records. Though industry voluntarily practiced HACCP for many years, the Preventive Controls rule has increased the number of required practices and, with them, record requirements. The FDA will have access to these records upon verbal request as part of a routine inspection. Plant personnel must understand inspectors will scrutinize these records. The records must be legible, accurate and accessible.

2.10 HACCP and Food Safety Plan Administration

A completed FSP should be inclusive of a facility's HACCP plan and contain the following components as appropriate:

- Identification of the team (recommended) and qualifications of the PCQI (required)
- Product/Product Category Description (recommended)
- Process Flow Diagram (recommended)
- Hazard analysis, including Ingredient/Packaging and Processing Step Assessments
- Allergen Cross-Contact Production Assessment
- Preventive Control (PC) / Critical Control Point (CCP) documentation
- Identification of other preventive controls (allergen, supplier, sanitation)
- Monitoring, Corrective and Verification Plans
- Validation for Process PC/CCPs
- Recall Plan (required if preventive control identified)
- FSP Approval

No regulatory requirement controls how a facility structures this information (e.g., the facility can use its own templates/forms) as long as the appropriate content is present. Forms can be acceptable if they follow NACMCF and/or Codex principles and guidelines; the Food Safety Preventive Controls Alliance has developed model forms that can be used to capture the additional elements that extend beyond HACCP that are needed to comply with the Preventive Controls rule. Example forms can be found in Appendix D.

Additionally, two illustrative examples (one related to thermal processing for *Salmonella* and one related to control of metal) are included as Appendix E. The FDA has stated that records related to the FSP must be maintained for two years.

2.11 Food Safety Plan Reanalysis Procedures

Verification of the FSP ensures the hazard analysis remains accurate, and every hazard is being effectively controlled to the degree necessary. This involves the collection and evaluation of scientific, historical and technical information to assess if the plan, when properly implemented, effectively identifies and controls all food safety hazards associated with the product or process, which needs to be performed when the plan is first developed and then on an ongoing basis, known as reanalysis.

2.11.1 When to Reanalyze the Plan

The FSP should be reanalyzed when any of the following occurs:

- Whenever there is a significant change in the process.
- Whenever there is a systematic or recurring product safety issue, industry recall of similar product, or consumer food safety complaint trend
- When there is an unanticipated problem (i.e.,no corrective action has been established)
- Existing plans (no changes): on a schedule determined by the processor or supplier that is no longer than three years as per regulatory requirement

The basic process is as follows:

Evaluate the product and process to determine if changes have been made that have not been reflected in the plan

- Review product information, including product description, formula or product listing, and ingredient listing documented in the hazard analysis
- Review the process flowchart to ascertain that appropriate equipment and current process steps are included

Evaluate the product (category) safety history

- Review PC/CCP deviation records
- Review test results from sample monitoring (e.g., analytical and/or microbiological, if applicable)
- Review industry recalls, withdrawals and import alerts for the product category

- Determine if any new or emerging hazards exist
- Review regulatory agency recommendations
- Review consumer complaints related to food safety

Evaluate new developments

- New product consumption or storage methods
  - New recipes for home preparation
  - Use as an ingredient by consumer
  - Retail display methods
- Technological advances
- Process authority recommendations
- Predictive modeling
- Changes in suppliers

Use the information gathered when creating the plan (refer to Section 2.2). Review documentation for each PC/CCP and other preventive controls to determine:

- Are all hazards that need to be addressed in the FSP addressed?
- If addressed by PC/CCP, is the PC/CCP the right one?
  - The modified Codex Decision Tree may be used (refer to Section 2.2)
- If no PC/CCP exists, is another preventive control appropriate?
- Do the critical limits control the hazard? Are the critical limits still adequate? - Consider history and new information
- Are the current monitoring methods and frequencies adequate to identify possible deviations? Are better methods available?
- Do corrective actions effectively correct or control deviations?

Use appropriate members of the food safety team to determine if the plan needs to be changed.

- Documentation of the reanalysis process can be done using a checklist (see an example below from the National Conference on Interstate Milk Shipments (NCIMS) to identify new food safety information. This organization uses the term “validation” rather than reanalysis and references HACCP rather than an FSP. Also, several Food Safety Reanalysis Checklist examples are available in Appendix D of this handbook.
- New information, if identified, should be evaluated by the team and documented.
- If needed, the plant HACCP coordinator/PCQI should update the FSP, as determined by the food safety team.

Whenever changes to product, package, or process occur, as appropriate, the food safety team should convene to review the effect on the existing plan. The review during reanalysis is intended only to verify that all changes made since the last evaluation are reflected in the hazard analysis and, as needed, in the plan itself.

Example from the NCIMS HACCP Program: HACCP Validation Checklist

Topic	Yes	No	If "Yes", Describe	Food Safety Implication?	Are modifications to the HACCP system required?
1. Evaluate product and process					
Product description changed, e.g., intended use, consumer?					
Formula changed?					
Ingredients/Packaging changed?					
Any new product consumption or storage methods?					
Any new suppliers?					
Process flow changed?					
Equipment/computer software changed?					
Finished Product Distribution changed?					
Other, e.g., production volume increased					
2. Evaluate product/process history					
Repeat PC/CCP deviations?					
Any recent industry recalls of similar product since the last annual validation?					
New or emerging hazards, e.g., recent CDC Morbidity and Mortality problems identified with product?					
Regulatory agency recommendations, e.g., guidance documents, regulations?					

SUBJECT **HACCP Validation Checklist** PLANT NAME ADDRESS	ISSUE DATE SUPERSEDES	PRODUCT PAGE **x of xx**

Validation Type (check one):

- □ Initial Validation (within 12 months of implementation)
- □ Validation (Reassessment) due to changes made in raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or intended consumers of the finished product and rate or type of consumer complaints.
- □ Annual Validation (Reassessment) of the HACCP plan including Hazard Analysis

Date Conducted: Conducted By:

Any confirmed food safety consumer complaints?					
Other					
3. Evaluate adequacy of PC/CCPs, critical limits, monitoring, corrective action, PC/CCP verification, and record-keeping procedures. Review current PC/CCP documentation.					
Do the PC/CCPs control the hazards?					
Are the PC/CCP critical limits adequate?					
Do monitoring methods and frequency demonstrate control?					
Do corrective actions properly address affected product and correct deviations?					
Does validation include review of consumer complaints?					
Other, e.g., PPs or procedures may affect the hazard analysis					

Chapter 3

PROCESS VALIDATION

3.1 Introduction

Various technologies are used for pathogen reduction in the processing of tree nuts and peanuts including oil roasting, dry roasting, blanching/hot water treatment, propylene oxide (PPO) treatment, ethylene oxide (ETO) treatment, steam/moist heat treatment, and combinations of these. Associated with each process, product, and production facility are minimum requirements that must be maintained to ensure product safety. These include environmental controls, basic current Good Manufacturing Practices (cGMPs), zoning requirements, adherence to validated nut processing requirements, and stringent post-process contamination controls. Appendix F describes registered uses for PPO and ETO in tree nuts and maximum allowable residue levels.

Salmonella has been identified as a biological hazard in incoming raw tree nuts and peanuts from the field or orchard and requires a preventive control. If other pathogens are identified as a hazard through product surveys, environmental sampling, or other means, appropriate preventive controls should be applied to control the specific hazard. As a reference, the FDA has published a research paper estimating the prevalence of *Salmonella* in cashews, hazelnuts, macadamia nuts, pine nuts and walnuts in the United States. Thermal and chemical processing (e.g., roasting, blanching, steam treatment, moist/heat treatment, and PPO) are effective control mechanisms for S*almonella* and other pathogens. In some nuts, *Salmonella* has been shown to be more resistant to certain processes than other pathogens. However, if multiple pathogens are identified as hazards requiring control, studies should be conducted to determine the pathogens of greatest resistance for each process. Processes must be validated to ensure the pathogens of greatest resistance (typically *Salmonella*) for each process and product are addressed. Refer to Chapter 2 for further information regarding to conducting a risk assessment and to the FDA's Hazard Analysis and Risk-Based Preventive Control for Human Food: Draft Guidance for Industry as it analyzes multiple pathogenic bacteria in different types of products. Furthermore, a product matrix (i.e., nut type) may have an impact on the resistance characteristics of a pathogen to a specific process.

Processors should defer to legal requirements for the appropriate log reduction for *Salmonella* (e.g.,7 CFR Part 981.442: Quality Control). The appropriate log reduction for *Salmonella* or other pathogens in a nut commodity should be determined by studies, such as a risk assessment. For example, the ABC has established a minimum four-log reduction of *Salmonella* bacteria on almonds as the appropriate standard on almonds. The "*Salmonella* performance standard" for almonds was based on years of survey data and risk assessment work (Danyluk et al., 2006; Lambertini Et. al., 2012; Farakos et al., 2017) and has been determined to

result in an estimated mean risk of illness below one case per year in the United States. To date, quantitative risk assessments have been conducted and published by FDA for almonds (2017) and pecans (2017).

To be effective, a treatment process must consistently deliver an appropriate lethality, typically a four-log reduction or greater of the target organism (e.g.,*Salmonella*) as demonstrated by a process-specific and product-specific validation study. The FDA currently suggests a minimum five-log reduction for peanuts and pistachios unless data are available to support that less than a five-log reduction is adequate (FDA 2009a and 2009b).

Validated processes should be audited, whether internally or by a third party at a frequency that demonstrates control, commonly 12–24 months (or as dictated by a reassessment) to verify performance against established critical parameters. In addition, the critical parameters should be reviewed against existing lethality in published literature, such as the types of documents described in this chapter. In addition, during auditing, attention should be paid to process contamination controls.

3.2 Validation Study Design Requirements

For processes used to reduce microbiological hazards, such as *Salmonella*, experiments should be conducted to validate the log kill in each piece of equipment for each nut type as well as nut form. There are two types of validation studies:

1. An inoculation challenge study of the process with the appropriate *Salmonella* strains or a surrogate organism(s) of appropriate and known resistance (thermal/chemical) compared to *Salmonella*
2. Measurement of the physical delivery of the process, e.g., for a time/temperature profile determination of the process measuring the temperature throughout the process in the coldest spot and/or at the surface or interior of the food

In some cases, a validation may include both studies. For all processes and validation studies, the work will involve identifying and establishing control and monitoring requirements for critical factors necessary to ensure the process is consistently achieved. Demonstrating microbial reduction without consistency and control is unacceptable. Table 3.1 below lists various processes and types of validation studies commonly used.

Table 3.1. Common Validation Type(s) by Process (NOTE: These are common critical process parameters. A process validation will require appropriate product and process (equipment) specifications.)

Process Type	Validation Type		Validation Objective	Process Critical Factors Examples (May or may not be considered critical factors depending on the process); List not exhaustive
	Inoculation Challenge Study	Measurement of Physical Delivery of Process		
*1 Oil Roasting		X	Demonstrate the nut is exposed to a minimum required oil temperature for a specific amount of time (e.g. 260°F for two minutes for almond five-log process)	Throughput (residence time, i.e., belt/chain speed; bed depth,); oil temperature; product incoming temperature, product incoming moisture, product immersion
*2 Dry Roasting	X	X	Demonstrate controllable operating conditions which will deliver a minimum required log reduction of target microorganism	Throughput (belt/chain speed; bed depth); air temperature; air flow; incoming nut temperature & moisture; cooling flow & temperature; fan and damper settings
*1 Blanching		X	Demonstrate that the nut is exposed to a minimum required water temperature for a specific amount of time (e.g. 190°F for two minutes for almond five-log process)	Throughput (feed rate setting); blanch water temperature, contact time if applicable
Steam/Moist Heat	X	X	Demonstrate controllable operating conditions which will deliver a minimum required log-reduction of target microorganism	Throughput / Product loading; steam temperature; chamber temperature; air temperature, initial product temperature, pressure
*1 PPO		X	Demonstrate that defined parameters are met during pasteurization cycle	Initial product temperature; chamber temperature; chamber vacuum; PPO volume / concentration / vaporization temperature; exposure time; post

*1. If safe harbor commodity-specific processes are unavailable, then an inoculation challenge study will likely be required in addition to temperature mapping studies

*2. Will likely require heat distribution/cold spot determination studies in conjunction with micro challenge testing; Where sufficient data exist; temperature data can be used alone with General Method calculations to demonstrate appropriate lethality.

An inoculation challenge study can be used for any process. In general, validation studies conducted in production areas must not use a pathogenic bacterial species. Surrogate organisms should be substituted if their behavior is well documented from a

reliable source/process authority. In extreme cases, if a surrogate is not available, work with a process authority and other food microbiology experts to determine an approach that does not compromise the manufacturing environment.

When a surrogate organism is used, it is important to establish the relationship between the resistance of the surrogate and the pathogen of concern for the thermal or chemical treatment under evaluation. The surrogate and the pathogen of concern need to respond in the same manner to the control measure for a reliable correlation. Surrogates of equal or greater resistance compared to the target pathogen can be used if a reliable correlation has been established. It is more practical to choose a surrogate of equal or greater resistance compared to *Salmonella* for the validation study due to ease of enumeration and an additional level of confidence. Detailed information on surrogates is provided in this chapter. Prior to conducting the challenge study, temperature distribution or cold spot determination studies should be conducted to do the following:

1. Identify and address issues related to process uniformity and control
2. Assist in determining where test samples should be located during the challenge study

The second method of validation study (i.e., measurement of the physical delivery of the process) requires comparison of data generated from plant studies with data generated from historical or published studies using the appropriate physical process (e.g., time/temperature). Published works on *Salmonella* inactivation must be available as part of the scientific basis for the validation. In using either method for validation, local regulatory requirements may differ and should also be taken into consideration.

For oil roasting and blanching process validation, a processor can use time and temperature data adequate to inactivate the target level of *Salmonella* from pilot plant or laboratory studies (*Salmonella* can be used to do these studies) followed by a study in the plant with thermocouples or other devices to validate the process delivers the required time/temperature profile.

For dry roasting and other processes, such as steam processing, the surrogate challenge in addition to a time/temperature profile in the commercial equipment is recommended because it is difficult to measure and mimic the time/temperature

profile of these processes in the laboratory. In addition, temperature mapping is needed to identify temperature uniformity and cold spots within the process. Ideally, the process should be tuned to minimize cold spots. If cold spots are unavoidable, the temperature devices should be placed in those locations.
Once cold spots are identified and addressed, specific locations or lanes for placement of microsamples can be determined. It is also beneficial to conduct time/temperature profiling simultaneously while running inoculated samples to determine specific temperature profiles during the run.

Processing units must be tested under "worst-case" conditions, e.g., highest bed height/density, fastest belt speed, lowest zone temperatures, coldest location, coldest possible initial product temperature, maximum load per batch, lowest concentration of PPO/ETO, lowest atmosphere humidity, shortest hold time, maximum throughput and, in most cases, lowest moisture content. It is critical that operational setpoints for validation purposes be set at conditions which will result in control variables being at worst-case conditions during testing.

For example, setpoints for a dry roaster temperature should be lowered from desired operational values for validation testing. Lowering the setpoints will result in reduced actual measured temperatures (control variables), which become the basis for establishing the minimum critical limits for temperature.

Process setpoints typically are not considered critical factors. Critical factors are the actual process values. For production purposes, setpoints are typically set at values to ensure the appropriate Process Value Critical Factor is met. For thermal processes, temperature readings are collected at various points in the process, e.g., across the belt, left, middle, right and the oil outlet. Unevenness of the degree of roasting (e.g., as observed as uneven color) may indicate a variation in nut moisture loss and/or a variation in the temperature exposure in the roaster. A review of the design of the roaster and the heat distribution in the roaster should take place prior to the validation to address major heat differentials within the roaster and/or to indicate the correct location for temperature probe placement. If the control/indicating temperature probe connected to the equipment setting cannot be located at the coldest spot, a correlation should be developed experimentally to account for this difference.

Validation studies must be conducted at least in triplicate for a set of process conditions, e.g., the temperature sensor must run three times through the equipment. It is desirable to do the three test runs on different days using three different lots of product to account for the potential variations between production runs and beginning and ending processing conditions. Once a process is validated, periodic work, such as time/temperature profiling may be conducted to verify the scheduled process is being achieved. Anytime the process/equipment (e.g.,new air source, change in throughput, new heater, change in airflow) or new products or formulations have changes, revalidation is required.

The minimum elements of the study documentation are listed below, and all should be included in any process validation report. Validation reports should be available for review by customer auditors and will be required as part of the Food Safety Plan (FSP) for facilities covered by the Preventive Controls rule. If a processor has

questions about the adequacy or completeness of the validation study, the processor may want to have the final report reviewed by a technical specialist who may be from the buyer's company, a trade association, an expert panel, university, or a third party.

3.3 Description of the Process

The validation study should specify the various factors, including the process, e.g., type and brand of processing equipment (batch vs. continuous), processing conditions, bed thickness, bed length, description of zones, PPO equilibrium (final) concentration (oz/ft^3), type of temperature sensors, location of the temperature sensors divert or shutdown features, utility connections (e.g., gas, steam, air) and exhaust/vent locations and sizes. In addition, the validation study should account for product characteristics, such as nut type, moisture, and size. Any changes to the process system should be documented and routed through the proper process authority.

3.4 Data Collection and Calibration

For time/temperature profile validations of thermal processes, temperature data are collected using calibrated temperature sensors, e.g., ThermoLog™ unit, Data Trace™, Super MOLE™, thermocouple wires, or an equivalent device. Before the trials, the uniformity of the temperature sensors should be checked at room temperature and be assured to be +/- 0.5°C. An accurate, calibrated reference device (e.g., NIST traceable thermometer) should be used to measure the temperature of the oil or water used in processing and the temperature of other heating medium, such as air in dry roasting. Determination of the cold spot must be conducted with the product in the process equipment. An example procedure for calibration check or verification of data loggers can be found in Appendix G. Prior to conducting the validation, all process equipment measurement devices, such as Resistance Temperature Detector (RTD) sensors or thermocouples, flow meters, moisture/humidity devices should be calibrated to NIST standards.

3.5 Validation Guidelines

A process-specific validation study should provide data to demonstrate that, under specific controlled conditions, the process will consistently deliver the minimum lethality of a specified target reduction of *Salmonella or other appropriate pathogen(s) of concern* on the incoming raw peanuts and tree nuts. Establishing the correlation between the surrogate and *Salmonella* in the nut under validation is important if such data are unavailable. Additionally, a separate validation study may need to be done on coated or seasoned nuts where the nut is coated before roasting.

The validation runs should only begin once the processing system, e.g., a roaster, settings are equilibrated, and measurement devices are calibrated after successful commissioning of the equipment. When a validation study is conducted, all elements of the validation study requirements should be included. The process validation must be conducted within 90 days of the initiation of a new line. (FDA, 2015 §117.160). All processes should be validated upon installation at the manufacturing location after initial validation if changes to the equipment are made or if the equipment is moved to another location.

3.6 Time/Temperature Profile Validations

For processes that rely on temperature, use wireless data-tracking units or thermocouple wires. Record the temperature of the nuts and heating environment throughout the entire run and the time through the system, e.g., a roaster. Use multiple data-tracking units or thermocouples to track temperature variations within a run. If using thermocouples, these may be distributed throughout the process and attached to the outside surface of the nuts. However, use of thermocouple wires may be impractical in systems with moving conveyors.

In a belt dry roaster, vary the location of the unit for each run to monitor the right, left and center of the roaster. Ensure the data-tracking units are placed within the center (top to bottom) of the bed. It is recommended to place the units on the belt so they can be easily retrieved at the end of the roaster. In a batch roaster, vary the location of the data-tracking units or thermocouples to account for circulation of the air and oil. For a drum roaster, data-tracking units should be used to capture temperature of the nuts and not the air within the roaster.

When using a surrogate, ensure that the nuts inoculated with the surrogate are exposed to cold spots and other worst-case conditions as described above. Rotary and drum roasters are particularly challenging to validate given that they primarily use product endpoint temperature as the primary process control and variations occur from batch to batch in the time it takes to reach the endpoint. Validation objectives for rotary and drum roasters should be to demonstrate an appropriate log reduction of the target microorganism under a specific set of controllable operating conditions. Critical factors for rotary roasters will likely include the following: endpoint temperature, burner (heater setting), burner temperature, pre-process roaster temperature (cold vs. warm start), initial product temperature, damper exhaust setting, nut moisture, product loading and cycle time (ABC, 2009)

For oil roasters (batch and belt roasters) or situations where the data-tracking device would be exposed to damaging heat, the use of a handheld temperature measuring device may be warranted. Alternatively, thermocouple wires could be used to map the temperature of the oil within a bath. For a batch oil process, the handheld device would need to relay the temperature throughout the process in all corners of the oil roasting tank or any predetermined cooler areas within the tank. For a continuous belt oil roaster, the time in roaster could be marked on the side of the roaster, coinciding with maximum 30-second intervals. The temperature could then be read at each of these locations in the center of the oil bed. The temperature

monitoring probes located in the roaster should be located at or as near as possible to the coldest spot(s) within the oil bath. If the probes are not located in the cold spots, a temperature offset value may be applied to compensate.

The profile data should be reviewed for consistency across runs. Data from each trial should be similar if the roaster is functioning properly. However, if anomalies or inconsistencies are seen, additional runs will have to be performed to better understand the system and to confirm the results.

If revalidating or verifying a line, the profiles should meet the minimum criteria documented in the initial validation profile performed at the time the process was established if available.

Deviations from the initial validation profile should be evaluated for impact to the efficacy of the process. Any change to the process should be assessed by the food safety team and, if necessary, revalidated by an expert such as a process authority to ensure the minimum criteria are met.

3.7 Challenge Study with *Salmonella* or a Surrogate

When processes are challenged using *Salmonella* or a surrogate organism, all elements of the Validation Study Report are required, using, for example, a time/temperature profile validation. Validation testing can be conducted using *Salmonella* (appropriate strains) or using a surrogate organism that has been validated for the nut type and process type (GMA, 2009; Larkin, 2008). For example, when time/temperature conditions of a roasting process can be mimicked (e.g., air flow rate, air temperature, oil temperature) in a laboratory situation, a challenge study with *Salmonella* can be performed to validate the process. When a laboratory study is not appropriate, e.g., if the processing conditions cannot be reproduced, a surrogate organism can be used for the plant roaster. The surrogate must be characterized for the specific process and product.

In studies with almonds, *Enterococcus faecium* NRRL B-2354 was found to be an appropriate surrogate for *Salmonella* Enteritidis PT 30 for dry and moist heat processes (Wang, 2008; Almond Board of California, Unpublished Studies). Further studies have confirmed that *E. faecium* NRRL B-2354 is a safe surrogate to use for thermal process validation. The Almond Board of California (ABC) has published a document titled, “Guidelines for Using Enterococcus faecium NRRL B-2354 as a Surrogate Microorganism in Almond Process Validation”. (ABC, 2014).

In studies with several varieties of peanuts, *E. faecium* was shown to be a conservative surrogate for *Salmonella* PT 30 in thermal inactivation studies (Goodfellow, 2009). It is important to identify a surrogate that has been validated for the specific type of treatment and the nut commodity under consideration, because surrogates identified for one type of treatment (e.g., dry heat) may not be appropriate for another type of treatment (e.g., PPO). At the time of this writing, no surrogates for *Salmonella* have been reported for non-thermal control measures, such as PPO treatment of almonds. See note *E. faecium* and *P. acidilactici* may be

considered as surrogates for *Salmonella* on whole macadamia nuts and cashews processed by using PPO.

Below are the validation parameters that should be evaluated for all nut types:

- The selection of an appropriate surrogate for a specific nut type, nut form and process
- The optimal culture preparation and appropriate inoculation procedure for *Salmonella*
  and the surrogate on the tree nuts and peanuts, especially in shell nuts
- The most effective method for recovering the surrogate from the processed nuts
- The appropriate procedure to confirm heat resistance of the surrogate prior to validation

Examples of a challenge study with *Salmonella* and a time/temperature profile validation study can be found in Appendix H.

3.8 Lethality Computation

For thermal processes, *Salmonella* heat resistance values are provided below (Table 3.2 is not to be used for processing critical limits. Processors must determine heat resistance parameters for their own PC/CCPs).

Table 3.2. Reference Example Times and Temperatures to Inactivate *Salmonella*

	Temp (°F)	Time(min) 4-log	Time(min) 5-log	z-value (°F)	Reference
DRY ROASTING Peanuts	284	16	19.3	77.5F	Goodfellow (2009)
DRY ROASTING Almonds	250 265 280 295 300	100 50 23 12 9		47F	Max temp of process is 300°F using aluminum almond or equivalent device Almond Board of California Dry roasting validation Guidelines (ABC, 2007)
OIL ROASTING Almonds	260	1.6	2.0	NA	ABC Guidelines; Harris and Du (2005)
BLANCHING Almonds	190 185 180	1.6 1.99 2.47	2.0 2.49 3.09		Almond Board of California (ABC, 2007b)

To calculate specific time/temperature parameters for a specific roaster when actual temperatures applied differ from those stated in the established process critical limits, the thermal process equation in Appendix I can be used.

Accumulated lethality values for the run are calculated by summing of the incremental lethality values measured at each probe. These values can be calculated for one process, and the nut processors should consult their processing authority to use accumulated lethality as the sum of two or more different processes. Calculated lethality can only be applied within the temperature ranges where the D values and z-values are established. Equivalent time at temperature should not be applied outside of this range. When it is necessary to extrapolate beyond the temperature range in experiments, such as in the case where processes are conducted at temperatures at which lethality is too rapid to be practical for determination of D values and z- values, it is important to conduct a challenge test at the actual process temperature to verify that the calculated lethality is achieved. This may be done in-plant where an appropriate surrogate is available and surrogate studies would be recommended in these situations.

3.9 Validation Study Report Requirements

Process validation determines if nut processing equipment, e.g., roasters or PPO chambers, can consistently deliver the minimal lethality stated above. In addition, procedures must be in place to protect processed products from re-contamination. The following checklist provides guidance on the minimum content requirements of a Validation Study Report:

- An executive summary should be included at the beginning of the validation report, outlining the date of test, process authority, and summary of work completed.
- A summary sheet should be included, outlining the critical factors necessary for ensuring the process is Met.
    - The critical factors summary sheet should be visibly near the equipment. An example of a critical factors summary sheet is shown in Appendix J and the key elements are described below.

Process Description

Thermal Processes (e.g., Blanchers, Roasters):

- Type, brand, capacity of equipment and number of zones (attach a diagram)

Processing Conditions:

- Variable/fixed parameters (e.g., bed height, throughput, nut flow rate, temperature, air flow rate, air flow pattern, type of oil, air flow)
- Heating medium
- Type and location of temperature sensors
- Divert or shutdown features
- Air source

- Calibration practices/schedule
    - Speed settings (Residence time) PPO Processes
- Type and brand of equipment (attach diagram)

Processing Conditions:

- Chamber temperature; product temperature, exposure time, oz of PPO/ft^3, off gassing and tempering
- Amount of product treated per chamber
- Shutdown and alarm features
- Calibration practices and schedule

Steam /Moist Heat Processes:

- Type and brand of equipment (attach diagram)

Processing Conditions:

- Steam pressure or vacuum achieved; steam temperature, hot air temperature (if used)
- Conveyor, belt and other speed settings (residence time)
- Amount of product treated per chamber
- Shutdown/alarm features
- Calibration practices and schedule

Product Description Processed in the above Equipment:

- Nut type
- Initial form of nuts (raw, or pre-processed)
- Final form of nuts (nut paste, pieces, sliced, diced, whole, in shell or shelled; coated, brined)
- Nut size
- Input moisture and temperature

Establishment of Worst-Case Conditions—Time (Continuous Process)

Describe the method and results to determine nut flow rate and, hence, minimum residence time (within the selected zone, see target parameters for monitoring below) under worst-case high flow rate.

Establishment of Worst-Case Conditions—Temperature

Describe the method and results to determine appropriate location of temperature probes including identifying temperature profile across the bed and shaft, coldest location(s) (within monitoring zone for continuous) under worst case air, water, or oil flow (highest density nuts). The temperature of the product entering the thermal process, or the PPO treatment chamber is also critical, because the tree nuts/peanuts may be added directly from a cooler. This initial temperature for validation should be the minimum temperature at which the nuts would enter the roaster or PPO chamber.

Establishment of Worst-Case Conditions—Other

The initial and final moisture of the nuts is critical to know prior to and during the validation. If the moisture varies from season to season, then the validation study must be conducted at the lowest moisture possible. If that moisture is determined to be a critical factor, i.e., dry roasting, the minimum moisture used during the validation will become one of the critical process parameters.

Describe method and results to determine the worst case for any other parameters identified as necessary for monitoring as in these examples:

- In a continuous roast, the selection of monitoring zone (from point A to point B) and flow rate measure
- In a drum roaster, the selection of temperatures to trigger start and stop times or peak temperature
- In a belt roaster, over time the belt can clog up with product and restrict airflow through the belt and product during roasting. The belt condition within a sanitation cycle should be understood to present the worst-case scenario during validation
- For PPO process, maximum loading capacity, initial product temperature, duration of and configuration of chamber for temperature variation

Target Parameters for Monitoring

Determine the target parameters to assure process variability remains above the critical limits. For studies conducted in triplicate, attach data and calculations, based on the monitoring method, which demonstrates that the targeted log reduction can be achieved under the set monitoring conditions.

Design/Monitoring Validation

Describe the confirmation of worst-case assessments and achievability of the appropriate log reduction using a data logger (cal. +/- 0.5°C).

Corrective Action

Describe the corrective action design features (e.g., alarm, automated divert, or shutdown) and the parameters that trigger them. Develop a plan that defines how to handle non-conforming product, whom to contact (process authority) and keep records.

Operational Aspects of Validation Report for New Equipment or Nut Type

Describe the assessment of start-up process to demonstrate at least a four-log reduction (at least five-log for peanuts and pistachios unless data suggest otherwise) is achieved on nuts during the start-up phase of a new piece of equipment or a new product. Confirm that the process is documented, complete, and available on-site and that records monitoring start-up conditions are available.

Monitoring Records

Attach examples (completed) of monitoring records (log sheets) and calculated log reductions to demonstrate that practices align with design assessment. All records should be verified by a qualified individual prior to shipping.

Validation of Process Capability (Lethality)

For processes where process critical limits are under development or monitored parameters cannot be adequately validated as reflecting the actual temperature profiles, describe the results of the inoculation trials and cross-reference the full trial report. Include all recommendations generated from the validation study.

Chapter 4

ALLERGEN PREVENTIVE CONTROLS

4.1 Allergen Management

The U.S. Food and Drug Administration (FDA) identifies eight major food allergens under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (FDA, 2006). It is important to treat each individual food item, even within the same major food allergen grouping, as a different allergen, e.g., each type of tree nut and each type of fish represents a separate allergen and cross-contact between these items must be prevented. Some individuals are allergic to an entire major food allergen grouping; others may be allergic to one sub-item or several sub-items but not an entire group.

- Milk
- Eggs
- Fish (e.g., bass, flounder, cod)
- Crustacean shellfish (e.g.,crab, lobster, shrimp)
- Tree nuts
    - Almonds
    - Beech nut
    - Brazil nut
    - Butternut
    - Cashew
    - Chestnut (Chinese, American, European, Seguin)
    - Chinquapin
    - Coconut
    - Filbert/hazelnut
    - Gingko nut
    - Hickory nut
    - Lichee nut
    - Macadamia nut/Bush nut
    - Pecan
    - Pine nut/Pinon nut
    - Pili nut
    - Pistachio
    - Shea nut
    - Walnut (English, Persian, Black, Japanese, California), Heartnut, Butternut
- Peanuts
- Wheat
- Soybeans

Additional Allergens

Although the “big eight” food allergens listed above reflects the FDA’s current major food allergens list, as of fall 2019, the FDA may consider adding additional food

allergens to this list when necessary, including, e.g., sesame. For this reason, processors should identify methods to be kept aware of such changes. The FDA also requires that the presence of sulfites be declared on food labels when added as an ingredient, used as a processing aid, or when present in an ingredient used in the food, when the concentration in the final product is ≥ 10 ppm.

Additionally, other countries have unique lists of recognized major food allergens which differ from the official the FDA list, a fact that processors who export must consider. The company's responsibility is to be familiar with the regulations for the countries in which business is being conducted, so the appropriate food allergens are included on the label. The Food Allergy Resource and Research Program (FARRP) maintains a number of valuable resources, including a listing of major food allergens by country at https://farrp.unl.edu/IRChart, with specific detailed information for the EU and various countries, and information about thresholds for allergenic foods at https://farrp.unl.edu/thresholds-for-allergenic-foods.

Under the FSMA Preventive Controls for Human Foods Rule (Preventive Controls rule), covered facilities must have and implement a written Food Safety Plan (FSP). Covered facilities must first perform a hazard analysis to identify known or reasonably foreseeable biological, chemical and physical hazards. These hazards could be present because they occur naturally, are unintentionally introduced, or are intentionally introduced. If the hazard analysis reveals one or more hazards that require a preventive control, the facility must have and implement written preventive controls for the identified hazards. Preventive controls are required to ensure that identified hazards are significantly minimized or prevented and can include process controls, food allergen controls, sanitation controls, and other controls. Food allergen controls are written procedures the facility must have and implement to control allergen cross-contact and ensure allergens are appropriately listed on the labels of packaged food products. Facilities must have an effective program in place to evaluate, identify and control food allergens to ensure that specific allergens are not inadvertently incorporated as an undeclared component of any product.
The Preventive Controls rule provides facilities with flexibility to tailor preventive controls to address hazards that occur in the products they manufacture. The rule requires facilities to ensure controls are consistently implemented and effective in mitigating or minimizing hazards. Specifically, the Preventive Controls rule requires that the facility perform monitoring, corrections or corrective actions, and verification activities as appropriate to the food, facility, nature of the preventive control and the role of that control in the facility's overall food safety system. Monitoring is designed to provide assurance that preventive controls are consistently implemented.
Corrections refer to actions taken to identify and correct minor, isolated problems that occur during food production. Corrective actions are taken to identify and correct a problem implementing a preventive control, reduce the likelihood the problem will recur, evaluate affected food for safety and prevent that food from entering commerce if the affected food cannot be assured to be unadulterated. Corrective actions must be documented in records maintained by a facility.
Verification activities are required to ensure preventive controls are consistently and effectively implemented and include reviewing records to verify that monitoring is occurring, and corrections or corrective actions are implemented if necessary.
Unlike other categories of preventive controls, the Preventive Controls rule does not require allergen controls to be validated, and some facilities choose to validate

allergen controls to ensure they are effective and meet customer or food safety certification expectations (such as third-party audit). The FDA intends to develop an Allergen Preventive Control Guidance for industry.

A robust, thorough, and comprehensive allergen management program addresses the following key areas: how to avoid inadvertent allergens in foods; allergen controls and verification procedures to minimize the potential for inadvertent allergen cross-contact by undeclared allergens; and label controls.

4.1.1 Product Development/Formula Management

Though some allergens are unavoidable because the allergen is a key component of the food product (e.g., peanut allergen in a salted nut mix), other allergens can be avoided. Whenever possible, allergens “designed out” of a food product to reduce the risk of cross- contamination in the facility and to increase the number of potential consumers for the product. This may be achieved by avoiding allergens in initial formulations or through reformulation to remove allergenic ingredients.

4.1.2 Supplier Control Programs

Under the Preventive Controls rule manufacturers must have and implement a risk-based supply-chain program if the hazard analysis identifies a hazard that requires a preventive control, and the control will be applied in the facility’s supply-chain. Facilities do not need to have a supply-chain program if the hazard is controlled in their own facility or if a subsequent entity (such as another processor) will control the hazard and the facility follows applicable requirements. Manufacturers are responsible for ensuring raw materials and other ingredients requiring a supply-chain-applied control are received only from approved suppliers or temporarily from unapproved suppliers whose materials are subject to verification activities before being accepted for use. Suppliers are approved by the facility after the facility considers several factors, such as a hazard analysis of the food, the entity controlling that hazard, and supplier performance. Another entity in the supply-chain, such as a broker or distributor, can conduct supplier verification activities, but the receiving facility must review and assess that entity’s documentation that it verified the supplier’s control of the hazard.

Good management of suppliers can reduce the risk of unintended allergens entering a nut manufacturing facility and ensure correct handling and storage of ingredients containing allergens. As part of an approved supplier program, the nut processor should review its supplier’s raw material specifications and allergen control programs to ensure the potential for unlabeled allergens is minimized. This requires that each supplier have its own established policies and procedures, including a documented Allergen Control Plan, to control allergens at each of its manufacturing locations. Suppliers must disclose all allergens in their formulations, e.g., spice blends, mixes, raw materials, processing aids. They should also make the receiving facility aware of any other allergens, which are not in the formula but are handled on shared equipment at the site. Suppliers must meet all regulatory requirements regarding the proper labeling of allergenic materials. The receiving nut manufacturing facility should also be notified of any changes to the allergen status of the ingredients supplied, prior to receiving such ingredients.

Under third-party certification, e.g., Global Food Safety Initiatives (GFSI) programs, a company's risk analysis should also evaluate chemical suppliers for items, such as food grade lubricants, to ensure no allergen cross-contact risk exists. Most suppliers have documentation readily available for companies to determine the allergen status of such items.

4.1.3 Allergen Controls

Nut processors must have an allergen control program to ensure no allergens are in a specific finished product other than those declared on the label. For example, even though packaged cashews may be handled in the same facility, they must not have traces of walnuts in them. Additionally, processors must have controls to ensure allergens contained in ancillary ingredients (e.g., milk in cheese flavoring, soy in spice blends) are managed to prevent allergen cross-contact with products that do not declare these allergens on their labels. Below are various control strategies that, when combined, make up an allergen control program. These strategies represent ways to help manage allergens and reduce risk to the product and consumers.

4.1.4 Identification and Segregation of Allergens

One component to managing allergens is keeping allergenic ingredients and products separate from non-allergenic ingredients and products, as appropriate. The segregation of allergenic ingredients and products begins when such ingredients are received at the dock door and ends when product leaves the facility. An allergen map can be used to illustrate where certain allergenic containing materials are stored and used. The practices below can be used to manage the segregation of allergenic ingredients and products.

4.1.5 Identification of Allergens

- Ensure allergenic ingredients are shipped in clearly marked sealed containers. The containers should not be damaged or broken.
- Visible identification of all allergen-containing materials throughout the facility and process is vital to the success of any allergen program. The specific allergen(s) in the ingredient should be easily identified in a manner that is visible and clear to any employee handling the ingredient, e.g., a flavoring containing whey is labeled with a color-coded label that states "Allergen: Milk".
- The visible identification must stay with the material from receiving, through storage, delivery to operations, through operations and into returned product to storage. Work In Progress (WIP) and rework containing any allergen must be identified in a similar manner. The finished products must have allergen identification, especially when packaged as an ingredient for further processing.

    A clear and visible identification that remains with the ingredient until it is completely used is a necessary element of allergen management.

4.1.6 Process and Product Design

- Run allergen-containing products on lines or equipment dedicated to that specific allergen profile, whenever possible, to reduce the risk of allergen cross-contact.
- Consider erecting a physical barrier, for lines in close proximity, to reduce the risk of allergen cross-contact (e.g., walls, curtains, partitions).
- Clean and inspect the equipment thoroughly prior to processing product that does not contain the same allergen profile if running the allergenic product on dedicated equipment is impossible. Though not a regulatory requirement in the Preventive Controls rule, validating the effectiveness of a sanitation protocol is a common practice. See the Time/Temperature Profile Validation section (Section 3.6 above) for further details.
- When adding an allergenic ingredient, add it as late in the process as possible to limit the amount of shared equipment that contacts the allergen.

4.1.7 Receiving

- Segregate incoming nuts by nut type and store in separate storage containers, e.g., almonds received in totes are separated from peanuts received in totes.
- Clearly and visibly identify incoming minor ingredients that contain allergens, including allergens as sub-components, e.g., spice blends.
- Handle damaged allergen containers in a manner to prevent allergen cross-contact of other ingredients/products.

4.1.8 Storage

- Store allergens in clearly marked sealed containers.
- Clearly and visibly designate the storage area for allergens.
  Store raw materials, ingredients, WIP, rework, and finished product in such a way that allergenic materials do not come in contact with materials that do not contain allergens, i.e., designate separate storage areas for peanuts, pecans, almonds, etc.
- Store allergen-containing ingredients on the lowest level of pallet storage racks to prevent spillage onto/into non-allergenic components below.

4.1.9 Traffic Patterns of People and Materials

- Limit traffic patterns of people (all employees, including maintenance and management, contractors, visitors, et al.), raw materials, forklifts, waste, packaging supplies, etc., into and out of a room/area that is processing an allergen-containing product to avoid allergen cross-contact.
- To the extent possible, restrict people working on a processing line that contains allergens from working on a different processing line that does not contain allergens or product with a different allergen profile.
- Identify restricted employees in an easily identifiable manner. For example, identify restricted employees with different colored outer clothing or different colored hair nets; if this is impractical, establish procedures for personnel to

minimize the potential for allergen cross-contact in higher risk areas. In addition, employees should wash hands and change gloves and outer clothing when switching between working on allergen and non-allergen lines.

- Manage employees' outer clothing to avoid allergen cross-contact in common areas within the plant (e.g., cafeterias, break rooms, locker rooms), requiring the use of dedicated outer clothing (e.g., lab coat, smock) that remains in the processing room during production or the "brush down" of employees prior to leaving the production area that removes gross soils from their clothing.
- Immediately clean up any spills or damaged containers of allergen-containing raw materials, ingredients, or finished products to avoid potential allergen cross-contact.
- Cover or protect portions of a production process where it crosses over other processes to prevent allergens from falling into or contaminating other product or processes. A redesign of product flow through the facility may need to be considered to eliminate any potential of allergen cross-contact. Use dust collection or other means to control airborne dust.
- If a process during manufacturing reuses materials (e.g., cleaning solutions, cooking or cooling water, oils) that contain allergens and/or reuses containers in contact with allergens, careful consideration must be made before reusing these materials and/or containers. If materials are reused, evaluate them to determine no cross-contact occurs for non-allergen products.
- Evaluate risk and implement restrictions on allergenic food brought into the facility for lunches, vending machines, or catering purposes.

4.1.10 Equipment, Tools and Utensils

Careful consideration should be given to all tools and utensils, which include but are not limited to scrapers, scoops, pails, brushes, sanitation tools and product handling equipment, such as forklifts and carts.

- Dedicate tools to the allergen profile when used during the production of the allergen containing product.
- Clearly identify dedicated tools, for use with each allergen, by using color coding or another easily identifiable system. Verification of cleanliness should be documented (e.g., pre-operational inspection list).
- Store the dedicated tools separately from other non-allergen use tools and tools used for a different allergen profile.
- Any water or oil that is recirculated or reused in the process, such as oil roasting or blanching, may carry a risk of cross-contamination. Companies with these processes must evaluate this risk and implement appropriate controls. This may include filtration, dumping and replacing fluids and a cleaning step. Data must be gathered to demonstrate the effectiveness of these measures, such as laboratory testing of the fluids for allergens, swabbing of the equipment for allergen residues and other means as appropriate.
- If the tools cannot be dedicated to each allergen or allergen profile, then thoroughly clean and inspect the tools prior to next use.

It is appropriate to evaluate all food contact surfaces for inclusion in the allergen cleaning validation.

Table 4.1. Example of an Allergen Changeover Matrix.

		TO				
	Product (Allergens Present)	**Product #1 (almond)**	**Product #2 (walnut)**	**Product #3 (none)**	**Product #4 (wheat, soy, almond)**	**Product #5 (walnut, milk)**
FROM	**Product #1 (almond)**		**Allergen**	**Allergen**	Regular	**Allergen**
	Product #2 (walnut)	**Allergen**		**Allergen**	**Allergen**	Regular
	Product #3 (none)	Regular	Regular		Regular	Regular
	Product #4 (wheat, soy, almond)	**Allergen**	**Allergen**	**Allergen**		**Allergen**
	Product #5 (walnut, milk)	**Allergen**	**Allergen**	**Allergen**	**Allergen**	

4.1.11 Production Scheduling

- When scheduling multiple products on the same equipment, plan to run the allergen- containing product last or after non-allergenic products. Scheduling longer production runs of allergen-containing products will reduce the risk of allergen cross-contact by minimizing the number of allergen changeovers
- If multiple allergenic products are being processed on the same equipment, review the allergen profiles of the products to determine if some allergenic products can be run prior to others, e.g., a scheduled production run including three products: one with wheat and walnuts, one that contains wheat and one that contains no allergens. Run the product with no allergens first, the product with 'wheat only' second, and the product with wheat and walnuts third. This sequence minimizes the risk of allergen cross-contact by minimizing allergen changeovers.
- Evaluate risk of cross-contamination due to physical state of the material, e.g., liquid vs. powder.
- An allergen matrix can be created to aid employees and production scheduling. This matrix will identify which products are being run on a processing line or equipment, which allergens those products contain and what level of sanitation is required to move production from one product to

another. Allergen matrixes are to be reviewed for new formulas and new ingredients (Table 4.1).

- Schedule sanitation of the equipment immediately after a production run that contains an allergen. This should be done prior to running product that does not contain allergens or products that do not contain the same allergen profile.

4.2 Control of Rework and Work In Progress (WIP)

4.2.1 Practices

Rework and WIP practices should be evaluated as part of the hazard analysis. If rework is identified as a possible risk, the following control requirements should be considered:

- A common practice for processors is to use rework only for “like-into-like” applications and as soon as possible, preferably on the same day or shift. Many in the tree nut industry follow the “exact to exact” method for rework, which ensures the material being reworked is identical to the product being made with respect to formulation, ingredient, and supplier processing aid consideration.
- If allergen-containing rework or WIP must be placed into storage, it should be stored in a manner that avoids the risk of allergen cross-contact. This could include the use of sturdy containers with secure covers and the use of interior disposable plastic liners, where applicable. Dedicated containers, lids and pallets may be used for these materials. When that is unfeasible, the containers and lids should be thoroughly washed using an effective cleaning method before reuse. Containers that hold allergen-containing materials should be movable without the use of equipment (e.g., totes on wheels) if possible.
    - To avoid the accidental use of allergen-containing rework in a non-allergen containing product, rework should be clearly marked to indicate the presence of allergens. This can be accomplished by using labels, color coding, or a combination. If labels are used, minimally, the following information should be provided:
        - Name of the rework or WIP material
        - Name of the allergen
        - Date and time of manufacture
        - Date and time put into storage
        - Date and time for using rework/WIP, where appropriate
- When rework or WIP is generated, its storage and re-entry into the process stream should be tightly controlled to minimize the potential for faulty product mixing.
- The transfer of rework or WIP from the staging area to the processing line should be accomplished without allergen cross-contact with other ingredients or products.
- If possible, assemble all allergen-containing items, including rework, for a specific batch in a dedicated staging area before transfer to the line. Allergen labeling should be maintained during staging.

- Re-entry equipment, utensils and tools should be dedicated for handling a specific allergen or allergen profile. Where this is unfeasible, the tools should be cleaned using an effective sanitation procedure, designed to remove allergens, to lower the risk of allergen cross-contact.
- If the use of lifting equipment, e.g., forklifts, is unavoidable, care should be taken to prevent the spread of allergen-containing debris to other parts of the facility.
- If the origin of ingredients in rework cannot be determined, the rework should not be used.
- If allergen-containing rework or WIP is added to product that does not list the allergenic material on its ingredient label, the affected product should be placed on hold (quarantine) and a corrective action should be completed and documented.

4.2.2 Procedures

Procedures for using rework or WIP should be developed to help employees safely handle allergens. These procedures could include work instructions on staging, transfer and add- back techniques that prevent spillage, dispersion and other forms of accidental allergen cross-contact. Procedures may include instructions on how to handle re-entry equipment before, during and after add-back, including inspection and cleaning procedures.

4.2.3 Documentation

The introduction of rework into the process stream should be documented to reduce the risk of accidental product mixing. If allergen cross-contact does occur, the documentation helps track the incident.

The documentation system should track the allergen-containing rework from generation to staging to add-back. Though specific systems often differ from facility to facility, certain basic records can help track the movement of these materials. Examples of techniques to track rework include the following:

- At the re-entry point, reconcile the pre-authorized production batch sheet with the information on the staged containers. A note of this reconciliation step should be entered onto the batch sheet, with the initials of the operator and the time of the activity.
- During add-back, consider entering the following information on the batch sheet:
    - Identity of the allergen
    - Amount of rework and WIP material added
    - Time of addition
    - Batch number
    - Production line number
- Document verification activities to ensure the integrity of the control system. Such activities include the inspection of re-entry equipment after cleaning, measures to ensure equipment is not used before inspection, periodic audits, and record review.

- Reconcile records of added rework with other production records to make sure all the materials are accounted.

4.3 Sanitary Design

The value of well-designed equipment should not be underestimated. Equipment built to sanitary design principles is easier and faster to clean, can be cleaned more effectively, requires fewer employees to clean, and typically meets cGMPs and regulatory guidelines. In general, no "dead spots" should exist that allow accumulation of food or ingredients, e.g., no hollow rollers, no holes in welds, equipment that drains. Furthermore, processing lines and equipment should be positioned for easy access to clean and inspect. Ten principles could be used in sanitary design of equipment, and these principles apply to allergen equipment as well as non-allergen equipment. See Principles of Equipment Design and Installation (in the Executive Summary) for more information.

4.4 Product Changeovers

Product changeover from an allergen-containing product to one containing a different allergen profile depends on effective sanitation practices to deliver a safe and properly labeled consumer product. Effective sanitation practices are important in preventing allergen cross-contact issues. Cleaning methods should take into consideration the form and amount of the allergen, the equipment, the facility structure and other risks. Sanitation can be accomplished by wet cleaning, dry cleaning, flushing, or a combination of these methods.
Each of these methods can be effective, depending on the product, the allergen and the equipment design.

An allergen risk evaluation should be completed to determine if flushing or push-through is the appropriate method for an allergen changeover and if the resultant product must be labeled for allergen cross-contact. Push-through changeovers are similar to flushing changeovers. The difference is that flushing uses a flushing agent (e.g., sugar or salt) while a push through uses the flowing product. A flushing or push-through changeover is used along with scheduling where production is going from one allergen into a product with the same allergen profile or into a product with additional allergens in its profile. When either of these methods are used to restrict allergen carry-over (and thus not declare the allergen on the subsequent product label), the effectiveness of the procedure should be evaluated. The goal is to reduce and manage allergen cross-contact without completely dismantling the production line as that is unfeasible in all operations. These methods should be used only after careful consideration and the changeover procedure may be considered a PC/CCP in HACCP or a preventive control in a firm's FSP.

4.5 Sanitation Expectations, Responsibilities and Procedures

Effective documented cleaning procedures are essential to remove product accumulation, debris, particulates, or individual pieces which could carry over into

the next product from food contact surfaces, tools, or from adjacent areas. The goal is to reduce and manage potential allergen cross-contact.

4.5.1 Allergen Changeover Procedures

- Empty the processing system, remove hand-weighed ingredients and recover and account for materials (e.g., ingredients, WIP, rework) and any previous labels or pre- printed packaging materials.
- During changeover, those employees involved in conducting cleaning activities must be mindful of the potential for contamination of any adjacent production areas. This involves employee training and monitoring of activities and may involve use of temporary or permanent physical barriers or air flow controls in a production area to minimize risk.
- Clean all food contact surfaces and niches of any size for accumulation, debris, particulates, or pieces of product.
- Various mechanical cleaning methods may be used to remove these materials in a manner that does not distribute them to other locations. Cleaning methods may include vacuuming, brushing, wet washing and/or wipe down.
- All product zone surfaces must be visibly clean and free of any accumulation, debris, particulates, or individual pieces of product.
- After surfaces are visibly clean, equipment is typically cleaned with an appropriate detergent or alkaline cleaner to remove any remaining allergen residues that are not visibly apparent.
- Separation, covering, or disassembly and removal of allergen-contact equipment from non-allergen contact equipment is acceptable.
- Dust socks can be cleaned as necessary to protect non-allergenic products. Dust socks should be changed in dust collectors where reclaimed material is returned to product stream.
- Effectiveness of cleaning can be verified either by properly trained individuals or analytical test methods. Results should be documented, using e.g., a pre-operational checklist. Items should be re-cleaned until found to be acceptably clean.
- Qualitative tests can be initially performed to validate effective cleaning protocols. Sampling should include areas known to be hard to clean. This may include equipment and conveyor nooks and crevices, scarred work surfaces, or any area where food residue buildup is a known concern.
- Consider risk of cross-contamination where clean in place (CIP) solution is collected and reused.
- CIP rinsate can also be tested. Any positive samples would indicate inadequate cleaning, and re-cleaning and re-testing should be performed.
- Be cautious of adding any water to what would be a dry system because it may create a microbiological hazard.

4.5.2 Flushing Changeover Procedures

- Empty the processing system, remove hand-weighed ingredients and recover and account for materials (e.g., ingredients, WIP, rework) and any previous labels or pre- printed packaging materials.

- Flush the line with non-allergen-containing product to remove residual allergens. Usable flushing agents (e.g., sugar, salt) should be compatible with the products and not create an allergen cross-contact or labeling issue.
- Verify that the implemented flushing process works by testing the flushing agent or the first product (considered an in-process product) after changeover from one allergen profile to another. Testing of first product can cause “hold” implications to the batch.
- Determine how much product needs to be flushed through and how many flushes are required to achieve the level of cleanliness necessary by quantitatively analyzing the flushing agent for the target allergen.
- The finding of allergenic material in the flushing agent or finished product would be entirely expected. The appropriate corrective action could be to increase the number of flushes or quantity of the flushes to reduce allergenic residues below detectable limits.

4.5.3 Flow-through/Push-through Changeover Procedures

- Empty the processing system, remove hand-weighed ingredients, recover and account for materials (e.g., ingredients, WIP, rework) and any previous labels or pre- printed packaging materials.
- Implement labeling programs to avoid misbranding.
- Determine how much product needs to be pushed through to achieve the level of cleanliness necessary by using quantitative analyses of the subsequent product as it is pushed through for the target allergen.
- Expect to find allergenic material in the product. The appropriate corrective action could be to increase the amount of product pushed through to reduce allergenic residues below detectable limits.
- Use quality specifications to determine an appropriate changeover was conducted. A set amount of product may be discarded as it may not meet the quality requirements of either product to be reused.

4.6 Validation of Allergen Cleaning

Validation is the process used to guarantee that defined sanitation procedures, when properly implemented, are adequate to remove allergens and meet a visibly clean or analytical testing standard. Once a cleaning procedure has been validated for a process or packaging system; ongoing verification may be needed to ensure the cleaning program and procedure is executed according to the validated protocol and remain effective relative to allergen control. “Managing Allergens in Food Processing Establishments” is available as a resource on the Consumer Brands Association’s website and includes additional information. The Preventive Controls rule does not require validation of allergen cleaning, but validation of allergen cleaning is a best practice applied by many processors and is often required by customers or under third-party certification standards.

4.6.1 Validation Procedures

- Develop documented sanitation standard operating procedure (SSOP) for the specific line to be cleaned. The SSOP should include a detailed list of procedures to be followed as well as methods used to determine the procedures have been effectively, e.g., allergen testing or inspection to ensure a visually clean system. See the SSOP **Guidance** Checklist (GMA, 2015).
- Consider inclusion of a critical equipment list that defines hard-to-clean areas and those pieces of equipment requiring disassembly in the SSOP.
- Perform a production run involving the allergen and then conduct the cleaning process as documented in the SSOP to clean the equipment and remove the allergen.
- Conduct a pre-operational inspection. Some firms find that using a documented pre- operational checklist helps.
- Ensure the "visibly clean" standard is achieved. If the visibly clean standard has been achieved, consider performing any applicable allergen analytical testing. as appropriate.
  (See Section 4.6.2 Analytical Testing for Allergens as Validation of a Facility's Allergen Controls for more information.)
  - If the "visibly clean" standard is not met or an acceptable allergen analytical result is attained, do the following:
    - Revise the facility's SSOP
    - Re-clean the line
    - Re-inspect the line
    - Retrain employees
  - Continue this cycle until acceptable results have been obtained.
  - If allergens cannot be effectively removed after repeated attempts, consider alternating strategies, e.g., product and ingredient reformulation, redesign of equipment, or dedicated equipment and line options.
- Document the approved and validated SSOP cleaning procedure. Retain these at the facility validation documents and records (e.g., procedures, checklists).
- Following SSOP validation, revert responsibility to the existing line inspector(s) for the ongoing allergen cleaning and verification process.
- Consider re-validation when changes occur in formula, allergen or allergen form, equipment, line configuration, product, process, chemicals**,** significant personnel changes, or sanitation procedures.

4.6.2 Analytical Testing for Allergens as Validation of a Facility's Allergen Controls

Reliable analytical test methods for finished products and equipment are available for certain allergens. The analytical test method must be validated for the product type ("matrix") prior to use for validation of a facility's allergen controls. A reputable reference (available at the time of publishing this document) is "Best Practices for Food Allergen Validation & Verification," produced by Neogen, which provides information about validation procedures, selection of test methods, documentation to maintain and areas to check on production lines. Other good references may also be available.

To validate an environmental swab test kit prior to regular use, make sure to test the equipment properly during a full validation study. This includes testing the equipment when the known allergen is present (positive control). Under these conditions, the kit should consistently read a positive result. The kit should also be able to consistently deliver a negative result on a surface where allergens are absent. Lateral flow devices may read a false negative due to allergen protein saturation; for this reason, use a three-line test with an overload line where available.

When no validated test methods are available for the allergen or product type of concern, the validation process can guarantee cleaning adequacy through careful visual examination of the processing equipment. Product or rinsate sampling is not necessarily required although sensitive protein swab tests or sensitive ATP test kits can be used as part of a company's post-cleaning inspection program. Results of all validation activities and routine pre-operational inspection of equipment must be documented and retained according to the company's document retention requirements.

When reliable validated allergen test kits are available, testing to validate a facility's allergen controls, e.g., effectiveness of SSOPs, may be performed. After completion of the SSOPs and attainment of the visibly clean standard, one or more of the following sample types can be collected and analyzed using an allergen test kit. Samples may include the following: equipment swabs, including clean out of place equipment, tools, and utensils; first product after start-up; intermediate or in-process product; and rinsate, if applicable. Obtaining acceptable results from this testing serves to further validate the effectiveness of a facility's SSOPs.

When conducting product-based sampling, collecting a statistically significant sample can be difficult, so equipment swabbing may provide an acceptable testing option. Equipment swabs should represent all equipment used in the process. If multiple lines are used, sample all the lines. Product testing indicate all equipment used in the process. Sampled material should be adequate for the test kit that will be used. Review kit directions or analytical testing service instructions. Additionally, more comprehensive sampling could be considered depending on the specifics of the product and the likelihood the sample will include the allergen if present. All product associated with a sample that is being analytically tested should be placed on hold until the allergen testing confirms adequate cleaning of the line.

Each production run should be treated as a separate lot. If all samples submitted for an individual run are negative, product may be released. If any sample submitted for an individual run is positive, management must determine action steps.

In some well-defined cases, small amounts of residue may be left in a system after a validated cleaning procedure. A knowledgeable team of experts should perform a risk evaluation to determine the level of risk. In some cases, residues, if non-allergenic, may be determined to constitute an insignificant risk. Examples may include trace ambient dust from products but may not include dust from allergenic

ingredients. In summary, these exceptions are rare and must be individually evaluated by experts on a case-by-case basis.

4.7 Monitoring and Verification of Allergen Cleaning

Monitoring is performed on an ongoing basis to guarantee SSOPs are implemented as written and are effective. Monitoring should be performed using a method that has been designed into the validated program; for allergen control, monitoring can include either guaranteeing the visually clean standard is met or using allergen analytical sampling and testing. Monitoring should occur at every allergen changeover.

The allergen cleaning program should be periodically evaluated for effectiveness and compliance as a part of ongoing verification.

Monitoring activities for allergens should include the use of the checklist developed during validation to ensure all cleaning steps and specific pieces of equipment and locations are cleaned in the defined manner. The completion of the checklist steps should be documented. Many facilities perform monitoring using a person that is unassociated with the facility's SSOPs. Monitoring records must be reviewed (or overseen) by a PCQI as part of the verification that the line has been cleaned according to SSOPs. Monitoring records should be retained according to the facility's record retention program and the Preventive Controls rule requirements if an allergen control is determined to be necessary to control the hazard.

4.8 Allergen Advisory Statements or Precautionary Allergen Labeling

Allergen advisory statements or precautionary allergen labeling on the label are a voluntary warning to consumers about the potential presence of unintentional ingredients in food products resulting from the food manufacturing process, e.g., may contain milk. The FDA's current guidance to industry refers to these voluntary warnings as allergen advisory statements; however, these warnings are internationally recognized as precautionary allergen labeling. The FDA advises that advisory statements should not be used in lieu of cGMPs because adhering to cGMPs is essential for effectively reducing allergen cross- contact. Manufacturers must take all steps necessary to eliminate allergen cross-contact and ensure the absence of allergens not intended to be in the product.

If an allergen advisory statement or precautionary allergen label is being considered, the manufacturer should conduct a risk assessment to assess its operational practices and evaluate the hazard that a food allergen may contact a food where its presence is unintended. Manufacturers should undertake reasonable and feasible changes to operations, which may include several of the control strategies detailed in this chapter, prior to deciding to include an advisory statement on the label.

4.9 Label Controls

Control of food labels and packages in the food production plant is as important as other food allergen management techniques in ensuring that allergen sensitive consumers do not consume a food to which they are allergic. Currently, labeling errors are the primary cause of allergen-related food product recalls.

The nut processor should have controls to assure labels are correctly and consistently applied to materials. Controls must ensure labels clearly and accurately reflect product formula and meet any applicable customer requirements. Some of the most important aspects of label management include design controls and inventory and label application controls.

4.9.1 Label Design Controls

Labels and pre-printed packaging can be designed under procedures to ensure accurate fulfillment of label design orders. These procedures could include the following:

- Using written orders, not verbal, for artwork and labeling copy
- Implementing a label revision control program to ensure each revision is separately identified for easy management and separation and that old label versions are removed from inventory
- Prior to printing labels, reviewing labels for regulatory compliance, including declaration of allergens
- Using commonly understood terms in consumer-friendly language for all allergenic ingredient declarations (e.g., milk, not whey or casein), a regulatory requirement under the FALCPA
- Implementing methods to confirm accurate listing of product ingredients in the appropriate order
- Assuring design and copy proofreading
- Requiring written approval of label and package proofs
- Using identity coding (e.g., color and/or numerical) of printed labels and packages
- Using a risk-based decision tree for allergen advisory statements, e.g., “May contain…” or “Manufactured on the same equipment that processes…”.

The labels should accurately describe the material and clearly exhibit the name and address of the manufacturer, packer, or distributor, along with net quantity, storage conditions and preparation instructions (if applicable).

4.9.2 Label Inventory and Processing Controls

Special attention should be given to packaging material changeover practices in-line. Procedures should be in place to account for unused pre-printed labels and packaging at the end of a run to ensure the next run of materials is not inadvertently mislabeled.

Examples of these procedures include the following:

Checking any packaging that includes ingredient statements (e.g., labels, cups, film, external cartons) upon receipt against approved standards to ensure the labeling statements are correct and any other additional allergen labeling requirements are present

- Removing unused packaging and labels after the production run without mixing unused packaging materials with other packaging materials during storage
- Preventing the co-mingling of labels and pre-labeled packaging inside shipping and storage containers
- Implementing effective control procedures should for label and packaging inventory
- Storing packaging materials, e.g., plastic cups and lids, in sealed boxes
- Permitting only labels or pre-printed packaging for the product currently being packaged in the packaging area
- Ensuring packaging samples are accurate before placing them into packaging machinery
- Monitoring, documenting, and verifying the correct label at all changeovers as they occur
- Inspecting product containers and labels during processing to reconcile allergen- related label information on the containers with the ingredient specifications of the product
- Immediately reflecting changes to product specification or formulation on labels
- Discarding all out-of-date or obsolete labels or packaging in a timely manner

Another technique to consider is accounting for quantities of labels used vs. quantity of packages produced during a production run. Units produced should approximately equal labels used. If these two numbers differ, the wrong label may have been used or there were unlabeled packages in the production run.

Food processors should educate line personnel on techniques for ensuring product labels are switched out appropriately at product changeover. Systems, e.g., barcode scanners or vision systems, for confirming correct product and label changeover may be warranted. The methods used to ensure the correct label is on a product should be verified and validated.

The use of colored striping on the edges of packages that are stacked flat in packaging machines should be considered. This practice is especially valuable for allergen-containing products because it reduces the chances for error by line operators.

4.10 Training

The successful control of allergens depends on employees and managers doing the right thing at the right time. Everyone involved needs to have a basic understanding of what allergens are and the importance of proper allergen control. Proper action by employees and managers is based on their understanding of allergens as they pertain to their associated responsibilities and why those responsibilities are important. Understanding allergens and the facility’s allergen control procedures is facilitated by a strong allergen training program.

Additionally, the Preventive Controls rule, specifically §117.4(b) requires that "each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must: (1) Be a qualified individual as that term is defined in §117.3--*i.e.*, have 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;…."

All company employees, regardless of level or position, should receive general allergen awareness training. All facility employees should also receive general allergen awareness training when they begin working at the facility and receive refresher training thereafter, e.g., annually. The training material should be refreshed at least annually.

Employees with allergen-related job responsibilities should receive training specific to those responsibilities. This job-specific training should occur when the employee is new to those responsibilities and as often as necessary thereafter but at least annually. Records documenting employee training should be kept on file. Examples of specific allergen related topics for training may include the following:

- HACCP/FSP Verification Duties
- Sanitation Cleaning Procedures for Allergen Changeovers
- Production Procedures for Allergen Changeovers
- Label and Inventory Controls
- Allergen Cleaning Validation/Testing Procedures
- Allergen Ingredient Spill Procedures
- Allergenic Ingredient Receiving Procedures
- Allergen Ingredient Storage Procedures
- Allergen Tool Cleaning and Handling Procedures
- Allergen Changeover Matrix
- Rework Controls

Additional information can be found at the following:

Food Allergen Labeling and Consumer Protection on Act of 2004 (FALCPA) Food Allergy Research and Resource Program (FARRP)

Reference Materials:
https://www.opxleadershipnetwork.org/sites/default/files/download_documents/Allergen%20 Cleaning%20Validation%20Checklist_live%20(002).pdf

Chapter 5

SUPPLY-CHAIN PROGRAM

5.1 Introduction

Many companies have general supplier approval and supplier management programs in addition to the FDA requirements in Subpart G of the Preventive Controls for Human Foods Rule (Preventive Controls rule. Many principles and approaches described in this chapter still apply to supplier management programs that are a part of prerequisite programs. The Food Supply-chain Handbook (GMA) provides comprehensive information on managing food safety through supply-chains and elements from that handbook were used to develop this chapter (GMA, 2008).

This chapter focuses on those circumstances that trigger the need to develop and implement a supply-chain program as a preventive control in a facility's Food Safety Plan (FSP). Subpart G (§117.405- §117.475) of the Preventive Controls rule requires that a facility develop and implement a supply-chain program if the hazard analysis identifies a hazard that requires a preventive control, and the facility relies upon its supplier(s) to implement that control.

In some cases, a facility may need to approve suppliers and to conduct ongoing verification of those suppliers. In other cases, a facility may be subject to such approval and verification by its customer. From a regulatory standpoint, these requirements must only apply when the supplier (which may be more than one step back in the supply-chain) is applying a process to control a hazard that has been determined during the hazard analysis to require a preventive control. For example, if a chocolate manufacturer receives roasted nuts for inclusion in some products, and the chocolate facility identified *Salmonella* as a hazard associated with nuts requiring a preventive control, the chocolate facility will need to develop and implement a supply-chain program that would include activities to verify the nut processor had adequately treated nuts to control for *Salmonella.*

5.2 Obtaining Ingredients

A Supplier Approval Program should be developed to assess the adequacy of control measures the supplier has implemented to mitigate the risk of hazards identified in the hazard analysis as requiring a preventive control. For much of the nut industry, *Salmonella* is a relevant hazard. The tools used for supplier verification can take several forms, and the appropriate verification program should be established by the facility based on the hazard and experience with the supplier.

Supplier Approval Programs should include the following elements:

- A written program that outlines the approval process for suppliers including which corporate and facility functions are involved, e.g., Research and Development (R&D), Purchasing, Quality Assurance (QA) and who ultimately signs off on such approvals
- The use of a detailed Supplier Information Form that includes obtaining answers to appropriate questions, e.g., are there significant hazards associated with the ingredient, and gathering technical data about the ingredient including its chemical make-up. Examples of questions to include on such a form are provided in Figure 5.1.
- A Quality Department that is involved in the ingredient approval and decision process. Review the technical data sheets when received by purchasing, R&D, and QA. Have a mandatory sign-off by all departments on final formulas and ingredients.
- Inclusion in the supplier specification that if the supplier uses or switches to any other supplier or facility (e.g., to obtain cost savings or increase availability), ensure of being notified beforehand. At that point, evaluate the risk of the new supplier or facility, and this supplier or facility will need to go through the approval process.
- Requirement to review ingredient technical data sheets and supplier information annually to ensure nothing has changed.

As per the FDA, the supplier approval process should consider the following:

- The associated hazard analysis
- Supply-chain controls, specifically when and where controls are applied
- Supplier performance as determined by one or more of the following:
  - Audit results and certificates
  - Food safety procedures, practices and programs
  - Regulatory compliance (e.g., import alerts, warning letters, recalls
  - Food safety history
  - Testing results
  - Responsiveness to issues
  - Supplier verification activities

5.3 Evaluating the Supplier's Food Safety Program

Include in your Supplier Approval Program mechanisms to ensure the adequacy of the supplier's food safety programs, risk assessment matrix, on-site audits and existing audits by qualified third-party auditors.

5.3.1 Risk Assessment Matrix and Associated Best Practices

In addition to the above components of the Supplier Approval Program, implement the following related best practices:

- Maintain a vendor/supplier contact information list with the risk assessments used to determine the audit frequency of each supplier. Review the list

annually to ensure contacts have not changed. Provide comments on each risk assessment as to why certain frequencies of audits are chosen.

- *Salmonella* is a hazard that can cause serious adverse health consequences or death to humans or animals, which is a Serious Adverse Health Consequences Or Death to Humans or Animals (SAHCODHA) hazard. The FDA expects that when a supplier has identified *Salmonella* as a known or reasonably foreseeable hazard and the supplier is responsible for controlling that hazard, that you're a designee, such as a third-party auditor, will conduct an annual on-site audit of the supplier/facility to ensure the pathogen hazard is being controlled except where another verification tool other than an audit can be shown to provide the same level of assurance that the facility/supplier is controlling the pathogen.
- Include whether a supplier is from a high-risk country and who is auditing that supplier.
- If an ingredient is sourced from a broker, the actual product manufacturer will need to be identified so that a supplier verification can be conducted directly unless the broker is conducting supplier verification and provides adequate documentation to ensure the identified hazards are being controlled. Also, if the broker is relied on to verify the manufacturer is controlling identified hazards, do not just accept the broker's assurance of ingredient safety. Determine how the broker is verifying and validating the supplier's FSP. Even if the broker performs verification activities, the FDA requires the receiving facility to approve the supplier, which is the location/facility where the hazard is being controlled.

5.3.2 Conducting On-Site Audits and Best Practices

- If an on-site audit is warranted based on the risk assessment of the ingredient or supplier, conduct the audit (using an employee who is appropriately qualified) or use a qualified third party.
- If doing the audit without outside assistance, use an audit template with probing questions about the supplier's food safety (*Salmonella* mitigation, allergen management) and supplier programs. See Vendor Approval Program Highlights, Figure 5.1, below. Send the audit template to the supplier/facility and request its completion prior to the on-site audit and verify the responses provided when on site.
- If a third party conducts the audit and the audit is acceptable in lieu of an on-site audit, ask for the complete audit report and not just the certificate. It may be required that signing a confidentiality agreement that states non-circulation of the document without the owner's permission; some of this information is available to the FDA to ensure regulatory compliance. Review the deficiencies and corrective actions closely.
- Follow up with the supplier for more detailed information if needed as listed below:
    - If the audit is identified in your company's supply-chain program as a verification tool, create a record of the review of the audit report. This record needs to include the following information:
    - Name of supplier

    - Documentation of audit procedures
    - Date
    - Conclusions
    - Corrective actions taken for significant deficiencies
    - Qualifications of the auditor
- Conflict of interest matters must be considered. The auditor must not have any relationship to the supplier or any vested interest in the product.
- Be comfortable and confident any identified risks from the audit were mitigated and verified.

5.3.3 Raw vs. Unpasteurized vs. Untreated

The use of the term “raw” to describe the status of nuts can cause confusion. Raw may be used on a retail label as a description of the sensory, nutritional and physical characteristics even if the food has been pasteurized or treated to reduce microbial contamination as is the case with almonds and oysters. The FDA does not object with the use of raw in such cases if the physical and chemical characteristics of the food remain unchanged. Used in this way, raw appears on the consumer-level label as a marketing component.

At a business-to-business level, raw may mean that the product has not been treated with a microbial reduction step. To avoid confusion between businesses, other terminology might be preferable to communicate the way in which hazards, e.g., *Salmonella*, have been addressed. More general terms that can be used are “treated” and “untreated”.

Facilities, that have identified a hazard requiring a preventive control but have not treated nuts to control the hazard because a downstream supply-chain member will apply treatment, must disclose this to their supply-chain partner in documents that accompany the product. In these instances, the terminology about the status of the product should be carefully considered.

5.4 Incoming Ingredient Testing

As an alternative to, or in addition to, on-site auditing, testing can also be used as part of supplier verification activities. Due to the low levels of *Salmonella* that may be in nuts and the low frequency of occurrence, the absence of *Salmonella* in sensitive ingredients, dry- mixed ingredients, or finished products cannot be assured through testing alone (FAO/WHO, 2006; EFSA, 2008).

- Testing Protocols:
    - For ingredients requiring *Salmonella* testing, have them tested prior to arrival at the facility. Have the supplier send samples to an independent lab with results to both the facility representatives and the supplier. (Who should pay for these tests should be predetermined.)

- Sampling and testing, at a minimum, should be in accordance with FDA Risk Category II, which requires 30 samples (FDA, 2003). Samples must be traceable to a specific facility, lot, or batch. To ensure defensible samples, the condition and chain of custody of the samples should be documented. This can be verified using a third-party sampling service.
- If testing must take place after receipt of the ingredient, provide clear communication to the intended supplier. Discovery of a potential SAHCODHA hazard could result in a requirement to notify the FDA through the Reportable Food Registry (RFR).
- If testing must take place after receiving the ingredient, ensure the entire lot remains "on hold" pending receipt of the testing results.

- Frequency of Testing
  - Establish and follow set frequencies of testing based on product and supplier risk.
- Retesting
  - Generally, retesting should not be performed if undesirable results are obtained for the initial or first sample collected; this is true for pathogen testing.

5.5 Corrective Actions for Non-Conformance

Corrective and longer-term preventive actions play a vital role in having an effective supply- chain program. When non-conformances occur, a corrective and preventive action (CAPA) program should be in place to address the problem and identify ways to reduce the potential for future reoccurrences.

Any CAPA system should contain the following elements of the Plan-Do-Check-Act (PDCA) Cycle:

- ***PLAN***: Root cause analysis to understand the cause of the nonconformity and identify the corrective and preventive action(s) needed to address the issue.
- ***DO***: Implement the identified corrective and preventive action(s).
- ***CHECK***: Verify that the identified action(s) taken were implemented and effective.
- ***ACT***: Standardize the process and continue ongoing monitoring activities as needed.

Suppliers should be made aware of any nonconformities and where possible, should be provided with a summary of the corrective action report. All nonconformances should have a documented corrective action(s) taken in response to the non-compliant observation.

The performance of all suppliers should be reviewed on a regular basis.

5.5.1 Reportable Food Registry (RFR) Notification

- This notification is required within 24 hours.
- Be prepared to notify the FDA through the RFR if incoming ingredients test positive for *Salmonella.* Be prepared to show that the affected lot is securely sequestered, as well as to demonstrate that no other product in your facility is affected.

5.6 Hold and Release Program

- Raw Material Receiving
    - Have a written protocol for receiving loads of sensitive ingredients.
    - Develop and implement a process to show that sensitive ingredients are only received from approved suppliers. This is required by FDA as part of the supply-chain program.
    - If you require pre-testing, ensure test results are traceable to the load and received prior to unloading or that raw materials are held in a designated, segregated hold area until acceptable test results are received.
    - Have qualified personnel meet the transporter and verify lots and counts are accurate and lot or batch codes on the product label match the test results.
- Tags and Electronic Holds
    - If testing will be done in house, tag ingredients and store in a designated, segregated hold area apart from other, similar approved ingredients to prevent use prior to approval.
    - Once testing results are received and approved, release the lot immediately and move it away from other hold stock.
- First In, First Out (FIFO)
    - Use the FIFO protocol to keep from pulling ingredients out of rotation and to aid in lot bracketing.
        - If another company receiving the same ingredients from the same supplier tests the lot and obtains positive results, your lots may be impacted. Insist that the supplier provide you with dedicated lots in proper sequence, when possible.
- Change Control Process
    - Ensure supplier-initiated changes are communicated to your food safety team.
    - Ensure purchasing and other departments recognize resources required to manage supplier controls and verification.
    - A new supplier or change in your ingredients by the supplier may trigger a need to reassess your FSP.

5.7 Emergency Vendor Approval Process

Situations may arise where materials may need to be sourced from an unapproved supplier. These situations will be handled with the involvement of the management group to determine if a temporary approval status will be granted. Where possible, the quality assurance department (or other responsible designated authority) shall take the effort to assess any potential risks the temporary supplier presents and implement any reasonable preventive measures as necessary to minimize the overall risk.

The duration of the temporary approval status shall be determined on a case-by-case basis under the approval of management.

5.8 Foreign Supplier Verification Program (FSVP)

5.8.1 Key Point

FDA's Foreign Supplier Verification Program (FSVP) rule ensures that imported foods meet the same food safety standards that are required of food produced in the United States and holds the U.S. importer responsible for ensuring that its foreign suppliers are doing what they need to do in to meet those requirements.

5.8.2 Key Principles of FSVP Rule

- Shared responsibility between the importer and the foreign suppliers to ensure safety of food imported into the United States.
- FSVP requirements are risk-based, i.e., based on types of food, types of hazards associated with the food, and supplier performance.
- Importers have flexibility in how they meet FSVP requirements.

5.8.3 Qualified Individual

An FSVP qualified individual is "a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required" by the FSVP rule, "and can read and understand the language of any records that the person must review in performing this activity…" 21 CFR 1.500 (21 CFR 1.503(a)).

5.8.4 Summary of FSVP Requirements

- Conduct a hazard analysis of the food, including hazard identification and hazard risk evaluation.
- Conduct an evaluation of the foreign supplier's food safety performance and risk posed by the food.
- Approve the foreign supplier (based on above evaluations).
- Establish written procedures to ensure that food is imported only from approved foreign suppliers (with limited exceptions).
- Determine and apply appropriate verification activities and assess results.
- Implement corrective actions(s), if needed.

- Re-evaluate foreign suppliers (at least every three years or whenever necessary).
- Identify the FSVP importer at entry.
- Keep required records and documentation.

5.8.5 Hazard Analysis

- Identify and evaluate known or reasonably foreseeable hazards to determine if they require a control including biological, chemical (including radiological), and physical hazards; and naturally occurring, unintentionally introduced, or intentionally introduced hazards for economic gain.
- You may rely on a hazard analysis conducted by someone else, but it must be reviewed by a qualified individual you employ or have retained.
- If you have evaluated known and reasonably foreseeable hazards in the food which is being imported and it was determined that there are no hazards requiring a control, you do not have to evaluate your foreign supplier's performance, approve your supplier, or conduct foreign supplier verification activities.

5.8.6 Foreign Supplier Performance Evaluation

The evaluation of your foreign supplier's performance must include and evaluation of:

- Procedures, processes, and practices related to food safety
- FDA food safety regulations and supplier compliance
- The supplier's food safety history. e.g., Import Alerts, import refusals, recalls
- Other relevant factors such as storage and transportation practices

5.8.7 Approval of Foreign Suppliers

Foreign suppliers must be approved **prior to** importing food from them. Supplier approval is based on the following:

- Evaluation of the risk posed by the food (hazard analyses findings)
- Who is responsible for controlling any identified hazards that need to be controlled
- Foreign supplier performance evaluation
- Other relevant factors

Unapproved suppliers may be used on a temporary basis, when necessary, if the food is subjected to adequate verification activities before importation.

5.8.8 Determine Appropriate Verification Activities

If a known or reasonably foreseeable hazard that needs a control is identified through the hazard analysis and the foreign supplier performance evaluation, then

appropriate verification activities must be identified. Written procedures must be established by the importer for conducting these verification activities.

5.8.9 Types of Verification Activities

Acceptable verification activities may be one or more of the following:

- Annual on-site audit
- Sampling and testing
- Review of supplier records
- Other appropriate measures

5.8.10 Conducting Verification Activities

Verification activities which the importer determines to be appropriate must be properly conducted and documented. Regardless of whether the importer, or someone else carries out the verification procedures, they must be conducted by a qualified individual. The results of verification activities must be reviewed and assessed for adequacy, and to determine whether any corrective actions are required. The review and assessment of verification activities must be documented.

5.8.11 Corrective Actions

If your verification activities indicate that the food is being produced, grown, stored, transported or otherwise in a manner that jeopardizes food safety, appropriate action(s) must be taken. Re-evaluation of your entire FSVP for that food and the foreign supplier is required, unless your corrective action is to discontinue using that supplier. Corrective actions must be documented.

5.8.12 FSVP Re-Evaluation

Re-evaluation of your FSVP must occur whenever you become aware of a problem or change with the imported food and/or foreign supplier, and at least once every three (3) years. These re-evaluations must be documented.

5.8.13 Records and Documentation

All documentation required by the FSVP rule must be complete, kept for at least two years, and made available to FDA upon request.

Figure 5.1. VENDOR APPROVAL PROGRAM HIGHLIGHTS

- Review the results of supplier visits /audits (both when conducted by your company or a 3rd party)
- Maintain sound ingredient specifications (review periodically; establish clearly detailed specs and testing requirements)
- Review of operations and QA programs of suppliers (HACCP/Food Safety Plan / Pest Control Program / Environmental Management Program (EMP) / Audits of their suppliers / etc.)
- Review microbiological environmental data from suppliers (detail frequencies / zones monitored / indicator organisms tested / pathogens and lots locked down)
- Review of sampling and testing programs and data from ingredient and finished good suppliers (Certificates of Analysis)
- Review sanitation practices of suppliers (Master Cleaning Schedules / frequencies / allergen control)
- Review supplier's process validation step (review testing done, plus results; review Corrective Action Report (CAR) if positive results are found.)
- When possible, it is best to purchase entire lots of material and not split lots. This keeps items in proper rotation and minimizes exposure to lots being sent to several customers if an issue develops or another customer decides to test the lot out of their control. If another company receives a positive pathogen test for the same lot, your product may be implicated and a recall may be necessary.
- Ensure supplier-initiated changes are communicated to your food safety team to determine if the food safety plan needs to be revised
- Have alternate suppliers when possible to ensure availability of ingredients or in case other issues arise.
- If supplier is a broker ask the same questions: who is auditing their suppliers?

Chapter 6

OTHER PREREQUISITE PROGRAMS

6.1 Introduction

Nut processors recognize that there are a number of programs that must be in place and fully functioning for a food safety system such as HACCP to perform effectively in assuring the production of safe foods. These “prerequisite programs” are the foundation and will provide operating conditions conducive to the implementation of a Food Safety Plan (FSP), e.g., a HACCP plan. They are intended to keep low-risk potential hazards from being likely to occur or becoming serious enough to adversely impact the safety of the foods being produced.

The guidance materials in this chapter are not intended to be an all-inclusive reference on prerequisite programs. Included are a number of key prerequisite programs that a processor should consider to provide a strong basic foundation for the production of safe nut products.

Table 6.1. List of Key Prerequisite Programs

Facilities*	Allergen Management Program*[1]
Personnel	Extraneous Matter Control*
Production Equipment*	Receiving, Storage, and Distribution*
Control of Raw Materials*	Product Tracing and Recall
Sanitation*	Hold and Release
Hygiene Area Assessment (Hygiene Zoning)*	Laboratory Operations
Pathogen Environmental Monitoring[1]	Training
Pest Control	Sanitary Transportation

* Additional information available in appendices.

[1]In some instances these programs may elevate from prerequisite programs to preventive controls, and are described in individual chapters

6.2 Facilities

6.2.1 Utilities Management

Utilities should be managed effectively so that the utilities themselves (air, compressed air, water, steam, etc.) are not a source of contamination. Common control methods used in the industry may include:

- Access: Access to the controls, access points, and water sources (e.g., well heads), as well as electricity, heating, and ventilation are controlled (locked door/gate, access codes, etc.). Access is granted to authorized and designated employees only.
- Air: Air itself is not a source of microbiological contamination. However, it can be a carrier if air handling equipment is contaminated. Air monitoring for microbiological quality is performed in production areas with exposed microbiologically sensitive materials. Suitable air pressure differentials are maintained between adjacent areas in relationship to positive, negative, or ambient airflow to prevent product contamination (e.g., air flows from high hygiene areas to other process areas).
- Compressed Air: Compressed air is dry, oil-free and filtered to remove foreign particles. Compressed air that comes in contact with product or product contact surfaces should be monitored for microbiological quality.
- Water: Water meets all applicable local and national regulatory requirements for potability.
- Steam: Steam is of the correct quality and purity to meet process and usage needs. Culinary steam is suitable for direct product contact.

6.2.2 Water

The facility should have effective programs to control water microbiological quality and to verify that water meets specified requirements.

Water quality programs should be documented. The programs should include, as a minimum, requirements for water used as/for (where applicable):

6.2.2.1 Ingredients
6.2.2.2 Cleaning
6.2.2.3 Reclaimed water
6.2.2.4 CIP make-up water
6.2.2.5 Process aid/post-process pack cooling
6.2.2.6 Incoming water from wells or municipalities
6.2.2.7 Drinking (fountains and coolers)
6.2.2.8 Ice (drinking or product contact)
6.2.2.9 Re-circulated cooling or heating water
6.2.2.10 Sanitation final rinse
6.2.2.11 Laboratory water

Water should be routinely tested for chemical disinfectants and/or microbial indicators as appropriate based on a review of past testing results and a risk evaluation for each application. Water should be tested for chlorine. For example, chlorinated water from municipal sources may be tested daily or weekly to verify that acceptable results are achieved. Frequency can then be reduced based on an evaluation of test results.

Well water sources should be tested daily and sampled after chlorination at the storage tank or plant inlet location. Testing and verification of free (residual) chlorine should be performed, unless the municipality treats the supply with chloramines instead of chlorine. In such cases, tests may be done for total chlorine (e.g.,

minimum 0.2 ppm) or per state and/or local regulations, regarding the tests, frequency, and acceptable limits.

A water testing plan should be in place, and it should contain the following:

6.2.2.12 Sample location and size
6.2.2.13 Test frequency
6.2.2.14 Required tests
6.2.2.15 Test methodology
6.2.2.16 Acceptance criteria
6.2.2.17 Corrective action procedures

Test data from water testing should be trended and reviewed and timely actions should be taken to correct out-of-standard results. Follow-up testing should be conducted when corrective actions are implemented to verify that corrective action procedures were effective.

Appendix K shows additional guidance for facility water and air treatment options and recommended limits.

6.2.3 Plant Structure

The physical facility and plant layout of the nut processing plant should be of adequate design and construction to assure production of safe quality food products.

Internal and External Structure

6.2.3.1 The structure should be free of cracks, holes, openings, and pest entry or nesting areas.
6.2.3.2 Laboratories (especially pathogen laboratories) should be separated from the production areas (at a minimum, a separate room with a door; additional requirements may apply to microbiological laboratories. See further guidance in Section 3.12 below).
6.2.3.3 During construction, adequate control should be in place to prevent contamination and pest entry.

Doors and Entrances

6.2.3.4 Doors should be self-closing and form an adequate seal when closed.
6.2.3.5 Loading docks should be protected to prevent pest entry.
6.2.3.6 The entrance should control foot traffic into the RTE area and provide the utilities necessary to wash and dry employees' hands.
6.2.3.7 Measures to reduce contamination from shoes (e.g., sanitizing door foamers for wet environments, or dry sanitizers and alcohol-based spray for shoes for dry environments) should be identified and implemented. If the potential exists for residue to collect in the shoe treads, brushes or other means of removing the residue should be applied prior to the sanitizing step. Disposable shoe covers may also be used to provide a physical barrier between shoes and the processing environment.

6.2.3.8 Entry of air should be limited by vestibules, air curtains or pressure differential, as appropriate.

Roof

6.2.3.9 The roof should drain freely so that there is no standing water.
6.2.3.10 The roof should not leak.

Windows and non-HVAC Ventilation

6.2.3.11 Windows should be avoided.
6.2.3.12 Windows that can be opened should be adequately screened to prevent pest entry.
6.2.3.13 All vents (including Louvered vents) and fans should be adequately screened to prevent pest entry.

Unauthorized People Control

6.2.3.14 All doors, windows, and other openings should prevent access by unauthorized people.
6.2.3.15 Facility grounds should be maintained to protect against security threats.

Designed for Separation of Raw and Ready-to-Eat Areas

6.2.3.16 The plant layout should be designed to physically separate raw and processed product areas. Forklifts should be assigned to each separate area.
6.2.3.17 Traffic patterns for personnel, ingredients, packaging and finished goods between different process hygiene areas should be controlled.

Cleanability of Walls, Floors, Ceilings, Overheads, and Drains

6.2.3.18 All should be cleanable and constructed to resist deterioration from product or cleaning chemicals.
6.2.3.19 Floors should be sealed, in good repair, and sloped adequately to avoid standing water.
6.2.3.20 Wall and floor junctures should be concave.
6.2.3.21 Floor drains should be trapped and vented to the building exterior to prevent sewer gas entry into process and storage areas. Drains should be accessible and cleanable. Existing floor drains that are not trapped and vented should be sealed or replaced.

Personnel Facilities

6.2.3.22 The location and number of hand washing, drying and sanitizing facilities provided should allow for optimum usage by employees.
6.2.3.23 Water of a suitable temperature (e.g., hot and cold water), soap/sanitizer, hand drying facilities and a waste bin should be available at hand washing and cleaning stations.

6.2.3.24 Separate sinks and cleaning stations should be provided for hand washing, food contact equipment cleaning, and waste disposal.
6.2.3.25 The location and number of toilet facilities provided should be adequate, and include hand washing and drying facilities.
6.2.3.26 Toilets and shower facilities should not have direct entrance to food production areas.
6.2.3.27 Toilet areas should have negative air pressure (draw in) versus their surroundings.
6.2.3.28 Toilets should have a flushing mechanism and be of appropriate design to prevent contamination of employees' clothes and shoes.

Appendix L describes an example for hygiene zoning, which includes a series of questions to consider to establish adequate plant layout and to minimize potential cross- contamination.

6.2.4 Maintenance Controls

Equipment and materials selected for production should be suitable for the purpose intended, and well maintained. A documented preventive maintenance program should be defined. The program should include a list of food handling equipment, frequencies of inspection/activities, and maintenance records. Priority should be given to maintenance on pieces of equipment that may impact food safety and employee safety.

A documented preventive maintenance program is a valuable tool to address potential foreign materials and potential physical food safety hazards. The program should be up-to-date for all processing equipment. Elements of the program should include a defined inspection for the evaluation of screens, filters, magnets, gaskets, etc., in addition to any potential points of metal- to-metal wear. If the line does not have detection equipment downstream (e.g., metal detector, magnets, screen), a more frequent detailed evaluation of wear and condition of product contact equipment (e.g., scraper blades, conveyer belts, tumbling barrels, grinder plates, valves, pumps, and gaskets) is necessary at defined intervals for detection of potential contamination. Equipment repairs are intended to be permanent and must be performed using proper materials (i.e., temporary fixes that may adversely impact the food safety/quality of a product must be replaced in a timely manner by permanent repairs).

Routine preventive maintenance for compressed air and air used in product manufacture or packing should be documented. This includes the inspection, cleaning, or replacement of air filters, O-rings, gaskets, pumps, bearings, etc. Preventive maintenance frequency should be adjusted in accordance with the outcome of the last intervention, equipment history, and vendor specifications.

Food-grade lubricants should be used on food processing equipment where direct and/or indirect contact between lubricant or heat transfer fluid and food products is possible. All metal welds in product contact areas should be non-toxic, cleanable, and smooth (free from pits, folds, cracks, crevices, or inclusions).

Tools should be cleaned, sanitized, and dried appropriately in a designated area. Appropriate sanitation procedures must be in place where tools are moved from raw

to cooked product areas. Equipment and tools used on the manufacturing machinery must never be placed directly on the floor or walking surface (e.g., deck).

Appropriate measures should be in place to protect products in the event that repair or maintenance activities occur during production. A program should be in place to isolate maintenance work areas from active production lines and for line release to production after completion of maintenance work. This program should include methods for ensuring that the equipment and area are cleaned and sanitized, as applicable, prior to release for food production, and ensuring that all tools and maintenance materials are removed from the area.

After maintenance activities (e.g., drilling, cutting, polishing, and welding) have occurred, it should be assured that the equipment and facilities are clean, sanitized, and in good repair prior to release for production. Each facility should have a program for the identification of maintenance and repair of equipment and its release back to production. The program should be tailored to the specific products or facilities.

6.2.5 Production Equipment

Each new capital installation or modification to existing equipment design should undergo a sanitary design review by a cross-functional team (e.g., quality, sanitation, production, maintenance) as part of the design phase of the project. The scope of the review is to address any known issues with the cleanability, accessibility, functionality, material selection (made of compatible material and smooth surfaces), and the workmanship of the equipment and/or process under review.

Nut processors can be aided in the manufacture of safe and wholesome product by using equipment that has been designed according to sanitary design principles. Further guidance on sanitary design is provided in Chapter 8 Equipment should be easily cleanable, be made of food-compatible materials with smooth and accessible surfaces and should protect the product from contamination. In addition, the equipment should be self-draining, free from openings that could allow product or water to penetrate voids and allow for proper ventilation. Other considerations for production equipment are provided below.

Piping, Ductwork, and Insulation

- Piping is identified at the time of installation. The piping identification program should be in compliance within local regulatory requirements.
- Where pipes and ducts are insulated, the insulation should be cleanable or coated to be cleanable and maintained in good repair.
- Ductwork should be designed to enable internal cleaning.
- Horizontal process piping that needs to be cleaned and emptied should be sloped to allow complete drainage of the system.

Passivation

- The chemical passivation process should be completed to protect wet-cleaned stainless steel from corrosion and to thoroughly clean the

equipment. Newly installed stainless-steel food contact piping and tanks designed to be wet cleaned should be passivated prior to use.

Food Contact Surfaces

- Food contact surfaces should be made of approved or suitable food contact materials.
- Product contact surfaces should be smooth, continuously welded, and should not have braided (woven wire or fabric) covers on hoses, exposed threads, piano hinges, cotter pins (split pins), all-thread rods, socket-head screws, or painted surfaces.
- Use of nuts and bolts in product contact zones should be avoided.
- Welds should be polished, de-scaled, and pickled to a standard of finish equal to that of the surrounding material.

Avoiding Product Contamination

- Equipment should have adequate covers for exposed products and ingredients unless technological reasons prevent this.
- Equipment should be designed such that it does not introduce extraneous matter.
- Nuts and bolts over exposed product zones should be self-locking.
- Only appropriate materials should be used to permanently modify equipment. Tape, duct tape, rubber bands, and wire are not appropriate.
- All lines, circuits and equipment cleaned by CIP should be designed for proper drainage, contain no dead ends and have smooth impermeable surfaces. For example, to assure no product stagnation occurs, any section extending from the intended product flow should not extend a distance greater than 1.5 times the diameter of the pipe.
- Tubular steel equipment framework should be totally sealed and not penetrated.

  Bolts, studs, etc., are welded to the surface of the tubing and not attached via drilled and tapped holes.
- Product contact equipment should be adequately elevated off the floor to avoid potential contamination during production and sanitation.

Valves and Pumps

- Use of butterfly valves (flap valves, throttle valves) is discouraged. If butterfly valves are in use, appropriate cleaning and maintenance schedules should be implemented.
- Ball valves should not be installed in microbiologically sensitive processing areas, as they are not suitable for mechanical cleaning. Existing installations should be disassembled completely for manual cleaning.
- Closed yoke valves (cup valves, bell-shaped valves) should be avoided for food contact equipment.
- Positive displacement pumps should not have pressure relief face plates. If they do, a regular scheduled cleaning and maintenance program should be

implemented to assure any product that seeps behind the diaphragm is cleaned out.

Equipment Fittings

- Strainers and magnets should be installed such that removal will not result in contaminants falling into the processing line. Check valves or stop valves may be required to allow element removal during production.
- Magnets, strainers, and other fittings should be designed and installed such that they do not create dead ends in the process.
- Installation of instruments should consider orientation for line drainage, accessibility for calibration and servicing, shut-off valves, or wells.

Vacuum and Dust Collection Systems

- Vacuum and dust collection systems should be designed to allow sufficient cleanability.
- Vacuum pumps should be designed to prevent oil from back-flowing out of the pump into the product.
- Portable vacuums should be fitted with HEPA filters if they will be discharging air back into the production environment.

6.3 Segregated Hygiene Area Assessment

The separation of one manufacturing area in a facility from another is generally done to minimize contaminant transfer from one area to another, e.g., wet to dry areas, “dirty” (relatively speaking) to clean areas, raw materials to finished products, or a basic hygiene area to a high hygiene area. Compartmentalization or segregation of the facility into specific areas is a common practice in food processing to prevent microbial cross-contamination of materials and products.

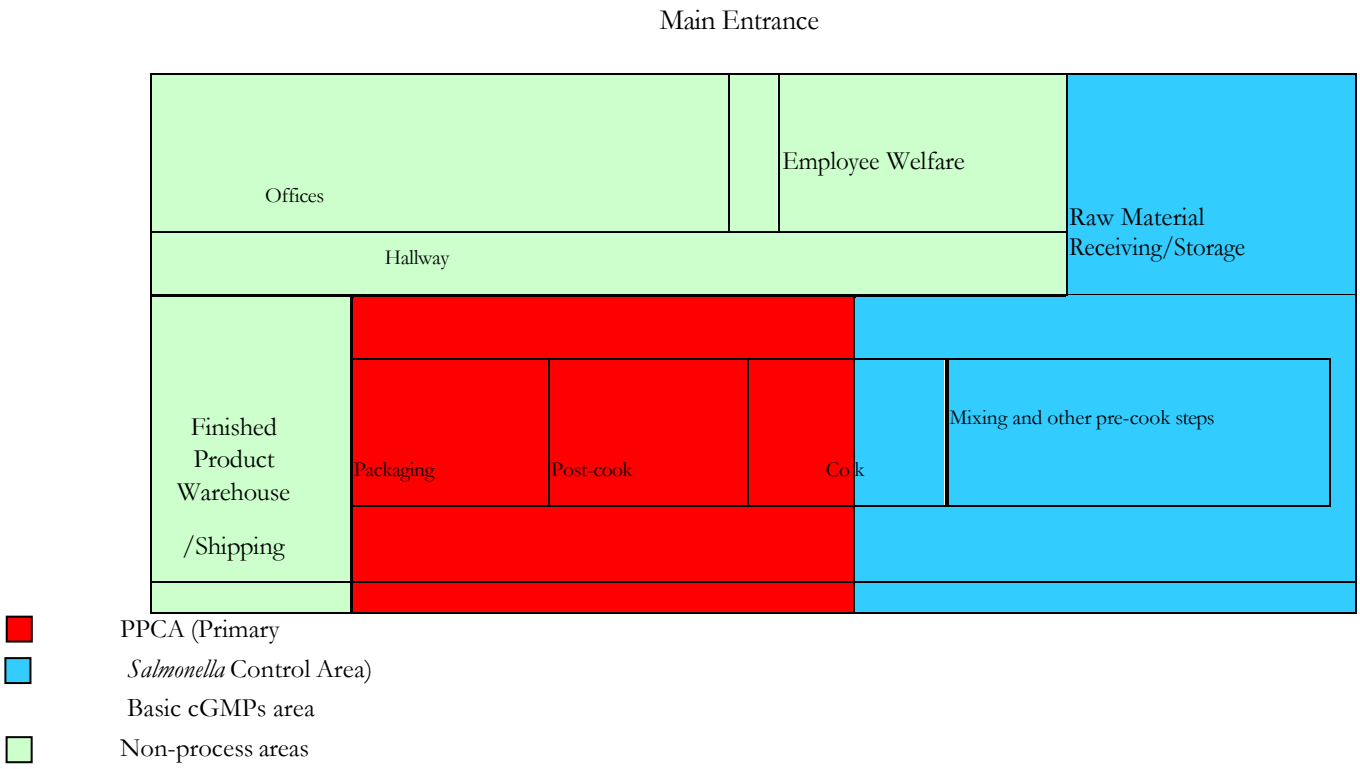
An emerging concept in pathogen control is the designation of a Primary Pathogen Control Area (PPCA). In a nut handling facility, the PPCA is the area where handling of ingredients and product requires the highest level of hygiene control. The PPCA is also referred to as the ready-to-eat area, the critical side, or the dry side of the operation.

Production areas outside of the PPCA are referred to as basic cGMPs or hygiene areas (GMA, 2009), and are often the non-critical side (e.g., for dry facilities) or wet side of the facility (e.g., raw material handling and mixing areas in a facility that has a wet side). In addition, non- processing areas are also delineated such as bathrooms, the plant entrance, locker rooms, hallways, the cafeteria, and refuse/recycle areas.

Depending on the type of operation, a facility may generally be divided into one, two, or three processing areas (in addition to the non-processing areas). A PPCA, a basic cGMPs, and a possible transition area that allows for a hygiene juncture between the PPCA and the basic cGMPs area may be included. For example, an operation that does not employ an inactivation step may designate the entire

processing area as the PPCA, e.g., a trail mix blending operation. An operation that employs an inactivation step may designate the processing area after the inactivation step as the PPCA and the rest of the processing area as the basic cGMPs area, e.g., a peanut roasting or peanut butter operation (Figure 1).

Figure 6.1. Example of a Conceptual Plant Layout Showing Two Process Areas with Different Hygiene Control: A Primary Pathogen Control Area (PPCA) in Red and a Basic cGMPs Area in Blue. The Need for cGMPs in Non-process Areas Should Be Assessed on a Case-by-case Basis.



6.4 Production Area Risk Evaluation

An assessment is conducted to define processing areas and establish the level of risk posed by or to different areas of the manufacturing facility. A practical approach is to obtain a diagram of the process facility and identify the designated control areas with color coding.

- Survey the entire manufacturing facility including production (processing and packaging) areas, storage, warehousing, and employee facilities such as entrances, locker rooms/washrooms, cafeterias, and offices/conference rooms.
- Define the PPCA and designate basic cGMPs areas.
- Identify and differentiate processing areas within the facility where products or the environment could be a potential source of microbial contamination

and have a high potential to cross-contaminate other products, people, or the environment, for example, raw material receiving and processing areas prior to a kill step. Consideration should also be given to non-product areas, e.g., refuse/recycling, utility rooms, restrooms, roof access, and emergency door exits to processing.
- Identify processing areas where water may be used or may be present due to leaks or condensate providing the potential for pathogen outgrowth.

6.5 Preventing PPCA Cross-Contamination

The objective of area designations is to identify high and low risk areas within the production site, then design area-specific pathogen control and monitoring strategies. The goal is to minimize to the greatest extent the spread of pathogens into the PPCA where preventing product contamination is the most critical. The following are commonly used control measures:

- Closed systems (e.g., tanks and pipes) to convey product
- Sanitary design of equipment and facilities. See more information on sanitary design in Chapter 8.
- Structural separation of the PPCA
- Optimized traffic patterns of people, materials, and equipment to protect the PPCA
- Use of a vestibule or hygiene juncture to enter and exit the PPCA
- Hand washing/sanitizing and foot barrier controls (captive boots, booties) established when moving between the PPCA and basic cGMPs areas
- Use of designated and/or coded tools and equipment for each area
- Adequate filtration and pressure/flow of room air to prevent cross-contact, e.g., positive air pressure from filling/packaging areas to other production areas such as raw or pre- processed areas
- Clean air systems (such as laminar flow units with high efficiency air filters, High Efficiency Particulate Air (HEPA) systems and air conditioning and humidity control systems)
- Separation of effluent and wastewater drains (e.g., flowing from areas with potentially higher risk levels of contamination to areas with lower risk levels of contamination)
- Effective sanitation using dry, controlled-wet and/or wet cleaning procedures, as appropriate. See more information in the Sanitation section below.

6.6 Designated Area Evaluation and Verification

Evaluate and verify segregated area programs periodically to assure effectiveness and compliance to hygiene requirements. Programs that are commonly used for verification include, but are not limited to the following:

- Routine pre-operational and operational inspections
- Hygiene monitoring (e.g., equipment swabs, air exposures assays)
- Pathogen environmental monitoring

- cGMPs audits

6.7 Personnel

6.7.1 Personnel Practices

Personnel and their practices can affect the safety of the foods they handle. Through training and monitoring employee practices, the potential for the contamination of foods is reduced. The FDA recommends that the managers of food operations be assigned the responsibility for assuring compliance by good personnel hygiene practices. To accomplish this, the expectation is that management assumes the responsibility for training personnel in food protection principles and food handling techniques.

Good personnel practices that nut processors should consider include:

- Disease control: Personnel with contagious illnesses, open lesions, boils, sores, or infected wounds should be excluded from areas where they would contact foods, food contact surfaces, tools, or packaging materials. In some instances, such as norovirus infections, workers should be excluded from the entire facility. Personnel should be instructed to report such conditions to their supervisor until the condition is corrected. Personnel should also be instructed to report any exposure outside of the workplace that would pose a potential food safety risk to the work environment. A comprehensive health policy outlining employee restrictions should be developed by each organization.
- Cleanliness: a) Employees should wear clean garments that are suitable for their activities; b) clean footwear should be appropriate for the work environment and available for use in production areas; c) uniforms, where provided, should be maintained and cleaned on a regular schedule; d) any outside clothing should be clean and sanitary if allowed in production areas; e) personal cleanliness should be maintained by washing hands prior to work, when they are soiled, after eating, and after using restrooms.
- Jewelry or other objects that are insecure (such as objects in shirt pockets, necklaces, earrings, watches, etc.) should be removed. Hand jewelry can be a source of microorganisms or a source of foreign material (such as when stone settings come loose) and should not be worn where nuts are processed. Jewelry in exposed piercings should be removed. The company policy should address exemptions for medical alert bracelets or necklaces.
- Effective hair covering, including beard/mustache covering, should be worn where products, food contact surfaces, and packaging materials are exposed.
- Foods, chewing gum, beverages, tobacco products, medicine, coins, and like products need to be confined to areas such as break rooms, offices, or other designated areas of the facility so as to prevent product contamination. Lockers or other isolated storage areas should be provided for workers to store personal items.

- Precautions should be taken to prevent contamination from foreign substances including, but not limited to, perspiration, cosmetics, chemicals, fingernail polish, false fingernails, and medicines applied to the skin.
- Each worker's job expectations, responsibility, and accountability should be documented in a clearly understandable manner.
- Personnel practices should be monitored through internal audits.
- Visitors and contractors, as well as temporary and seasonal workers, should follow the same rules and be so instructed when entering a facility.
- No glass should be allowed inside a production area.
- Only impermeable gloves should be used; they should be kept clean and sanitary during use.
- Cross-contamination between the high hygiene process area (e.g., the PPCA) and the raw or "dirty" (relatively speaking) areas should be strictly controlled through segregation of use of equipment and personnel.

Appendix M describes more detailed recommendations for personal hygiene practices for nut processors to consider in their operations.

6.7.2 Establishing a Training Program

Personnel responsible for identifying sanitary failures or food contamination should have training, education, or experience, or a combination thereof, to provide the level of competency necessary for production of clean, safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food protection principles and should be informed of the danger of poor personal hygiene and unsanitary practices. Special training should take place on food allergy and for the need for special care to prevent cross-contamination/mislabeling. All training conducted should be documented for each worker, and show that all federal, state, and local requirements are met. This training should apply to temporary and contract workers as well as permanent employees.

All employees, including supervisors, full-time, part-time, and seasonal personnel should have a good working knowledge of basic sanitation and hygiene principles. They should understand the impact of poor personal cleanliness and unsanitary practices on food safety. Good hygiene not only protects the worker from illness, but it reduces the potential for contaminating nuts, which, if consumed by the public, could cause a large number of illnesses. The level of understanding needed will vary as determined by the type of operation, the task, and the assigned responsibilities. Handlers/Processors should develop a sanitation training program for their employees. Depending on the situation, formal presentations, one-on-one instruction, or demonstrations may be appropriate. Depending on the workers' job requirements, periodic updates or follow-up training sessions may be needed.

Training on the Importance of Proper Hand Washing Techniques

Thorough hand washing before commencing work and after using the restroom is very important. Employees must wash their hands before working with nuts. Any employees having contact with food should also wash their hands before returning

to their workstation. Many of the diseases that are transmissible through food may be harbored in the employee's intestinal tract and shed in the feces. Contaminated hands can also transmit infectious diseases. Do not assume that workers know how to wash their hands properly. Proper hand washing before and after the workday, and after using the bathroom, eating, drinking, or smoking is a simple eight-step process:

1. Wet hands with clean warm water
2. Apply soap
3. Scrub hands and fingernails (for 20 seconds)
4. Rinse off soap thoroughly with clean water
5. Dry hands with single-use towels (or automated hand dryers if acceptable based on a risk assessment and environmental monitoring results)
6. Discard used towels in trash
7. Sanitize hands with an appropriate sanitizer
8. Dry hands

The following list shows pathogens/diseases that can be transmitted by food that has been contaminated by an infected person.

Table 6.2. List of Microorganisms Transmitted by Humans

Often Transmitted	**Occasionally Transmitted**
Hepatitis A virus	*Campylobacter jejuni*
Noroviruses	*Entamoeba histolytica*
Salmonella Typhi	Enterohemorrhagic *Escherichia coli*
Shigella species	Enterotoxigenic *Escherichia coli*
Staphylococcus aureus	*Giardia lamblia*
Streptococcus pyogenes	Nontyphoidal *Salmonella*
	Sapoviruses
	Taenia solium
	Vibrio cholerae
	Yersinia enterocolitica
	Cryptosporidium parvum

6.8 Sanitation

The facility should have a documented sanitation program in place that addresses sanitation schedules, procedures, verification of sanitation effectiveness, record keeping, records review, and corrective action plans. It should include routine and

periodic cleaning. The established sanitation program should assure cleanliness of food processing equipment and the environment.

6.8.1 Master Sanitation Schedule (MSS)

The facility should create and manage a master sanitation schedule for the cleaning activities within the facility. The MSS should include all periodic infrastructure cleaning, periodic equipment cleaning, and routine cleaning activities. The MSS may also include other cleaning activities that are indirectly related to the processing environment (e.g., seasonal tasks such as cutting grass, and janitorial tasks such as administrative office cleaning). Cleaning tasks in the MSS should have set frequencies based on sanitation verification results, microbial monitoring results, hygienic design of the equipment, soil characteristics of the product, and overall effectiveness of the processor's sanitation program.

One technique is to build the MSS on a 52-week interval to ensure cleaning tasks are completed in a timely manner and assist in the overall management and coordination of the MSS. On time completion rates should be tracked and reported along with the completion of backlogged (items not completed on time) tasks.

6.8.2 Sanitation Procedures

The facility should originate and maintain written cleaning methods for all process equipment and processing environments. Where applicable, written operating work instructions should include the following:

- Method to ensure the most current procedure is in use
- Frequency of cleaning
- Chemicals to be used along with chemical concentrations and procedures for verifying concentrations
- Temperature of water and chemicals
- Equipment disassembly/reassembly procedures
- Proper sequencing of cleaning tasks
- Post-cleaning inspection procedures
- Procedures to ensure production area is appropriately dried
- Safety precautions and requirements
- Method to review and update the sanitation procedure
- Methods to avoid cross-contamination

6.8.3 Sanitation Methods

Salmonella growth cannot occur without water, so it is preferable to dry clean whenever possible. When wet cleaning is necessary, water could be minimized in the processing environment. Some examples of cleaning methods that reduce the use of water are "bucket and brush" methods, dry steam technology, CO_2 technology, and taking wet cleaned parts out of the processing room for cleaning in

cabinet-style washers or washrooms. If full wet cleaning is done, the equipment should be designed for wet cleaning and sanitation procedures should limit the risk of cross contamination. Additionally, the processing environment could be microbiologically monitored.

Many techniques and principles exist for cleaning food equipment. Examples of cleaning principles are described in Appendix N (the “Seven Steps of Dry Sanitation”) and Appendix O (the “Seven Steps of Wet Sanitation”). These principles lay the foundation of sanitation sequencing to reduce the risk of cross-contamination from the process environment and sanitation activities.

Additional suggestions for good sanitation practices are described in Appendix P.

During wet cleaning and dry cleaning, disassembled product contact equipment should be prohibited from direct floor contact. When dry cleaning, the use of air blowing/compressed air should be discouraged since this moves material to other surfaces instead of actually removing it. Other tools (e.g., brushes, scrapers, vacuum cleaners, dry steam) may be more effective and could be used instead. If a vacuum is used, it should be designed to be cleanable (e.g., stainless steel, tight fittings, easily disassembled, and HEPA-filtered). The vacuum should also be part of the microbiological monitoring program. CO_2 blasting is another method of dry cleaning, but it should be used in a controlled manner so as not to spread material to other surfaces. At times, CO_2 blasting is used in conjunction with vacuums or other cleaning tools.

Listeria species thrive in wet areas. When wet cleaning, the hygienic design of the equipment is important. Microbial harborage areas should be eliminated to the greatest extent possible and the equipment should be disassembled frequently. Wet-cleaned equipment should be sanitized after cleaning and the equipment should be microbiologically monitored. To aid in restricting microbial growth, the equipment should go through thorough drying after wet cleaning. Further guidance on sanitary equipment design is provided in Chapter 8.

Specific work instructions that reduce the risk of microbial cross-contamination should be in place for floor drain sanitation, including a facility map with the exact location of each drain. High pressure hoses should not be used, as this promotes aerosol formation and potentially enhances the spreading of organisms. Cleaning of drains should not be performed during production.

Brushes and utensils for cleaning food contact surfaces should be clearly identified (i.e., labeled and/or color-coded) and stored separately from raw material area tools and non- food contact tools. Floor drain cleaning brushes and equipment should be clearly identified as such and maintained completely separate from other cleaning equipment. Proper tools and materials should be utilized to prevent extraneous matter or microbiological contamination of the product. Items that are known to be potential sources of contamination should be prohibited. Appropriate sanitation-related measurement devices (e.g., thermometers, gauges, meters, solution strengths, circulation velocity) should be calibrated.

6.8.4 Monitoring Sanitation Effectiveness

A system for verifying and documenting the effectiveness of the sanitation program should be in place. Verification activities may include pre-operational/post-cleaning

inspections, cleaned equipment teardown and inspection, and the microbiological monitoring of the equipment, records review to confirm compliance with SOP including sanitizing step.

Post-cleaning or pre-operational inspections should be performed to confirm that equipment is clean, properly assembled, visually free from chemical residues, and dried prior to use.
These inspections should document any deficiencies and the corrective action response. Pre- operational inspections should be performed as close to the process start up as practical (usually no more than 8 hours prior to start up). The pre-operational inspection should be performed by someone other than the individual(s) that cleaned the equipment.

The facility should have a specific Non-Pathogen Environmental Monitoring Program. All equipment that is wet cleaned may be included in the program, but the equipment that is after the microbiological control step (e.g., after a roasting step to inactivate *Salmonella*) should be an area of focus. Air quality, compressed air and the employees' hands may be included in this program.

Setting microbial limits for this program could be variable depending on equipment, product, and environmental factors. One possible set of microbiological limits is specified below.

Table 6.8. Cleaned Equipment—Guidelines Only

		Post-heat treatment - taken before sanitizing		Post-heat treatment - pre-op taken after sanitizing	
		CFU/100 cm²	CFU/40 in²	CFU/100 cm²	CFU/40 in²
Aerobic Plate Count (APC)	Target	< 50	< 100	< 5	< 10
	Acceptable	< 500	< 1000	<50	< 100
Coliforms	Target	< 5	< 10		
	Acceptable	<50	< 100		
Yeast & Mold	Target	< 5	< 10		
	Acceptable	<50	< 100		

Due to the variable conditions found within each facility, each facility should establish a baseline of microbial results that can be achieved under an effective sanitation program. With these data established, a facility can then trend microbial results. An upward trend or sudden increase in microbial numbers should then initiate an investigation and corrective action.

Corrective actions should be taken and documented whenever the results are above the specified limits or trending towards the upper limit. If out-of-specification results are obtained, swabs should be repeated after taking correction to ensure the action taken has been effective. One technique would be to repeat verification testing until three consecutive acceptable results are obtained.

Ideally, routine swabbing before sanitizing is recommended to verify the effectiveness of cleaning procedures. To verify the effectiveness of the entire sanitation process, periodic swabbing after sanitizing can be performed. If swabs are taken after sanitizing, proper buffer solutions must be utilized to prevent inaccurate results. Whether swabbing is performed before or after sanitizing, the sequence of swabbing should be consistent to help establish a baseline for reference. The individual performing swabbing must receive proper training.

Adenosine triphosphate (ATP) measurements are based on the detection of ATP by bioluminescence and can be an initial tool in monitoring the cleaning efficiency after a visually clean standard has been met. It is a rapid measurement of the actual hygiene status of a sampled surface that allows fast initiation of corrective actions in case of inadequate cleaning. However, ATP measurement should not completely replace traditional techniques (i.e., microbiological swabbing), and therefore should be integrated with traditional cultural techniques as part of a coherent surface cleanliness monitoring system. Although manufacturers of ATP measuring devices give general guidance on acceptable ranges for routine hygiene controls, internal standards have to be set for the given processing environments. Additionally, these standards do not necessarily transfer from one brand of ATP measuring devices to another, so a change in equipment should be accompanied by the setting of new internal standards.

Results from sanitation monitoring programs (visual inspections, equipment teardowns, and microbiological monitoring data) should be collected and trended for analysis, and corrective actions and preventive measures should be implemented if needed. The overall monitoring program should be periodically reviewed for effectiveness (at least every two years).

6.8.5 Clean Equipment Swab Program for Dry Product

The specifics of a Non-Pathogen Environmental Monitoring Program could vary dependent on the nature of the product and the food manufacturing environment (equipment and infrastructure). A suggested program could include the following:

- Swabs should be tested for aerobic plate count, coliform, yeast, and mold a minimum of once monthly per equipment unit.
- Swabs should be taken after sanitizing for routine verification, or after cleaning the equipment but prior to the addition of sanitizer for special circumstances
- Examples of swabs that could be used include Culturette Transwab™, Cotton, Rediswab™, Quickswab™.

6.8.6 See chart above for guidelines on clean equipment microbiological limits.

The facility should take appropriate corrective actions for out-of-specification results. Suggested actions include the following:

- The appropriate facility personnel should be notified when out-of-specification results are obtained.
- Review sanitation procedures to ensure they are appropriate and that the employees are following the procedures correctly.

- Identify possible microbial harborage areas and potential sanitary design deficiencies.
- Thoroughly clean/sanitize and dry the positive site and the surrounding area. Use dry, controlled wet and/or wet cleaning, as appropriate. See GMA/CBA guidance on *Salmonella* control for recommendations for controlled wet cleaning (GMA, 2009).
- Re-sample out-of-specification swab sites after corrective actions have been taken. One technique is to continue re-sampling until a minimum of three consecutive results are acceptable. If re-sampling results remain out of compliance, possible corrective actions could include:
    - Break down equipment further and inspect for microbial harborage areas.
    - Re-sample the equipment to identify potential niches.
    - Re-clean the line while it's disassembled.
    - Further investigate and validate cleaning effectiveness prior to startup.
- Corrective actions and preventive measures should be documented.

A chemical control program for the storage and use of cleaning and sanitation chemicals as well as other chemicals (e.g., pesticides, fumigants, non-food chemicals) used in or around the facility should be in place to eliminate the possibility of cross-contamination of product, ingredients and/or packaging materials. All chemicals should be properly labeled and stored in an area separate from food storage areas, and the chemical storage area should be accessible to appropriate personnel only.

6.9 Pest Control

A documented pest management program should be in place to effectively monitor and control pest activity in the facility and the surrounding area. To reduce the risk of product contamination for pest control practices, pest control activities should be performed by certified pest control contractors or facility personnel with equivalent training. If a contracted service is used, the facility may need to keep a copy of the valid contract and a copy of the license, given by the relevant local authority and including insurance coverage.

Pest management practices (i.e., strategies of exclusion and trapping of pests) or alternative methods and tools for controlling pests are preferred over pesticide use and should be employed wherever feasible and practical.

Exclusion should be the first line of defense and primary method of controlling pests. Some external building practices that aid in keeping pests out of the building include:

- Eliminating all possible entrances into the facility.
- All doors, windows, and screens should fit tightly. Note that a mouse can enter through ”" (1 cm) openings.
- Doors should be kept closed.
- Pipe openings through facility walls should be sealed.
- Exterior product transport pipes should be capped when not in use.
- High grass and weeds around the facility or in adjacent areas should be eliminated where possible since these provide excellent hiding areas for rodents.

- Maintain a vertical border free of vegetation (e.g., 3-ft wide/3-ft vertical border from the ground to above the roof around the building perimeter including tree limbs and shrubs).
- Scrap, pallets, pipes, drums, etc., should not be accumulated on the grounds or parking lot.
- Metal refuse containers should have tight-fitting covers and be stored on racks.
- All rat holes and burrows should be closed.
- All ingredients, equipment, and supplies received should be inspected upon receipt for rodent excreta or any signs of gnawing and chewing on the containers, since mice often enter the facility on supply loads.
- All openings on wall and roof penetrations should be screened to prevent insect or rodent ingress.

The overall cleanliness of the facility, proper sanitation, housekeeping, and storage practices help control pests by removing food and harborage.

One rodent trap technique is to set rodent traps in three perimeters of control (lot line, exterior of the building, and interior of the building). Rodent traps are recommended on interior ground level floors and basement levels of facilities. A complete and accurate map should be maintained showing the location of indoor rodent traps, glue boards, insect light traps, outdoor bait stations, pheromone traps, etc.

Chemicals used for pest control should be accurately labeled and inventoried. When chemicals are not in use, they should be securely stored (by locked door/gate) with access granted to authorized and designated personnel only. Insecticides should be applied according to label.

Baits should be used in situations where a specific pest is the target. Where used, bait stations should be of solid construction, tamper-resistant, and secure.

Many variables should be considered when determining which pest control chemical to use. In general, rodenticides should be used in block form only (rodenticidal granulates, pellets, or powders should not be used) to reduce the risk of product contamination. Rodenticides should normally be focused on the outside of the facility. Traps rather than bait stations are preferred for use inside of a building.

Light bulbs from insect light traps should be replaced regularly (as per manufacturer specification) for the maximum efficiency of these type of traps. The insect light traps should be installed in the receiving or warehouse areas close to entrances but should be located so as not to attract insects into the building. Light bulbs should be shatter resistant.

Routine inspections should be conducted at a frequency necessary to identify pest activity, harborages, and entry points. Pest activity inspection results should be recorded along with the application of pesticides. Documentation of pesticide use should include: the brand name of the pesticide, traceability information (e.g., lot numbers), quantity applied, the method used to apply the pesticide, targeted pest, and time of treatment. All pesticide labels and Safety Data Sheets (SDS), or equivalent material, addressing safety precautions should be available at the facility. Pest activity data should be analyzed to show trends in activity and, if pest activity is noted, controls should be increased appropriately.

6.10 Control of Raw Materials and Products

6.10.1 Control of Raw Materials

Incoming Raw Materials, Ingredients, and Packaging: Supplier Management

All nut processors should have a program in place to approve their own suppliers. The safety of finished products produced in a facility is influenced by many factors. One very crucial factor is the integrity of incoming goods: raw materials, ingredients, and food-contact packaging. All nut processors should have a program in place to ensure that these goods are sourced only from approved suppliers to make sure they are capable of providing safe and high-quality ingredients on a consistent basis. It is a prudent practice for the nut processor to purchase only from those suppliers who are approved.

Food safety expectations, requirements and/or specifications for purchased goods should be developed, documented, and provided to suppliers. Suppliers of purchased goods should be monitored and tracked relative to their performance and compliance to the safety requirements, expectations, and specification requirements on an ongoing basis. Feedback should be provided to the suppliers to facilitate continuous food safety improvement.

In some instances, based on the hazard analysis and the point in the supply-chain the hazard is being controlled, there may be a regulatory requirement for a supply-chain program. This is described in Chapter 5.

Previously, GMA had developed a handbook that can be used as a guideline for supplier approval. For further reference for supplier management see GMA's 2008 *Food Supply-Chain Handbook*.

Incoming Raw Materials, Ingredients, and Packaging: Inspection and Testing

All nut processors should have a program in place to evaluate their incoming raw materials, ingredients, and packaging material. The processor should have controls in place to assure incoming materials comply with specifications, including biological, chemical and physical criteria (see Chapter 2). Testing requirements, parameters, and specified limits to assure food safety for all raw material, ingredients, and packaging material should be established and available. Practices and techniques often used in the industry may include:

- Raw agricultural commodities. Raw agricultural commodities are evaluated to determine if pesticide residues comply with established standards. This evaluation may be conducted through analysis of the commodity or through communication with and oversight of the grower, producer, and other persons handling the product. Special care should be taken to assure that only pesticides approved for the specific purpose are used on or100ndustnd products. If suppliers are subject to the Preventive Controls rule and are not controlling identified hazards, they need to share documentation related to the treatment status of the ingredient.
- Delivery vehicles. Prior to accepting incoming materials, it is a good practice to verify that delivery vehicles (such as trucks or railcars) have maintained the safety of the involved materials during transit. Such verification activities may include inspection of internal cleanliness, structural integrity, seal

integrity, and internal temperature for items (as appropriate for the materials). State or local regulations may have specific requirements. Loads suspected of any type of tampering should be investigated. If it is determined the load has been tampered with, and the source of tampering cannot be determined, the customer should consider rejecting the product.

- Verification of seal integrity. When inbound truckloads and rail shipments are sealed, receiving personnel verify that the seal numbers match the transportation documentation (e.g., bill of lading) upon arrival at the facility.
- Tankers or other bulk shipments. Tankers should be dedicated to food only.
- Tankers should be clean and sanitized prior to use. Records should be available for the previous product shipped.
- Product acceptance. Incoming product should not be used until it has been verified as conforming to specified requirements. This may involve the use of a Hold and Release procedure, especially when pathogen testing is conducted.

Incoming Raw Materials, Ingredients and Packaging: Specification Compliance

Nut processors should assure that authorized specifications are in place at the production location. Appropriate plant personnel should have access to the latest specifications for materials. Where Certificates of Analysis (COAs) are part of the specification requirements or have been separately requested by the customer, these must be received prior to acceptance of the material at the customer locations (i.e., COAs must precede or accompany each shipment of material). If a pathogen test of the material is required by the customer, the test must be performed by an accredited laboratory. The customer may reserve the right to sample each delivery and disposition accordingly. Lot numbers should be dedicated to one facility and not shipped to multiple customer facilities or multiple customers. For U.S. locations, supplier (“seller”) is required to provide the customer (“buyer”) a Continuing Pure Food Guarantee that is signed by authorized agent of the supplier.

6.10.2 Receiving, Storage and Distribution

Nut processors should assure that materials are stored according to specification and controlled in a clean and secure environment, appropriate for the specific material involved. Designated storage areas or stock rooms should be used to prevent damage, deterioration or tampering of material. To detect deterioration, due to such things as pest infestation, unsanitary conditions, and temperature/humidity control abuses, the condition of product in stock should be assessed at appropriate intervals.

Considerations for storage areas or facilities include the following:

- Materials should be stored away from the walls to aid in sanitation and pest control. For example, spacing equipment or material storage 30-50 cm/12-18 inches from walls.
- Damaged bags or drums must be sealed to prevent product spillage and contamination. Ingredients contaminated through damage should not be used without an evaluation due to possible extraneous, microbiological, or allergen contamination. Spills should be cleaned up to prevent potential for infestation or cross-contamination.

- Procedures should be in place that identify and track shelf life of raw materials and release status of finished goods. An effective stock rotation system should be in place.
- Temperature/humidity-controlled versus ambient conditions should be provided as required per specification. Storage temperatures and humidity (where applicable) should be measured and documented using calibrated recording equipment.
- Storage should be off the floor. Pallets, racks, and equipment should be maintained in good condition to prevent physical damage (free from nails, splinters, etc.).
- Airflow from heaters, refrigeration units, etc., should be directed away from products. Direct sunlight on product should be avoided where possible.
- Glass containers should be isolated from products during storage.
- Products with strong odors should be segregated to avoid odor migration.
- Bulk storage of liquid ingredients susceptible to microbiological spoilage should have adequate controls in place to prevent spoilage or contamination (e.g., insulated, temperature-controlled, and monitored).
- Where packaging materials are not in individual containers (e.g., film roll stock, cartons, etc.), the pallets should be covered and stretch wrapped, shrink wrapped, strapped, or net wrapped to maintain integrity and prevent potential for contamination.
- Pallets used for food products should be in good condition: clean, no broken boards, no evidence of mold or infestation, and no off-odors.

Appendix Q describes additional considerations for proper storage practices. Considerations for distribution may include:

- Procedures in place should assure that products are pre-chilled to required temperature prior to loading, and vehicles are pre-chilled prior to loading for distribution (where applicable).
- Temperature-controlled vehicles should carry suitable on-board temperature monitoring devices. The devices should be verified at defined intervals.
- Deliveries should be on clean, dry, undamaged pallets (or slip sheets), free from off- odors and wrapped according to customer specifications.

  Trucks should be verified to be in good condition, dry, clean, and free of off-odors before loading.
- Additional requirements for bulk tankers: cleaning certificates should be available, and verification frequencies for equipment sanitation should be specified. The frequency should take into account the microbiological sensitivity of the material transported.
- Inbound and outbound bulk containers should be sealed. Examples of acceptable seals include:
  - Drums with a locking ring secured with a numbered seal and number annotated on the shipping documentation.
  - Drums without a locking ring secured with tamper-evident tape readily identifiable with the supplier's name and logo.
  - Large bags, such as super-sacks or totes, containing plastic liners having a bag closure that will readily reveal any tampering and will not permit removal and reinstallation without breaking the seal.
  - Corrugated cases effectively sealed with tamper-evident tape, readily identifiable with the supplier's name and logo.

- When possible, all openings (doors, inspection ports, hatches, etc.) on outbound shipments (including outbound trailers) should be sealed with a numbered seal and the seal number(s) annotated on the shipping documentation.

In cases where third party warehouses are used to store raw materials, packaging materials, semi-finished or finished products, periodic assessments should be conducted to assure that the nut processor's requirements are met.

6.10.3 Product Tracing and Recall

Companies should have an effective program for traceability of all ingredients used and finished products produced. Special care should be taken not to create "blind spots" when ingredients are procured from brokers or distributors. Nut processors should assure that traceability is maintained back to the supplier. The processors should have the ability to trace one step back and track one step forward the movement of ingredients and finished goods through the supply-chain. Being able to locate where all ingredients, including food contact packaging, came from and where all finished goods were sent may be useful in the event of a recall or crisis. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, also known as "The Bioterrorism Act" or the BT Act, mandates that all members of the food chain shall be able to trace goods one step forward and one step backward, as well as know the shipper/transporter of the goods.

Processors must at a minimum trace back to the immediate previous physical location of the ingredients. Simply knowing the address of the broker is not adequate. The manufacturer can be identified either on the label or the bill of lading from the broker/distributor. If requested, a supplier should provide such information to the customer, especially in the event of a product-related issue such as a product recall involving products containing this ingredient.

This program should enable traceability of all components used in the manufacture of the specific lot, including all raw materials, primary packaging, printed packaging and labels, pre-mixes, rework, work in process, etc. Upon receipt at the facility, the ingredient's lot number(s) should be documented. Where internal plant identification systems are used, these should link back to the original lot code in receipt records. For ingredients that may not have a specific lot number, a method for unique identification and tracing should be developed and implemented. Bulk use of ingredients should be required to have a documented time frame of known use. Each component should be clearly identified and coded to enable traceability back to the lot or source and traceability forward to the material containing the component.

All production runs should be identified with lot numbers that enable complete linkage from raw material receipt through final packaging. Traceability should be maintained to enable linkage back to the date of manufacture and location for all finished packages.

Annual mock (simulated) recalls should be conducted to validate the effectiveness of the traceability process. It is recommended that representative samples from all lots produced be kept until the expiration of the material.

6.10.4 Hold and Release

Nut processors should assure that a written Hold and Release control program is in place with roles and responsibilities clearly established. The Hold and Release system should include the processor's premises and any contracted facilities.

The program should include controls for non-conforming raw materials, materials pending pathogen testing, COA verification, packaging, labels, work-in-progress, finished product, and rework. Records must be maintained to enable reconstruction of each hold event's history.

An example of a hold/release procedure is one that addresses at least two levels of holds: e.g., a major or critical level (Category I hold) and a second level (Category II hold):

- Category I Hold is used for cases when a non-conformity poses a potential food safety, major regulatory or major quality concern. The affected product must be placed in a segregated and secured area or physically obstructed. Inventory must be visually confirmed daily. Each shipping unit must be visibly marked.
- Category II Hold is used for cases when a non-conformity poses a potential product quality or minor regulatory concern. Computerized hold may be sufficient if the system effectively blocks selection and shipment. Each shipping unit should be visibly marked.

If any product (including raw materials, rework, intermediate product, or processed product) is tested for pathogen presence, the material should be placed on a Category II hold pending pathogen test results or COA verification. If pathogen test results are positive, the material must immediately be placed on Category I hold. Materials that potentially contain unlabeled allergens should be placed on Category II hold. If the material is determined to contain unlabeled allergen (e.g., due to mislabeling), it should be immediately placed on Category I hold.

If pathogen testing is initiated on either a lot/code of product or any ingredients used in the lot/code of product, it should be completed before the release of the ingredients for production or the release of the lot/code of product to the customer. Effective pathogen testing hold and release controls are necessary to prevent the release of product undergoing pathogen testing prior to obtaining acceptable test results.

When any material produced for the customer is either inadvertently released from hold or is suspected of non-conformity but has already been shipped to the customer, the customer contracting representative must be notified immediately.

6.10.5 Non-conforming Products

Products with (but not limited to) the following defects should not be shipped to customer:

- Products found to deviate from critical parameters of a preventive control

- Products found to contain pathogens or toxins
- Products found to contain extraneous material
- Products found to contain allergens not declared on the product label
- Products found to have illegal chemical residues (e.g., pesticides or heavy metal contamination)
- Products that fail to meet regulatory standards

Disposition of held materials should be effectively managed, documented, and controlled. Documented procedures should be in place for the identification, documentation, evaluation, segregation (where practical), and determination and execution of the final disposition of non- conforming products.

Rejected material should be clearly identified. The reason for rejection of the material, code dates, quantity involved, and its disposition should be noted on the batch/lot record. Records of actions and outcomes should be maintained (for example, certificates or other evidence of product destruction or burial). Disposition should be completed in a timely manner.

Nut processors should assure that written retrieval procedures are in place that promptly and effectively respond to product issues that represent an unacceptable risk to customers and/or the consumer. Retrieval procedures may include:

- Defined notification procedures including contact lists and customer contacts
- Protocol for retrieval and disposition of all affected product, with designated authority and assigned responsibilities to assure that sufficient controls are followed to allow for complete retrieval of product
- Identification of delivery points, dates, and quantities for affected product delivered further into the supply-chain or to customers
- Protocol for isolation of affected stocks and/or materials remaining under control

The retrieval system should be tested within the scope of the facility's control on an annual basis and after any major system changes to confirm the accuracy of all product and contact data and the continuing effectiveness of procedures and traceability systems. The results of these tests and any corrective actions necessary should be documented.

6.10.6 Rework Control

The nut processor should have a system in place to control the use of rework material in any product. If rework is to be reincorporated into product as an 'in-process' step (not simply repackaging or re-casing finished product), then the product formula and/or specifications, and equivalent local documents should clearly state the type and quantity of rework that can be added to the target product. In addition, procedures should be in place for conditions of storage, reprocessing steps in which it will be added, method of addition, identification of allergens, shelf life, special handling requirements, and lot number identification for traceability. For rework potentially containing allergens, see the Allergen Management Section 3.7.2.2 for further guidance.

All rework should be handled and stored in a manner that assures the maintenance of product safety. Rework should be protected from exposure to microbiological, chemical, or extraneous matter contamination risks. All rework should be clearly identified with product name, production date, and any other relevant information. Amounts and identification used should be documented on production records to assure complete traceability.

Use of rework should not violate any regulations, including labeling requirements, for the use of specific materials in the target product. For example, use of rework should not cause the nutritional data information provided to the customer to be incorrect.

Where rework activities involve removing product from filled or wrapped packages, there should be effective controls to assure the removal and segregation of all packaging materials to avoid extraneous matter contamination of the product (e.g., use of appropriate sieves, filters, metal detectors).

Rework inventory and usage controls should be in place, including stock rotation practices to assure that the oldest rework is used first. Procedures should assure that rework is disposed of when it has expired.

6.11 Extraneous Material Control

Foreign materials may enter a nut processor's product stream at many locations. Shell fragments, agricultural debris, machine parts that have fallen off, and shavings from metal- to- metal contact all can deposit unexpected foreign objects of public health significance into finished products. This Section describes control measures to address extraneous matters in a prerequisite program. In the event metal is identified as a hazard reasonably likely to occur given the prerequisite programs in place, it should be controlled by a PC/CCP (see Section 2.4 in Chapter 2 for guidance).

A variety of devices are available to nut processors to limit the presence of foreign materials. Nut processors may want to consider the use of these devices, where appropriate, to minimize the potential for product to contain foreign material. Foreign material control devices should, where necessary, be placed in the process flow in the location(s) where they will have maximum product protection and effectiveness. Control devices should be routinely calibrated and checked.

Appropriate strategy for minimizing extraneous matter should be developed based on a hazard analysis, including:

- Confirming control strategies at suppliers or sources of materials
- Designing the risk of extraneous matter out of the process (e.g., eliminating metal-to- metal contact on equipment, replacing metal screens with Nitex™ or equivalent)
- Preventing introduction of extraneous matter into the product (e.g., cGMPs, equipment design, preventive maintenance, covers on tanks or conveyor belts)

- Detection and removal of extraneous matter (e.g., installation of strainers, screens, filters, magnets, sieves, metal detectors, X-ray, or other devices/programs deemed necessary on the line).

Detection and removal devices should be managed in such a way to maximize the effectiveness of these devices. Devices installed throughout the production line should be adequate to address the risks identified, including the type of device and established detection limit. For example, when screens are used in sifters for free-flowing powders (for example, salt, sugar, starches), the use of nylon screens (e.g., Nitex™ or equivalent) is recommended. If nylon screen is not available and it's necessary to use metal screens, 400 series stainless steel screens should be in place with a control program (e.g., a screen inspection program and rare earth magnets following the metal screens) to assure that screens for all products are intact and operational prior to production and at the end of each production run. Screen sizes should be selected based on maximum ability to extract foreign material.

When a metal detector is used, a functionality verification method should assure 100% detection and rejection of the test piece(s). An example of such verification could be at the start of production each day and at each package or product change, two passes of each test piece (ferrous, non-ferrous and stainless steel) should be detected and rejected.

Consideration should be given to using a combination of leading edge and trailing edge passes where possible. The verification test pieces/packages should be clearly identified and differentiated from product. If a metal detector is not working at its design limit (e.g., if it fails to detect a test piece), the material produced since the last time the metal detector was verified to be operating at its design limit should be placed on hold.

The metal reject mechanism 107houldd direct product rejects from the process flow automatically into an identified area, bin, or container. An action level based on the number of rejects and the size of the fragment should be defined on the basis of historical trend analysis. If this action level is exceeded, then all diverted packages or product rejects must be evaluated to determine the cause for rejection. Action limits should be available to the responsible operator, and corrective actions described. Action limits should include unusual findings and excessive rejects that would trigger an immediate corrective action. All the findings should be documented. The responsibility and methodology for evaluating rejected packages should be specified and documented.

When glass and hard plastic exist in the production area, a specific program should be in place for the management of these materials. The same should be applied to devices that can be a source of extraneous matter when damaged (e.g., sieves). Appropriate and timely corrective action should be implemented in case of any source of extraneous matter with a potential of falling into the product.

Examples of foreign material control devices and guidelines for their effectiveness:

Metal detectors

- Often used for end product testing or located as close as practical to end product packaging.
- In-line metal detectors are also available. These are often used when finished product packaging contains metal or is too large (50-lb cardboard boxes) to run through most metal detectors.
- Metal detectors function well with an automatic reject or conveyor stopping mechanism and an alarm where appropriate.
- The units can be calibrated for effective rejection of product containing metal at the time of installation and tested during production to ensure rejection of appropriate test pieces.
- Most metal detectors should be calibrated to specific products. Changes in consistency or polarity (e.g., due to salt content) can affect performance.
- It is often useful to trend metal detector rejects to define a normal level of rejects, both for cause and for false rejects (rejects where no metal is found). If the rejection rate for either of these historical rates is exceeded, corrective actions can ensue.

The detecting limit for an end-point metal detector will depend on type of product, package, and the detection equipment. Detection equipment settings should be determined and applied to achieve the most sensitive level possible to provide maximum protection from metal contamination. As a guide, the detection sensitivity under production conditions should be capable of detecting and rejecting pieces equal to or less than:

- 1.5 mm for ferrous
- 2.0 mm for non-ferrous (brass)
- 2.5 mm for stainless steel (316 grade)

Functionality verification for electronic detection and rejection devices should take place during production with the normal product flow. Examples of frequency for system verification could include:

- Start-up (e.g., the beginning of each shift or production start-up if part way through a shift)
- End of each shift
- After a production change (e.g., product or primary packaging changeover)
- Following any repairs, maintenance, or adjustments
- On a regular basis as determined by the site (e.g., every four hours)

An example of a company-specific metal detector program is shown in Appendix R.

Magnets

- Rare earth construction provides the strongest, most aggressive magnets.
- Magnets should be tested for effective placement, coverage, and pull strength at the time of installation, and routinely thereafter.
- Magnets, like all foreign material control hardware, should be routinely monitored and the results of this monitoring should be recorded.

Filters Screen/Scalper/Sifters

- These devices should be routinely checked for breakage and proper placement.
- For maximum efficiency, these should utilize a mesh size that is the smallest possible but does not restrict product flow.

Other Devices

- Cyclones
- Tilt tables
- Flotation or water tanks
- De-stoners
- Optical sorting equipment
- Strategically placed protective line covers
- Bottle/jar washers, inverters, rinsers, and other pre-filling clean-out devices
- X-ray or other vision control systems

A common practice is to have written procedures describing the maintenance, set-up, and verification tests required of specific foreign object control devices. An effective procedure normally describes the initial set-up and frequency of verification checks during the shift, if any, and at the end of production. The same procedure often addresses corrective actions to be taken if the foreign material control device is found to be compromised (metal detector not working, hole in a screen or filter) including disposition of affected product. It is advisable to record the results of all monitoring tests.

6.12 Corrective and Preventive Action (CAPA)

The nut processor should develop documented procedures for implementation and tracking of corrective and preventive actions. An effective corrective action program should assure that non-conformities are dealt with in an appropriate and timely manner, analyzed to determine their root cause, and action taken to prevent their recurrence. Preventive action procedures should address actions to identify and prevent potential non-conformities of processes, products or the Food Safety Management System.

Data sources should be analyzed and aligned with the following aspects:

- Out-of-specification process or product (manufacturability)
- Products found to deviate from critical limits of a PC/CCP
- Customer/Consumer feedback, including complaints
- Failure to meet external, regulatory, or customer requirements
- Issues arising from internal or external audits, including regulatory inspections and contacts
- Product retrieval
- Supplier performance measures

The corrective action program should address proper means of managing incoming customer contacts to enable an accurate, appropriate, and timely response. The procedure in place should include the following steps:

- Identification of CAPA opportunities
- Determination of immediate action(s) to be taken (including responsibility and timing)
- Root cause analysis and quantification of the problem (prioritization)
- Identification of long-term (permanent) solutions (including responsibilities and timing). When required, resources (personnel, capital, equipment, etc.) should also be identified
- CAPA plan implementation
- Further analysis of data to validate if the desired results were achieved (e.g., was the plan effective in resolving the root cause)
- Periodic review of CAPA by the management team

6.13 Laboratory Operations

All plant laboratories and laboratory personnel should comply with good laboratory practices, including:

- A procedure for the identification of samples submitted to the laboratory should be implemented in such a way as to assure traceability from the sample to the reporting of a final result.
- Laboratory chemicals with high toxicity, bacterial positive control cultures, and solvents not in immediate use must be secured and locked, with access restricted to authorized personnel. A secured laboratory (access controlled, locked when not occupied, and inventoried periodically) is adequate for the storage of chemicals used on a routine basis. Laboratory materials should be restricted to the laboratory, except as needed for sampling or other appropriate-use activities. Unexplained additions and withdrawals should be immediately investigated and reported to appropriate law enforcement and public health authorities, as well as to the customer.
- Positive control, tracking, and disposition of sensitive materials should be in place.
- Pathogen testing required for materials delivered to the customer should only be performed by laboratories that have been approved by the customer. If the processor has an internal pathogen laboratory, special requirements should be applied. The lab design and practices should prevent potential for cross- contamination with pathogens:
    - The lab for pathogen testing should be in a building separate from production.
    - Access to microbiology laboratory facilities should be restricted to authorized personnel only. Positive access should be controlled by use of devices such as card keys. Signs should be posted to advise that the area is restricted.
    - Any potentially infectious material should be sterilized prior to disposal.
    - Air relative pressure of the pathogen laboratory should be negative to the adjacent rooms. The make-up air for the lab should be filtered at

95% efficiency at 1-micron filter and the intake should be airtight to prevent entry of microorganisms. Exhaust air ducting should be airtight, and the exhaust vents not located near intake vents. If the exhaust air is located near the intake, the exhaust air should be HEPA-filtered. All windows should be secure against opening (except as emergency exits) and the plating/transfer room should be physically separate from the entrance area of the laboratory if the lab does not have an entrance vestibule. Handling of pathogens is performed in the specific pathogen laboratory room or under a microbiological safety cabinet, Class II. Facilities should be available near the laboratory exit door for storing protective covering (coats, smocks, aprons). Additional guidance on good laboratory practices is available in the literature (Scott and Walls, 2003) and from the CDC guidance "Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition". GMA/CBA has also published a 2016 Guidance on Laboratory Selection and Evaluation.

6.14 Training

Nut processors should determine the necessary competence for personnel performing work affecting food safety across all functions (e.g., production, maintenance, logistics), and provide training or take other actions to satisfy these needs. In the revised cGMPs updated in the Preventive Controls rule, FDA introduced the term "qualified individual". The rule requires that all individuals with a role in food safety must be trained on their specific role.

This training must be documented. They should evaluate the effectiveness of training and maintain appropriate records of education, training, skills, and experience. In addition, a Preventive Controls Qualified Individual, who is qualified either by training or experience, has defined roles and responsibilities related to the development and implementation of the FSP.

Training for production employees (including seasonal and/or temporary) must include a general awareness of the principles of food safety and quality including hygiene and cGMPs, and should include topics such as allergens, Food Defense and foreign object prevention. Refresher training should be provided periodically, e.g., annually. Training should be provided for new employees before starting work in production. Site-specific programs should include any necessary information and instruction for visitors and contractors prior to performing activities that may affect product safety. A method of assessing the effectiveness of the training (i.e., testing or visual observation) should be used.

Employees responsible for implementing or monitoring preventive controls need to have documented specific training including monitoring, documentation, verification, and corrective actions if the critical limits/ parameters are not met.

6.15 Sanitary Transportation

Nut processors must ensure that their incoming raw materials and supplies, as well as their outgoing finished products are transported under conditions that meet Sanitary Transportation requirements.

Nut processors should, at a minimum, conduct and document inspections of incoming carrier loads, noting any conditions of the product or trailer which may have caused the goods to become contaminated. If conditions exist, the situation must be evaluated to determine if the risk is such that the entire load should be rejected.

Prior to loading finished product, the trailer or vessel should have a thorough documented inspection to ensure that the product will not potentially become damaged or contaminated during transport. If this potential for harm exists, the carrier should be rejected.

Items to consider during trailer/vessel inspection:

- Physical damage
  - Holes in roof or missing/damaged door gaskets can allow the product to get wet
  - Damage to the side walls can penetrate finished product package
  - Openings in the side walls can create a potential harborage point for pests.
- Off-odors
- Potential for cross contamination from the trailer or other cargo (LTL). Contamination could be microbial, chemical, or allergen.
- Temperature controls (if applicable)
- Sanitation / cleanliness
- Security measures (padlock, numbered seals, etc.)

Chapter 7

PATHOGEN ENVIRONMENTAL MONITORING PROGRAMS

7.1 Introduction

The food processing environment plays a major role in the microbiological safety of nuts and can lead to contamination of product unless effective controls are in place. According to the International Commission of Microbiological Specifications for Foods (ICMSF), the microbiological safety of industrially manufactured foods is based on the effective design and implementation of current Good Manufacturing Practices (cGMPs) and Food Safety Management Systems, such as the FDA Preventive Controls rule or a Hazard Analysis Critical Control Points (HACCP) program as described in Chapter 2 (ICMSF, 2002). Even when controls are applied to a food product to ensure reduction of pathogens to acceptable levels, recontamination from the processing environment (known as post process contamination) remains a serious concern.

The Preventive Controls rules establish requirements for certain domestic and foreign human food facilities to develop and implement hazard analysis and risk-based preventive controls. If a hazard analysis indicates that contamination by environmental pathogens is a reasonably foreseeable hazard, then the manufacturing facility must implement a preventive control or a group of preventive controls to significantly minimize or prevent such potential contamination. In addition, verification procedures such as a Pathogen Environmental Monitoring Program (PEMP) are also required. FDA stipulates that environmental monitoring must be implemented if contamination of a ready-to-eat (RTE) food with an environmental pathogen is a hazard requiring a preventive control (FDA, 2015).

An environmental pathogen, as defined by FDA in the Preventive Controls rule, is a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. The environmental pathogen relevant to most nut processes is *Salmonella* spp., although *Listeria monocytogenes* (*L. monocytogenes*) should also be considered in a facility's Food Safety Plan (FSP) hazard assessment. A PEMP could target the environmental pathogen identified in the hazard analysis, or an appropriate indicator organism (such as *Listeria* spp.). However, FDA has stated in the preamble to the rule that they do not recognize an indicator for *Salmonella*.

The Preventive Controls rule for human food (21 CFR 117.165(a)(3) and 117.165(b)(3)) and food for animals (21 CFR 507.49(a)(3) and 507.49 (b)(3)) stipulates the requirements for environmental monitoring as a verification activity. Environmental monitoring is appropriately used as a verification activity in areas where RTE food may be exposed to environmental pathogens, such as in areas where product is packaged, or adjacent operations.

For low moisture foods, such as nuts, *Salmonella* contamination has long been a concern (GMA, 2009). Of particular relevance to the nut industry is the ability for *Salmonella* spp. To survive for long periods under dry conditions, both in the environment and in food products (Harris et. Al. 2019). For example, studies have shown that *Salmonella* Enteritidis Phage Type 30 can survive for up to 550 days on almond kernels held under a variety of common storage conditions (Hiramatsu et al, 2005; Uesegi et al., 2006). *Salmonella* Tennessee and *Salmonella* Typhimurium DT104 have also been shown to survive well in a peanut paste held at 20°C for 1 year (Kataoka et al., 2014). Studies have also shown that *Salmonella* spp. Can survive for long periods of time in foods and in a farm/food plant environments when they become desiccated (Hiramatsu et al., 2005). Given the history of *Salmonella* contamination of nuts, and its ability to survive for long periods of time in the processing facility and in the finished product, it is considered a significant pathogenic hazard in nuts (Yada et. Al. 2019).

Listeria is found naturally in the environment in which nuts grow and may be more prevalent on those harvested off the ground. *Listeria* cross-contamination from the environment, raw product, or personnel may also be of concern. *Listeria monocytogenes* has shown the ability to survive on almonds and pistachios unchanged for up to a year when frozen or refrigerated, although population decline rates ranged from 0.71 log CFU/g/month and 0.86 log CFU/g/month, respectively, when stored at room temperature (Kimber et al. 2012).

Studies have also shown the ability for *L. monocytogenes* to survive for several months on walnuts stored at room temperature even when initial levels were low (Blessington et al.
2012). *L. monocytogenes* has not been implicated in any outbreaks to date but has been the cause of recalls involving nut products including cashews, almonds, macadamia nuts and walnuts (Yada et. Al. 2019).

An effective PEMP should be developed with the purpose of aggressively seeking out, destroying and preventing the establishment of pathogen growth niches before they lead to product contamination. However, each facility should design their PEMP to address all environmental pathogens of specific concern for their product(s) and operation including *Salmonella* and *L. monocytogenes.* It cannot to be overemphasized that early identification of *Salmonella* or other pathogens, through a PEMP and subsequent interventions, is crucial for ensuring food safety. Those engaged in collecting environmental samples must be encouraged to aggressively find sources of contamination so that they can be eliminated before becoming an issue affecting product.

It is important to stress that an environmental monitoring program is a verification activity, and not a control program. The PEMP should be designed to verify that current Good Manufacturing Practices (cGMPs) and Environmental Control programs, such as facility and equipment sanitation, facility (hygienic) zoning, equipment design, air flow, personnel practices, and water and traffic controls are effective in preventing post-process contamination. A well-executed PEMP is a more preemptive and effective use of microbiological testing resources than ingredient or finished product testing. This is because contamination of a product is often sporadic and at low levels, whereas environmental niches may be expected to have higher levels that are more readily detectable (Tompkin, 2002).

The intent of this chapter is to provide information to the nut industry to help them design a PEMP to verify efficacy of Environmental Control and cGMPs programs. The document will discuss five components of a PEMP:

1. Zoning principles
2. Sampling location, frequency and target microorganism(s)
3. Sampling procedures
4. Laboratory methodologies
5. Corrective actions

This chapter will also discuss the need to conduct extensive investigative sampling when a potential harborage is identified, when to escalate environmental monitoring activities, and when to consider finished product testing. Using these techniques over time with appropriate data analysis and corrective actions will help to reduce the likelihood of contamination with a pathogen such as *Salmonella* spp., and thus reduce the overall incidence of consumer illness.

7.2 Hygienic Zoning and Hygiene Areas

As cited in the FDA's Preventive Controls, 21 CFR 117.135 ©(3)(ii), "Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product." Hygienic zoning (HZ) maybe employed to minimize transfer of microbial hazards from one area to another, protecting both the product and the processing environment in which exposed RTE product and materials are handled. The basic concepts of HZ include the separation of one manufacturing area in a facility from another based-on risk and sanitation control. Segregation between wet and dry areas, "dirty" (relatively speaking) and clean areas, and raw material and finished product areas (before and after a pathogen reduction step) are examples of areas that may be classified into different hygienic zones. Physical barriers, cleaning procedures, employee practices and control of movement of people, equipment and materials are practices that may be used to implement HZ.

Depending on the type of operation, a facility may generally be divided into one to four different hygiene areas (in addition to the non-processing areas). Generally, the area with the highest level of hygienic control is designated as the Primary Pathogen Control Area (PPCA). The PPCA is sometimes referred to as the high hygiene area or the high-risk area. The PPCA is also referred to as the RTE area or the critical side.

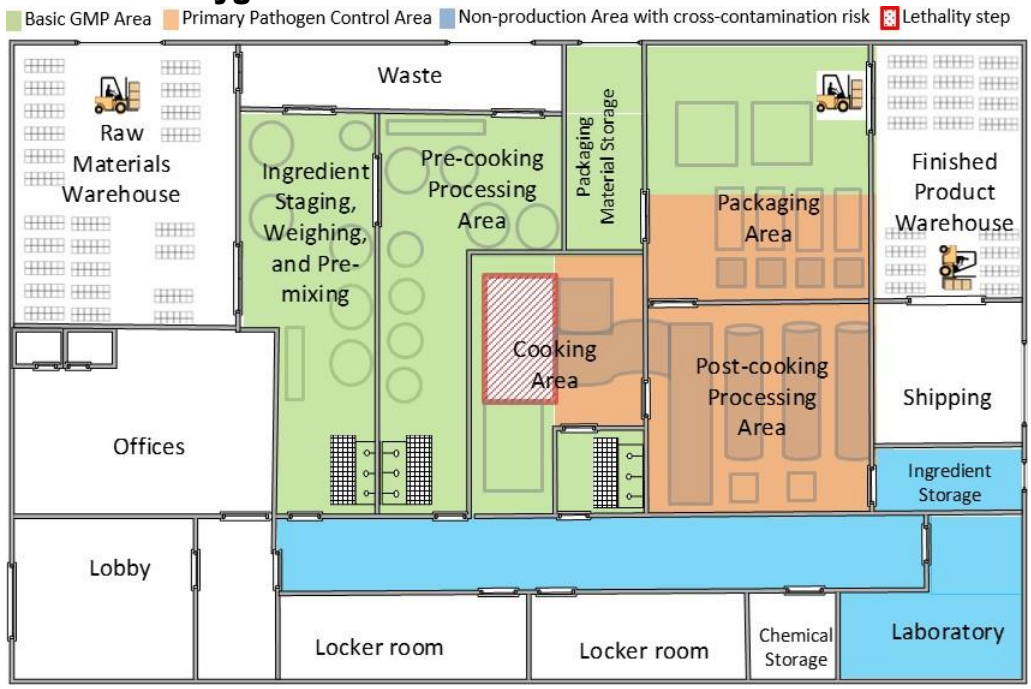
Production areas outside of the PPCA are referred to as basic cGMPs or hygiene areas, and are often the non-critical side (e.g., for dry facilities) or wet side of the facility (e.g., raw material handling and mixing areas in a facility that has a wet side). In addition, a transition area that allows for a hygiene juncture between the

PPCA and the basic cGMPs area may be included. For example, an operation that does not employ an inactivation step, such as a trail-mix blending operation, may designate the entire processing area as the PPCA. An operation that employs an inactivation step, such as a peanut roasting may designate the processing area after the inactivation step as the PPCA and the rest of the processing area as the basic cGMPs area. Non-processing areas such as bathrooms, the plant entrance, locker rooms, administrative offices, storage areas for non-exposed (packaged) products, hallways, and the cafeteria are defined as the non-process hygiene area. A process diagram of the facility to identify designated hygiene areas with color coding can help to differentiate hygiene areas and therefore reflect the level of risk and care needed in each area. Figure
7.1 provides an example of a manufacturing facility with differing hygiene areas.

Figure 7.1. Example of a Conceptual Plant Layout Showing Three Process Areas with Different Hygiene Control: PPCA in Orange, a Basic cGMPs Area in Green, and Non- production Areas with Cross-contamination Risk in Blue.

The need for cGMPs in non-process areas should be assessed on a case-by-case basis.

7.2.1 The Hygiene Area Risk Assessment



Once the hygiene areas of a production facility have been identified, a zoning assessment is conducted to design hygiene area-specific pathogen control and monitoring strategies. The goal is to minimize to the greatest extent the potential spread of environmental pathogens into the PPCA where preventing product

contamination is most critical. Control and monitoring strategies that should be taken into consideration include:

- Sanitary design of equipment and facilities as discussed in Chapter 8.
- Structural separation of the PPCA from less hygienic process areas.
- Optimized traffic patterns for people, materials, and equipment to protect the PPCA.
- Use of a vestibule or hygiene juncture to enter and exit the PPCA.
- Hand washing/sanitizing and foot barrier controls (captive boots, overshoes, disposable booties, alcohol-based sanitizer sprayed on shoes) (Burnett, 2013) established when moving between the PPCA and basic cGMPs areas.
- Use of designated and/or coded tools and equipment for each area.
- Adequate filtration and pressure/flow of room air to prevent cross-contamination e.g., positive air pressure (blows out) from the PPCA to areas such as raw or pre- processed areas.
- Clean air systems with air filters, air conditioning and/or humidity control systems, as appropriate.
- Process area drainage that flows from the PPCA to other areas outside the PPCA.
- Effective sanitation using dry, controlled-wet and/or wet cleaning procedures, as appropriate. See more information in the Sanitation section and Appendices N, O and P.
- Identify and implement any special employee practices or sanitary design requirements for each of the designated areas.

Appendix L provides additional examples of points that should be evaluated during the zoning assessment to minimize the spread of environmental pathogens to the PPCA area and product contamination.

7.3 Pathogen Environmental Monitoring

A comprehensive PEMP is designed to find environmental pathogens such as *Salmonella* spp. and *L. monocytogenes* in nut processing environments*,* assess the effectiveness of *Salmonella* and *L. monocytogenes* control programs, and identify potential risk conditions. In and of itself, the PEMP does not control the environment. However, the testing performed as part of an effective PEMP is a tool to measure and target control program activities providing such information as the following:

- A baseline microbiological assessment of a plant's environment
- Potential sources of *Salmonella* and *L. monocytogenes* contamination and possible vectors that may harbor or spread contamination
- Verification of the effectiveness of sanitation practices
- Verification of the effectiveness of procedures used to segregate and control traffic (including personnel and equipment)

When developing a PEMP, a best practice is to first map the facility delineating processing areas and noting placement of equipment, traffic flow, areas with water

use, and locations of sinks, drains and piping. Identification of areas in need of repair should also be included.
Following this activity, a “deep dive” into the environmental state of the facility is recommended, taking many swabs throughout the facility to create a baseline and identify areas which will require greater surveillance.

The types of samples taken may include swabs of surfaces within the production environments, sweepings, scrapings, and other types such as dust collected by a vacuum cleaner or a dust aspiration system. Analysis of samples (e.g., floor debris, fines, and sweepings) and sponges used to swab the process environment provide critical information to improve pathogen control in the plant environment. This information is used to identify and correct problem areas before they pose a risk to finished product. With this understanding, it is crucial that the program be designed and implemented to maximize detection of environmental pathogens in the timeliest way possible to allow for rapid corrective action. An effective environmental monitoring program coupled with well-executed and documented corrective actions are fundamental elements of a facility’s food safety program.

7.3.1 Designation of Pathogen Monitoring Sampling Sites

Environmental monitoring for pathogens is typically conducted on non-product contact surfaces (non-PCSs) within the PPCA (Zones 2 and 3, see Table 7.1). In the low-moisture (dry clean) environments found in nut manufacturing facilities, product contact surfaces (PCS) and product scrapings (Zone 1, see Table 7.1) are generally sampled and tested for pathogens under certain circumstances. These include investigating possible high-risk pathogen contamination issues (e.g., an abnormal moisture event in the PPCA), investigation of a pathogen positive finished product result, verification of cleaning and sanitation following an incident, or commissioning of new equipment upon installation.

Because testing for a pathogen such as *Salmonella* or *L. monocytogenes* on a Zone 1 site can implicate finished product, this type of testing should include the same precautions used for holding potentially implicated product as is used for finished product testing. This also necessitates the delineation of the scope of the product (the “lot”), should a positive pathogen result occur. In a facility with limited sanitary break points (complete cleaning and sanitation to a microbiological level), this designation of lots can implicate long production periods.

Many facilities manufacturing low-moisture products with limited wet cleaning choose to test for ATP levels or indicator organisms such as Aerobic Plate Counts or Total *Enterobacteriaceae* to verify the hygienic state of PCS within the PPCA. While these general indicator assays do not typically correlate directly with the presence or absence of environmental pathogen, they can be very useful in verifying the general hygienic state of PCS (lack of microbial growth niches build-up, lack of moisture) and identifying pathways for pathogen ingress. When using these quantitative assays, it is recommended that a baseline be established for each area routinely sampled, and statistical process control be applied to the results, with action levels developed for each area.

Non-PCSs in the PPCA should be the main focus of routine monitoring for environmental pathogens. Pathogen monitoring programs usually target areas in

close proximity to processing equipment, areas that see frequent personnel activity, and areas that may be more likely to be at higher risk for contamination based on the physical facility structure and the nature of the operations. However, environmental monitoring for environmental pathogens could also be conducted in other areas of the facility (e.g., wet processing or handling of raw materials). Monitoring in these areas can provide insight into the potential for pathogens to be present and potentially spread into the PPCA and information for establishing proper traffic patterns and implementing effective post-process controls.

An effective environmental sampling program divides the sampling surfaces into four sampling zones based on proximity to the process equipment and the subsequent risk to exposed product and/or product contact surfaces. Examples of sampling sites within each zone are detailed in Table 7.1.

Sampling sites within segregated areas (Figure 7.1) should be selected considering the likelihood of finding *Salmonella* or *L. monocytogenes* as well as less likely investigational sites. Environmental sampling sites should include both facility surfaces and non-product contact equipment. Process areas should be mapped, and swab/sampling locations coded (or numbered) within each zone.

Some areas to consider swabbing for *Listeria spp*. in nut processing include but are not limited to (1) wet nut processing areas (blanching, steam pasteurization, cook/tempering tanks; soak tanks), (2) floor drains, (3) wet cleaned equipment, (4) areas of potential condensate build up, (5) cleaning / sanitation wash rooms and tools (floor scrubber, squeegees/mops, etc.), (6) hand wash stations, (7) floor areas where this is damage, stagnant water, or high traffic areas and/or (8) coolers and areas directly below HVAC units. For additional information, FDA's "*Control of* Listeria monocytogenes *in Ready-to-Eat Foods: Guidance for Industry*" provides detailed information on the development of a PEMP applicable that may be applicable to nut processing (FDA, 2017).

Pathogen monitoring programs should include, at a minimum, documented best practices, action/reaction criteria, and historical trending (if evaluating quantifiable data). It may also be advantageous to include more generalized pathogen samples that can serve as a composite sample of the PPCA, such as floor sweepings, vacuum cleaner dust, and samples from dust aspiration systems. If these types of samples are negative, it likely means that the PPCA is well-controlled. However, if a positive sample is found, it may be difficult to determine where to conduct follow-up sampling, since the positive sample represents a composite of a large area. The risks and benefits, and the type of investigation that would be conducted if a sample tested positive should be considered in advance.

Table 7.1. Pathogen Monitoring Sites Are Categorized into Four Sampling Zones Based on Proximity to Process Equipment.

Zone	Examples of Sampling Sites	Test For	Frequency

1	**Direct or indirect product contact surfaces[1],** e.g., product conveyors and product discharge chutes; pipeline interior and storage hoppers to product fill; filler hoppers, nozzles, product scrapers/utensils, product scrapings	Quantitative hygiene indicator organisms (e.g., Aerobic Plate Count; *Enterobacteriaceae*) *Listeria spp.* - A qualitative indicator of conditions that could favor presence of *L. monocytogenes* (FDA, 2017)	Post-sanitation or as needed for investigational, validation or verification purposes
2	**Environmental surfaces immediately adjacent to product-contact surfaces in production area,** e.g., equipment supports, frames, outside of tunnels, outside of enclosed filling cabinets or below filling equipment, control panels, weight scales, motor housings, catwalks, scrap carts, floor drains[3], HVAC vents, vacuum cleaners if used near PCSs, air filters, etc.	*Salmonella, Listeria spp.*[4]	Weekly, twice monthly, or monthly
3	**Environmental surfaces further removed from product contact surfaces but still within the PPCA,** e.g., hand trucks, forklifts, walls, ductwork, floors, ceilings, equipment legs, fork truck and cart wheels, tools, brooms, squeegees, floor scrubbers, debris from vacuum collection points, floor debris, trash cans, floor drains, traffic pathways into process area, ceiling drain pipes, wall/floor junctures, wash stations, ingredient storage areas, etc.	*Salmonella, Listeria spp.*	Weekly or monthly
4	**Outside of the PPCA, e.g., warehouses, bathrooms, cafeteria, plant entrance, locker room, mechanical room, hallways, offices, and refuse/recycle areas, raw product area**	*Salmonella, Listeria spp.*	Monthly or quarterly

[1] Direct Product Contact Surfaces are surfaces exposed to product during normal equipment operation. Indirect Product Contact Surfaces are surfaces from which liquids or dust or other material may drain, drop, diffuse, or be drawn into the product or into the container, and surfaces that touch product contact surfaces or the container.

[2] Special circumstances include but are not limited to: response to possible pathogen contamination issues (e.g., roof leaks, drain back-ups), investigation of a positive finished product, verification of cleaning and sanitation following an incident, or commissioning of new equipment upon installation. If Zone 1 pathogen swabs are used to verify preventive controls, it is advisable to wet clean, sanitize and dry the equipment swabbed as part of routine SSOPs and hold finished product until results are obtained.

[3] Ideally a floor drain should not be located at a site immediately adjacent to product-contact surfaces. However, if this situation occurs, it should be included in Zone 2 environmental monitoring.

[4] *listeria* spp. is typically tested in an environmental monitoring program since *Listeria* spp. are generally easier to detect and would allow for increased identification of *L. monocytogenes* harborage sites. However, the direct monitoring for *L. monocytogenes* could be appropriate depending on the facility's circumstance. Also, a positive *Listeria* spp. test result can be further speciated to determine if *L. monocytogenes* or another *Listeria* species is harboring in the environment.

NOTE: Zone 1 designation also may be given to equipment surfaces and building structures (e.g., beams, overheads, ceilings, cover surfaces) that are immediately over a direct PCS and compromise the PCS below them (indirect-PCS). Making a determination as to whether a surface (e.g., a ceiling) above a direct PCS (e.g., a transfer belt) is a Zone 1 surface will depend on factors such as the likelihood the surface will contribute to the contamination of the product, the likelihood that condensate will form on the surface and contaminate the product below, the regulatory implications associated with the Zone 1 designation (described in 3.3.2), the ability to clean and sanitize the surface effectively on a routine basis, and the consequences of the Zone 1 designation. The designation of a surface that is not a direct PCS as a Zone 1 surface should be made by the Preventive Control Qualified Individual in consultation with microbiologists.

7.3.2 Frequency of Environmental Pathogen Monitoring

Risk levels inherent to the product and process will determine the frequency of sampling and the swab locations within a facility. The number of samples collected and tested should be at a sufficient number and frequency to detect an issue if it occurs. This should be determined by the facility, and factors to consider include the size of the facility, the number of lines, the degree to which product is exposed to the environment, the history of the facility (e.g., past test results), and the nature of the process. Products produced without a process lethal to pathogens that are intended for direct consumption (e.g., trail mix) would require a more comprehensive sampling program in that the frequency and number of samples should be increased. Areas with water use, high traffic, a history of positive pathogen results, and areas where microbiologically critical raw materials (e.g.,

spices, processed nuts) are handled or stored would be swabbed at an increased frequency.

In addition, production areas following a validated lethality step are swabbed more regularly to monitor for potential product recontamination. In general, a greater number of samples are taken in Zone 2 than Zone 3 and in Zone 3 than Zone 4. Each facility is different and should determine monitoring frequencies for the sampling zones. The appropriate sampling frequencies may vary from facility to facility depending on the risk levels, and the frequencies described below are suggestions. The PEMP should be reevaluated on a routine basis (at least annually) or when problems, such as recurring positives, are noted, to continually optimize the program to find environmental contamination and prevent product contamination.

Zone 1 PCS samples are viewed for regulatory purposes in the same way as finished product. *Salmonella* would not be expected to multiply (form growth niches) on PCSs of low- moisture product production lines (FDA, 2008). In addition, it may be difficult and dangerous to access PCSs while the equipment is running. For these reasons, Zone 1 samples for pathogens are not typically part of a routine PEMP for low-moisture facilities. While a robust PEMP can minimize the need for finished product sampling, an exception to this might be the unique circumstances surrounding an extended plant shut-down or wet cleaning.

It has been noted by many manufacturers of low-moisture products that *Salmonella* contamination of finished product is a greater risk immediately after start-up. This is often attributed to water remaining after wet sanitation. Testing this first product produced at start- up and holding, destroying or reprocessing that product can be a good way of sampling the entire process during this period of elevated risk. If Zone 1 sites are tested for *Salmonella* or *L. monocytogenes*, it is advisable to wait until swab results are communicated before operating the equipment to manufacture product. The alternative approach is to place all finished product on hold from the time the equipment was swabbed until test results are received. A positive pathogen finding in Zone 1 will lead to an examination of product disposition for products that were produced on that equipment prior to swabbing if product was produced on contiguous shifts without a clean sanitation break.

Zone 2 sites are non-PCS within close proximity to PCS in Zone 1. If contaminated, they could reasonably lead to PCS contamination under normal operational practices. Zone 2 sites should be sampled weekly, twice monthly, or monthly. Sampling frequency is based on an assessment of the activities conducted in the area, the frequency of cleaning, the traffic patterns, and whether the product stream is closed to the environment. For example, Zone 2 sites in a tote filling area would be swabbed weekly and Zone 2 sites in a case packing area could be swabbed twice monthly or monthly. Specific sites selected are adjacent to or in proximity to PCS. The type of Zone 2 site that should be selected are areas that, if not cleaned properly, may pose a risk to product, or areas that employees could frequently contact that could lead to post-process contamination (e.g., control panels, operator buttons, and equipment exterior). Zone 2 sites meeting these criteria present no direct immediate process risk and do not implicate product. Care should be taken in

selecting Zone 2 sampling points as these should not represent areas that may be indirect Zone 1 sites.

Zone 3 sites are non-PCS within the PPCA but more removed from PCS. If contaminated, they could not reasonably lead to PCS contamination without mechanical or human intervention (e.g., employee using compressed air to clean floors or a piece of equipment being moved). Zone 3 sites should be sampled weekly or monthly for *Salmonella* and *Listeria spp.* (as appropriate*).* Weekly monitoring may be considered as a starting point to establish a solid baseline and the frequency may be revised based on results over time.

Zone 4 sites are non-PCS sites outside the PPCA. Contamination in this zone could spread to the processing area via foot or equipment traffic (e.g*.,* waste carts picking up contamination in the compactor room). Zone 4 sites should be sampled monthly for *Salmonella* and *Listeria spp*. (as appropriate) if immediately adjacent to a production area and quarterly in other areas not directly related to production. Another alternative is to only sample Zone 4 sites as part of an investigation of pathogen findings in the other Zones.

A common industry practice is to map and document swab locations. A recommended approach is to take swabs within a designated area; however, swabs should not be taken in the same specific location each time. Multiple sites within a designated swabbing area are identified, then rotated with each swab cycle. The swabbing protocol should not be set up in a manner that excludes the sampling of an area of concern identified in “a non- schedule” area. The sampling plan should be flexible and allow for additional samples to be collected, where appropriate, and investigational swabs, as needed, in response to such observations as a cracked floor tile, floor debris, or standing water.

Sampling site locations should be audited and changed on a periodic basis. Using only preset sample sites is not recommended, since it significantly limits the scope of sampling and will likely miss emerging areas of concern. However, some sites may be sampled on a continuing basis to assess trends. Sampling data should be reviewed on a routine basis.

The sampling program should be dynamic and responsive to the data generated. It should also be noted that *Salmonella and L. monocytogenes* often reside in sites that are not easily accessible, and sometimes partial disassembly of equipment, and sampling hard-to-reach nooks and crannies can be of great value.

Environmental samples are usually taken during production, at least 3 to 4 hours after start- up. The time frame for taking swabs (e.g*.,* shift, midweek, end of week) should be changed on a periodic basis.

7.3.3 Pathogen Monitoring for Special Circumstances

Sampling and testing for pathogens are performed in construction areas, adjacent areas and associated traffic patterns during construction. The frequency of swabbing should be increased during and after construction, after equipment installation, and after major repairs are completed because these activities may

result in significant changes such as different traffic and airflow patterns. The sampling sites and swabbing frequency are determined based on a team evaluation of the following:

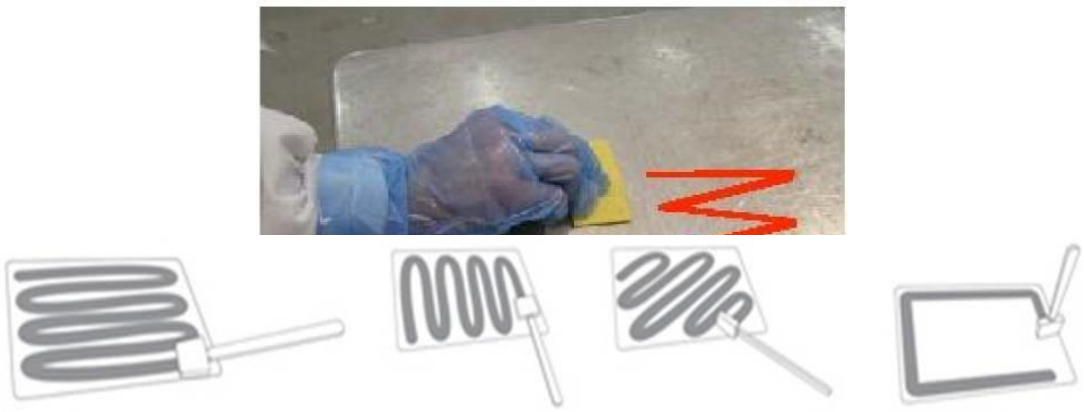
- Plant location of construction activities
- Type of construction (e.g., installation, demolition, material removal)
- Time duration of construction activities
- Types of environmental controls implemented during construction such as physical barriers, changes in air flow, traffic and re-routing.

7.3.4 Environmental Sampling Procedures

Sampling procedures and methods should be consistent with standard industry practices and performed by trained personnel (often those from Quality Assurance). These personnel should be knowledgeable about the entire program and capable of taking investigational swabs.

The use of sterile sponge swabs is one effective method for sampling large areas for pathogen testing (Figure 7.2). Prepared hydrated sponge swabs in sterile Whirl-Pak® bags are commercially available. They are typically hydrated with a sanitizer neutralizing agent such as Dey/Engley (DE) neutralizing broth. Polyurethane sponge swabs are also available. The neutralizing buffer should be determined based on the sanitizing agents used in the facility, and care should be taken that they are compatible with the sampling device and test method. Pre-moistened sponge swabs with removable handles may be preferred for ease of use. Q-tip type swabs are available and are appropriate for small areas (sampling such as bolts or crevices) if hydrated with the appropriate buffer.

Figure 7.2. Hydrated Sponge Swabs Are Used to Sample a Process Area Surface.



Swabbing should proceed from Zone 2 to Zones 3 and 4. A common swabbing procedure is detailed below.

1. Use a permanent marker to label the sponge sample bags.
2. Thoroughly wash and dry hands. Put on sterile gloves. Use precaution to prevent glove contamination.

3. Using sterile gloves, remove the sponge from the Whirl-Pak® bag or equivalent.
4. Sponge an area as large as reasonably possible. The size of the sample area may vary, for example, an entire surface, 10 x 10 cm, up to 400 sq. inches and no less than 40 in^2, might be specified swabbing parameters. Several sponges of the same site could be used and composited for analysis. The intent is to locate potential harborage areas. Replace the sponge in the Whirl-Pak® bag.
5. Small areas may be more appropriately sampled using a Culturette (Q-tips®-type) swab (e.g., head screws, small water collection points, screw holes, threaded surfaces or interior corners of equipment). Swab the entire area as indicated by the surface description. Replace the swab in the Culturette tube.
6. Change gloves between sponge samples. The use of an alcohol-based hand sanitizer prior to putting on gloves is also recommended to prevent cross-contamination from one sponge to the next.
7. Place the collected swab samples (in their original Whirl-Pak® bags) in an unused clean container designated for the purpose. Other disposable materials (gloves, tear strips, etc.) should be placed in the garbage or a third bag or container used to collect the disposable items.
8. If an area is to be sampled for both *Salmonella* and *L. monocytogenes*, separate sponge samples should be taken.
9. After sampling, immediately return the samples to the lab and refrigerate until they are tested internally or shipped to an approved external testing laboratory. Samples should be analyzed or shipped on ice packs within 24 hours of sampling. Samples should arrive at external testing labs within 48 hours of collection.
10. A blank swab (negative control) should be included on a monthly basis or for each new lot number of pathogen swabs.

Environmental samples other than swabs, such as floor scrapings or sweepings, debris from vacuum collection points, and materials from trash containers, are collected with sterile collection tools such as scoops, spoons, and scrapers. The samples are placed into pre- labeled sterile Whirl-Pak® bags or specimen cups. Optimally, 50 grams of material should be collected; however, even small quantities are useful for assessment.

7.3.5 Methods of Analysis for Environmental Samples

A scientifically valid official method of analysis (e.g., AOAC, FDA BAM or ISO) proven to be appropriate for the environmental surface or a scientifically validated unofficial method must be used to test samples taken from the environment.

- The FDA BAM assay (Bacteriological Analytical Manual Chapter 5 *Salmonella* online) and the ISO 6579 assay (2002) apply to various products described in the methods, as well as to environmental samples. The FDA BAM method and the ISO 6579 method are considered the official method in the United States and European Union, respectively. A method that has been validated to be equivalent in specificity and sensitivity to one of these official methods may also be used. According to the FDA BAM, a validated rapid method is generally used for screening, with negative results accepted

as such, but positive results requiring cultural confirmation by the appropriate official method.

- Investigations to determine the root cause of pathogen contamination can be greatly enhanced using some type of strain tracking. Determination of the serogroup or serotype can be useful. Molecular fingerprinting of the pathogen isolate using such methods as Next Generation Sequencing (NGS) systems, pulsed field gel electrophoresis (PFGE), or Whole Genome Sequencing (WGS) can provide even greater strain differentiation. These and other subtyping methods, such as riboprinting that identify genetic diversity may be used for tracking and troubleshooting purposes as they greatly assist in determining a root cause.

- Compositing environmental samples (combining multiple sponges or swabs into one pre-enrichment) is generally not recommended. A positive finding on a composited sample cannot identify the specific location of the positive and results in broader, less focused corrective actions. However, there may be some situations where compositing may be appropriate, e.g., samples taken from multiple drains in the same processing area, where it is less important to pinpoint the site. Compositing of environmental samples, if used at all, should only be used for samples within the same zone and within the same area or on the same piece of equipment. Typically, no more than 5 swabs are combined in a composite. Because compositing can slow investigations, this method should only be used when there is a good history of excellent pathogen control.

- Mixing 2-5 post-enrichment samples into one test sample to be run on a rapid method may be used, provided that the original enrichment broths are retained. If a mixed sample result is positive, the individual enrichments that made up the mixed sample can be immediately retested separately to pinpoint the positive sample(s). However, this process adds delay in determining the location of a positive compared to testing samples individually and may reduce the sensitivity of the assay. The ability to composite or pool samples is method-dependent and must be validated. Implications of mixing enrichments should be carefully considered.

- More than one type of *Salmonella, L. monocytogenes* or other *Listeria* species could be isolated from an environmental sample. Multiple strains/serotypes *of L. monocytogenes* and *Salmonella* have been isolated from raw nuts and from processing environments (Danyluk et al., 2007). The presence of one strain in a raw

  product and a second strain in the process environment does not necessarily rule out a connection between the two results.

- If using an internal testing laboratory, controls are needed to prevent pathogen contamination to the production environment. Considerations include proximity and separation of the internal pathogen testing laboratory to the manufacturing facility, good laboratory practices, limited/controlled access to the lab, proficiency testing, use of controls, and proper disposal of biohazardous materials.

7.3.6 Corrective Actions

Corrective actions must be taken when a pathogen is detected in an environmental monitoring sample. Many facilities begin corrective actions upon receiving“a“"presumpt”v”" positive from a rapid detection method. This may be preferred to waiting for confirmatory pathogen test results, since the final confirmation results could take up to a week.

- It may be advantageous to have a pre-assigned team to assist in the investigation and to help direct corrective actions. A facility must have a predetermined plan of action ready to initiate should a positive pathogen result be reported for an environmental swab, and this should be included in the facility's FSP. This protocol should include:
  - Immediate corrective actions
  - Activities to regain and verify control
  - A root cause analysis
- If a positive is found in any of the four sampling zones, the site should be examined both visually and through vector swabbing prior to cleaning and sanitizing to preserve “evidence” necessary to determine the extent of the contamination and ascertain potential causes of the problem. In advance of vector swabbing, the following should be documented: state of area, presence of water, activities conducted in the area, personnel working in the area and movement of people, materials and supplies into and out of the area. Vector swabbing then proceeds and entails taking additional environmental samples around the initial positive site, following traffic patterns and including points of entry/exit.
- Vector swabbing is usually done in a typical “star burst” pattern around the initial positive site, with an additional 10 to 15 sponge or swab samples taken around the site (although the number of additional swabs to be taken will be highly dependent on the complexity of the area). Sampling, where possible should radiate out from the initial positive site in all directions, including up and down, if appropriate (ABC, no date). If a vector sample result is presumptive/positive, that specific site is then subjected to a separate investigative process as described above.
  - Corrective actions to be taken should be based on an assessment of the potential for finished product contamination given the location of the positive site in the environment. (A positive in Zone 2, 3, or 4 (non-PCS) does not automatically implicate finished product.)
  - Corrective actions should include appropriate procedures, such as those described in Table 7.2, and be accompanied by re-sampling of the initial positive site, the investigational vector sites and other adjacent areas on three consecutive occasions.
  - All corrective actions taken, including re-sampling results, must be documented.

Table 7.2. Examples of Corrective Action Procedures Following Positive Environmental Pathogen Findings.

one 2, 3, or 4: Response to a Single Positive Corrective actions must be taken when a *Salmonella*-positive is found in any zone. Corrective actions should be initiated based on presumptive positive test results. The actions should aim to eliminate potential sources of the contamination. Corrective actions common to Zones 2, 3, and 4 may include the following: • Initiate pre-assigned response team to conduct a preliminary investigation to determine potential cause or source for the contamination (e.g., water leaks, maintenance activity, and construction). The suspect site and surrounding areas should be examined as part of the investigation. • Take immediate actions to correct any cGMPs deficiencies based on findings. These may include: - Quarantine the suspect area and limit access to the area. - Reinforce hygienic practices with appropriate employees (retrain if necessary). - Re-examine cleaning frequencies and revise, as appropriate. - Eliminate water and water collection points, if present. - Repair damaged floors/walls and other structural damage, as appropriate. - Re-examine traffic patterns. Where necessary and feasible, limit traffic flows (both employees and mobile equipment) through the area, restrict fork truck movement, redirect high-risk traffic patterns from adjacent areas, etc. • If desired, conduct investigational sampling of the suspect and surrounding areas prior to cleaning. Precaution should be taken to avoid spreading potential contamination from the suspect area to other areas in the plant. Thoroughly clean/sanitize and dry the positive site and the surrounding area. Use dry, controlled wet and/or wet	**Special Circumstances: Multiple and/or Consecutive Positives (all Zones)** When a sound control program for pathogens is in place, finding multiple and/or consecutive positives may indicate that the primary source is a growth niche, where the organism may have become established and is multiplying. This can lead to an increased risk for spreading the organism and, ultimately, process line contamination. Corrective actions outlined below may be followed for problem resolution. • Map the contamination sites on a layout of the facility to aid in locating the source of contamination, or at least suggest additional sites to sample. It is critical that a harborage site, if one exists, be found and eliminated. This usually means taking more samples than those taken during routine monitoring in the affected and traffic flow areas. • Reinforce cGMPs training and hygienic practices and provide additional attention to sanitation procedures. • Visually inspect areas for potential harborage sites or growth niches. Intensify cleaning activities around these areas. • Visually inspect handling practices (production, sanitation, maintenance, material handling) and correct non-hygienic employee practices. • Review equipment cleaning and preventive maintenance protocols and revise, if necessary. • Examine processing equipment and consider equipment redesign, if necessary. • PCS or product testing may be necessary or need to be intensified for <u>Zone 2 consecutive positives.</u> In some operations, enhanced monitoring may involve testing of worst-case samples on the line, e.g., sifter tailings on a spray dryer system. Line samples may be taken at various times and/or from various locations to help pinpoint potential contamination sites. Investigational samples should be analyzed individually, not as composites.

cleaning, as appropriate, according to guidelines described in this document and appendices, the GMA *Salmonella* Guidance (GMA, 2009) and FDA's guidance on the control of *L. monocytogenes* for RTE foods (FDA, 2017). □ Re-sample the implicated area and other sites within the surrounding and traffic pattern areas. If the positive is found in Zone 3, Zone 2 sites in the implicated area should be sampled and tested to verify that contamination has not spread to areas closer to PCSs; if the positive is in Zone 4, all Zone 2 and 3 sites close to the implicated area should be sampled and tested to verify that contamination has not spread into the process area. □ Increase sampling frequency of positive sites and other sites within the surrounding and traffic pattern areas identified in the above bullet point, e.g., from weekly to once every two days in Zone 3, from weekly to daily for Zone 2. After 3 consecutive negatives, the routine sampling frequency and rotation plan for the *Salmonella* monitoring may be resumed. Zone 4 areas are remote from production and generally present low risk to product. However, results from Zone 4 do provide information about the non-production environment and traffic flow. Although it is expected that *Salmonella* may be found occasionally in Zone 4, a positive finding should prompt additional actions beyond routine sanitation. A Zone 3 positive, in the absence of a Zone 2 positive, may be an early indicator of a sanitation program that is not robust enough. The implicated process may or may not be suspended based on the positive location and its proximity to product contact surfaces.	Depending on the location of the positive, consideration should be given to testing Zone 1 sites. For example, consideration should be given to testing Zone 1 sites (i.e., PCSs) as a response to multiple positives in Zone 2. Consideration may also be given to Zone 1 testing under other circumstances such as qualification of new equipment, relocation of equipment, or recertification of equipment that has been disassembled for cleaning or maintenance, although finished product testing may be more sensitive in this situation. Zone 1 sites may also be tested when a product tests positive, or products are implicated by epidemiologic investigations in an outbreak. When testing Zone 1 sites and using equipment for production, all implicated product and rework must be placed on hold until acceptable results are generated.

7.3.7 FDA Requirements for Environmental Monitoring

When employing environmental monitoring, as appropriate to the nature of the hazard and the preventive control and its role in the overall food safety program, FDA has codified necessary components of environmental monitoring verification methods.

According to the Preventive Controls rule (21 CFR §117.165 (b) (3)), procedures must:

- Be scientifically valid (see discussion of the term "scientifically valid" in Section 7.3.8)
- Identify the target microorganism(s)
- 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 must be adequate to determine whether preventive controls are effective
- Identify the test(s) conducted, including the analytical method(s) used
- Identify the laboratory conducting the testing; and
- Include the corrective action procedures

Facilities must keep records of environmental monitoring activities including corrective actions, if any. The records must be reviewed within a reasonable time after their creation by (or under the direction of) the Preventive Control Qualified Individual, who is responsible for management of the facility's FSP. Corrective actions must be reviewed within 7 days.
Records must be made available to FDA upon request at the time of an inspection.

Records must be kept as part of a PEMP program and these records must be provided to FDA personnel upon verbal request during a FDA inspection. Sampling and testing performed as part of a PEMP must employ scientifically valid procedures.

7.3.8 Scientifically Valid Procedures

Sampling and testing activities performed as part of a PEMP, as well as other areas of a food safety system (e.g., product testing), must employ "scientifically valid" procedures. The FDA defines the term "scientifically valid" to mean testing and sampling programs that are based on scientific information, data, or results obtained from published scientific journals, references, text books and/or proprietary research (FDA, 2013).

Methods that have not gone through formal validation processes but have been published in scientific journals, for example, may also be "scientifically valid". All methods must be shown to be appropriate for their intended use. FDA does not require the use of an accredited laboratory for routine environmental monitoring (and product) testing. FDA inspectors will, however, review the results of environmental monitoring and other verification programs during inspections.

7.4 Management of Pathogen Environmental Monitoring Program

Under FSMA, the designated PCQI, responsible for the development and management of the facility's FSP, including verification activities (such as a PEMP). By definition, the PCQI must have the training, education, or experience, or a combination thereof, to provide the level of competency necessary for establishing the program.

The need for a PEMP, the environmental pathogen of concern, the determination of the stringency of the PEMP, and the defining of the PPCA should all be derived from the facility's hazard analysis. If contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventative control, then environmental monitoring is a required verification activity (FDA, 2015). Development of the PEMP will include an appropriate plan for location, number of samples, and frequency of swabbing, appropriate laboratory analyses, record keeping systems, and action/reaction criteria when a positive result is found.

7.4.1 Establishing a Training Program

The PCQI is responsible for the training provided to those personnel tasked with conducting routine aspects of the program. Training should include formal presentations covering such topics as Food Safety science, Food Safety Culture and an introduction to Food Microbiology. Employees conducting pathogen environmental monitoring will require a thorough knowledge of facility products and processes and be able to identify sites that require further investigation. One-on-one instruction and demonstrations are common training approaches for learning how to take a swab properly. Training should focus on how to determine which sites to sample, as well as collecting, recording, and mapping data.

Employees involved in pathogen environmental monitoring programs must also be trained to respond to a positive result and have the authority to take necessary steps, such as quarantining suspected areas, product holds, etc., or know who must be immediately contacted. Periodic updates or follow-up training sessions should be scheduled as needed. All employees should be retrained, at a minimum, on a yearly basis. Training records must be kept and available for inspection.

Chapter 8

EQUIPMENT DESIGN AND INSTALLATION

To ensure safe food and adequate sanitation programs, the equipment used for nut processing should be designed, fabricated, constructed, and installed according to sound sanitary design principles. Equipment that does not meet basic sanitary design principles or is installed or used improperly cannot be adequately cleaned and sanitized. This section has been developed based on principles described by the American Meat Institute (AMI, 2014) with modifications, to provide a better understanding of the impact that poor sanitary design practices can have in terms of spoilage, recalls, and foodborne illness outbreaks.

GMA has developed sanitary design checklists for both equipment and facilities.

8.1 Principle 1: Cleanable

Equipment should be constructed to be cleanable to a current Good Manufacturing Practice (cGMPs) level and to avoid being a source of product hazards (microbiological, chemical, physical) as validated and verified by active monitoring programs. Reference NSF 5.1

Food equipment should be constructed and maintainable to ensure it can be effectively cleaned and sanitized over the lifetime of the equipment. The removal of all food materials is critical. This means preventing bacterial ingress, survival, growth and reproduction and includes product and non-product contact surfaces of the equipment.

Processors should ensure that a piece of equipment can be cleaned to a microbiological, chemical and physical level. This principle, compatible with HACCP, refers to any kind of unwanted contaminant including pathogens, allergens or physical contaminants.

8.2 Principle 2: Made of Compatible Materials

Construction materials used for equipment should be completely compatible with the product, environment, cleaning and sanitizing chemicals, and the methods of cleaning and sanitation. Equipment construction materials should be inert, corrosion resistant, nonporous and nonabsorbent.

This principle emphasizes the importance of making sure that a product surface is impervious to the materials to which it is exposed. This is important because the use of incompatible materials may cause subsequent corrosion or pitting on a material, such as aluminum, if exposed to chemicals and/or some food products. Once corrosion or pitting occurs, harborage points are created where microorganisms, water, soil or food can collect.

Fundamentally, the nut processor should minimize areas where microorganisms or allergens can harbor and potentially contaminate products. By eliminating incompatible materials in the construction of the processing equipment, the nut processor reduces the likelihood of creating a hospitable environment to harbor a food safety hazard.

8.3 Principle 3: Accessibility

All parts of the equipment should be readily accessible for inspection, maintenance, cleaning and/or sanitation. Accessibility should be easily accomplished by an individual without tools. Disassembly and assembly should be facilitated by the equipment design to optimize sanitary conditions.

If a part of equipment cannot be seen or touched, then it can't be cleaned, inspected or sampled. In other words, in a non-clean-in-place environment, processors should have access to food contact surfaces to enable cleaning. There are four elements of cleaning that nut processors may use: mechanical action, temperature, a chemical that will break up fats and proteins, and time. The below table provide further information on these elements.

Element	Description	Example
Mechanical action	• loosens soils and disrupts biofilms • need to have contact with all surfaces • use turbulent flow	Foam cleaning, manual cleaning (scrubbing), COP (Clean Out of Place) and CIP (Clean in Place)
Temperature	• use the correct temperature according to the SSOPs • water should be 120°F at the end of the wash cycle • too hot: proteins denature and deposit, dangerous for personnel	Follow chemical's label recommendation, some chemical work better with cold water than with hot water.

Chemicals	• Break up fats and proteins • too little: not enough cleaning power • too much: may reduce efficiency, may leave residues, wastes money • just right: does the job ○ Concentration verification method and schedule should be developed to ensure chemicals are at their optimal concentration.	Heavy degreaser (chlorinated or non-chlorinated) When selecting a cleaning chemical consider the following: • soil type • surface type • application method (clean-in-place, clean-out-of-place, manual • environment • water quality
Time	• too little: not enough surface interaction • too much: temperature cools, detergent deposits • just right: surface wets, soils are removed and washed away	The minimum time requirements are on each chemical's label – on average minimum time ranges from 1 – 5 minutes contact exposure.

Above reference is from Penn State Extension- "Key concepts of Cleaning and Sanitation" by Kerry E. Kaylegian, PhD: https://extension.psu.edu/key-concepts-of-cleaning-
and-sanitizing

With these four elements, the nut processor should be able to remove any food soil from equipment, so long as they get the mechanical action and chemicals for the needed time, temperature and in the right concentration into areas where soils are present. Designing equipment to increase accessibility for cleaning ensures the success of this four-element protocol.

The more accessible the equipment is for cleaning, the easier it is for employees to do the job properly and procedurally. If the employees need to clean an inaccessible area, maintenance must be called to remove a guard or gain access to the inaccessible area. This takes more time and makes it difficult to get the job done right. This principle underscores the benefit of making processes easy for people to do the right things.

8.4 Principle 4: No Product or Liquid Collection

There should be no product build-up or liquid collection areas. Equipment should be self- draining to assure that residues do not accumulate or pool on the equipment or product zone areas. Reference NSF 5.1.5, B.1, B.2

There should be no product or liquid collection because the nut processor should not have any areas in the system where water or product can collect and later develop into a foreign material as it dries out, crusts and hardens. Standing water can serve as a harborage or growth point for microorganisms, and when moisture is introduced into an environment, there is an increased chance for microbial growth. It is important to note that for dry cleaning, there is generally little water, if any, used; however, there are some situations where the need may be warranted. If water is needed and used, it is critical to emphasize the need to assure thorough drying.

8.5 Principle 5: Hollow Areas Eliminated or Sealed

Hollow areas of equipment should be avoided or eliminated whenever possible. In cases where they must be used, they should be permanently sealed. Items such as bolts, studs, mounting plates, brackets, junction boxes, nameplates, end caps and sleeves should be continuously welded to the surface and not attached via drilled and tapped holes.
Reference NSF 5.2.1

In most food processing plants, there is a great deal of framework supporting equipment. It is important to ensure that there are no penetrations that would allow moisture and/or food materials or organic matter to get inside or under the surface of equipment. If this occurs, microorganisms will grow, leach out and potentially contaminate the environment.

Eliminating hollow areas or sealing them is a principle easily addressed by equipment designers. An example of this is when an equipment manufacturer would attach a nametag on the piece of equipment, using a pop rivet. A pop rivet is a penetration of the equipment surface that is not sealed, allowing water to penetrate the hollow area. Many designers are eliminating the pop riveted nametags today.

8.6 Principle 6: No Niches

All parts of equipment should be free of niches such as pits, cracks, corrosion, crevices, recesses, open seams, gaps, lap seams, protruding ledges, inside threads, bolt rivets, or dead ends. All welds must be continuous and should be ground and polished smooth.

Reference NSF 5.1.1, 5.1.7, 5.1.9

This principle means just what it says: food-processing equipment should not have harborage points. Not only should equipment be evaluated to ensure that the original welding by the manufacturer is continuous and niche-free, but nut processors also should take care when modifying equipment. Often equipment is

modified by the nut processor to make it fit into a room or to make it consistent with other designs or product lines existing in the plant, and during such modification activities, care must be taken to ensure that a hollow framework is not penetrated creating a microbial growth niche.

8.7 Principle 7: Sanitary Operational Performance

During normal operations, the equipment must perform so it does not contribute to unsanitary conditions or the harborage and growth of bacteria. Reference NSF5.1.13.3, 5.13.4

This principle is linked to Principle 4. A nut processor should not have anything on the production line that potentially causes microbial levels to increase over time. During operation moisture and product buildup should be absolutely minimized. In today's world, processors should optimize production runs while at the same time meeting food safety parameters and regulatory requirements. This is where sanitary operational performance becomes important. For example, if the processor operates in a wet environment, it is likely that moisture would be continually available to nurture growth of microorganisms on the conveyors. Designing the conveyor or other equipment parts to minimize product and moisture buildup would allow the production run to be maximized, while minimizing any potential for a food safety related defect.

8.7.1 Hygienic Design of Maintenance Enclosures

Human/machine interfaces such as push buttons, valve handles, switches and touch screens, should be designed to ensure product and other residues (including liquid) do not penetrate or accumulate in or on the enclosure or interface.

During normal operation of a process or a production line, operators typically touch control panels and could potentially transfer allergens, pathogens and spoilage organisms to those panels. This principle supports design and placement of hygienic maintenance enclosures in production rooms. This principle not only addresses product contact surfaces, but the entire asset represented by the piece of equipment. This moves the consideration beyond the surface to ensure that all the maintenance enclosures and other connections to the equipment are appropriately designed and also can be cleaned and sanitized.

8.7.2 Hygiene Compatibility with Other Plant Systems

Equipment design should ensure hygienic compatibility with other equipment and systems, such as electrical, hydraulic, steam, air and water systems.

Ensuring the hygienic compatibility of the equipment with other systems is as much the processor's responsibility as it is the equipment manufacturers. The processor should assure that equipment introduced to a facility is designed to be usable and cleanable with existing plant systems. Processors can communicate to equipment manufacturers the established electrical, hydraulic, steam, compressed air and oil filtration, and water systems information to assist in improved design strategies prior to the equipment arriving at the plant.

8.8 Principle 8: Validated Cleaning and Sanitizing Protocols

Procedures for cleaning and sanitation must be clearly written, designed and proven effective. Chemicals recommended for cleaning and sanitation should be compatible with the equipment and the manufacturing environment. These procedures should be jointly developed with the nut processor to assure that procedures and chemicals meet the capabilities of that facility. Reference AMIF 2013

Equipment manufacturers are usually not cleaning experts; their manufacturing facilities resemble machine shops, with lathes and metal shaping equipment. It is a rare equipment manufacturing operation that would have the ability to test wash and sanitize a piece of equipment. However, food processors utilize cleaning and sanitizing systems and protocols every day and can provide useful insight to the most effective cleaning procedures in given plant environments. This principle recommends that the equipment manufacturer work with the individual nut processor during the equipment design stage, so while the equipment is under construction, the equipment manufacturer will have a vision of how the equipment will be cleaned and sanitized once installed in a plant. Once delivered, the processor will have a specific understanding of the cleaning requirements and procedures.

8.9 Principle 9: Separate Processes Wherever Possible

Dissimilar processes, e.g., raw vs. RTE, in plants or on a single line or equipment should be properly separated to prevent cross contamination based on an evaluation of risk. This is particularly important for pathogen management in a facility and is critical in any process where there is a HACCP-based microbiological kill step. Microbial contamination can occur if raw product / raw dust or even persons who work in raw areas enter into an RTE area. Reference AMIF2013

8.10 Principle 10: Equipment and Personnel at Installation Should Meet Hygiene and Sanitation Requirements

All plant personnel, contractors, and visitors to processing plants must be trained in and required to follow plant hygienic and sanitation requirements. Programs must be in place at equipment manufacturing locations to assure elimination of the potential for physical, chemical or microbiological contamination of food products from equipment once installed at the processor's location. At equipment supplier manufacturing locations, used equipment being rebuilt or retrofitted should be separated from new equipment construction to comply with Principle #9. Reference NSF 6.2.2

When suppliers and contractors visit or work to install new equipment, they need to follow all of the company's cGMPs procedures. However, it goes beyond behavior in the processor's facility. In many equipment supplier locations, equipment is repaired and reconditioned that has been in service in food processing plants for years. Some of this equipment may have been out of service for some time or may have even been stored outside and possibly was not thoroughly cleaned prior to being sent to the Original Equipment Manufacturer (OEM) to be rebuilt. When this happens, there is the potential to cross contaminate other equipment under

construction in the OEM's facility. Since most equipment suppliers do not have cleaning capability, cross contamination could occur from their facility to equipment and then to a processor's facility when they deliver a new piece of equipment. This is a potential contamination vector that nut processors should be aware of and prevent.

Equipment must be thoroughly cleaned before delivery to a processor's location. Once installation is complete, equipment must be thoroughly cleaned, sanitized, inspected and swabbed prior to release for production.

Chapter 9

FOOD DEFENSE

9.1 Introduction

"Food defense" and "food safety" are often terms that are used interchangeably. Although both apply to the unified goal of protecting the food supply from contamination, they address different types of contamination. Food safety programs are in place to reduce the risk of *unintentional* contamination while Food Defense programs are in place to reduce the risk of *intentional* contamination by someone who means to do harm. The notion of "Food Defense" developed in the aftermath of the September 11, 2001, attacks because the U.S. government became concerned that terrorist organizations might seek to contaminate parts of the American food supply. FSMA was the first law to include the term "Food Defense" and it gave the FDA direct regulatory authority to require regulated facilities to develop Food Defense Plans with mitigation strategies to protect against the intentional contamination of food. The final rule, *Mitigation Strategies to Protect Food Against Intentional Adulteration* (IA rule) (81 FR 34165), became effective in 2016, requiring all domestic and foreign businesses that must register with the FDA as food facilities because they manufacture, process, pack or hold human food for consumption in the U.S., to develop and implement a facility-specific Food Defense Plan.

9.2 Definitions

Actionable Process Step: a point, step or procedure in a food process where a significant vulnerability exists and at which mitigation strategies can be applied and are essential to significantly minimize or prevent the significant vulnerability.

Contaminant: (in regard to Food Defense) any biological, chemical, physical, or radiological agent that may be added to food to intentionally cause illness, injury or death.

Facility: a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), in accordance with the requirements of 21 CFR part 1, subpart H.

Food Defense: the effort to protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm,

Food Defense Monitoring: to conduct a planned sequence of observations or measurements to assess whether mitigation strategies are operating as intended.

Food Defense Plan: a set of written documents that is based upon Food Defense principles and incorporates a vulnerability assessment, includes mitigation strategies, and delineates Food Defense monitoring, corrective action, and verification procedures to be followed (21 CFR 121.126).

Food Defense Qualified Individual: An Individual who meets the requirements in 21 CFR 121.©)(1) and (2) to do or oversee the activities listed in 21 CFR 121.4(c)(3).

Food Defense Verification: the application of methods, procedures, and other evaluations, in addition to Food Defense monitoring, to determine whether a mitigation strategy or combination of mitigation strategies is or has been operating as intended according to the Food Defense Plan.

Intentional Adulteration (in the context of this Food Defense section)**:** the deliberate contamination of food with a biological, chemical, radiological, or physical agent by an individual or group of individuals with the intent to cause wide scale public health harm. For further information about other types of intentional adulteration, see food fraud, section 10 of this manual

Key Activity Types (KATs): Four activity types have been identified by FDA as the most vulnerable, regardless of the food commodity. The four KATs are listed below.

1. Bulk Liquid Receiving and Loading
2. Liquid Storage and Handling
3. Secondary Ingredient Handling
4. Mixing and Similar Activities

Mitigation Strategies: risk-based, reasonably appropriate measures that a person knowledgeable about Food Defense would employ to significantly minimize or prevent significant vulnerabilities identified at actionable process steps, and that are consistent with the current scientific understanding of Food Defense at the time of the analysis.

Significant Vulnerability: a vulnerability that, if exploited, could reasonably be expected to cause wide scale public health harm. It is identified by a vulnerability assessment conducted by a qualified individual, that includes consideration of the following:

- Potential public health impact (e.g., severity and scale) if a contaminant were added
- Degree of physical access to the product
- Ability of an attacker to successfully contaminate the product (must take into consideration external and internal attackers)

Significantly Minimize: to reduce to an acceptable level, including to eliminate.

Vulnerability: the susceptibility of a point, step, or procedure in a facility's food process to intentional adulteration,

Vulnerability Assessment: the identification of vulnerabilities and actionable process steps for each type of food manufactured, processed, packed or held at the food facility.

9.3 Food Defense Plan

The Food Defense Plan (FDP) is a set of written documents that incorporates a vulnerability assessment, includes mitigation strategies, and delineates Food

Defense monitoring, corrective action, and verification procedures to be followed (21 CFR 121.126(b)). The FDP is essential for minimizing or preventing significant vulnerabilities related to the intentional adulteration of food, and therefore must be prepared by an individual or individuals with knowledge and expertise of the facility's operations in addition to general Food Defense principles. The IA rule allows for the contracting of outside resources for the creation and reanalysis of the FDP if the facility does not have a qualified individual to perform these tasks. For facilities with the employee resources to do so, the creation of a Food Defense team to create, implement, and reanalyze the FDP is ideal.

There is no standardized or required format for a FDP, so facilities have the flexibility to format and organize their plan anyway they like as long as the plan includes all the components required by the IA rule. The FDA website provides resources and tools to assist in the creation of a FDP.

9.3.1 Plant Information

The FDP should include adequate information about the facility and processes. More specifically, the FDP should contain the following facility specific information:

- Company/facility name
- Facility address
- Facility phone number and name of primary contact person
- Facility description including a general description of and the physical attributes of the facility
- Information about the number and types of employees at the facility
- A description of the facility's product or product categories, the main processes involved, taken from the FDA Food Defense Builder

9.3.2 Food Defense Team and Responsibility

Having a team is not required by FDA for the Food Defense Plan but optional and highly recommended. For facilities with the employee resources to do so, a designated team should be assembled to oversee the development and implementation of the FDP. The team should be diverse and include members who are directly involved with food processes and have general knowledge of Food Defense concepts. Each team member should be assigned clear responsibilities to help develop the FDP and provide oversight of the implementation of the plan.

The team should be led by a Food Defense qualified individual as identified by the facility or company. The IA rule, requires special qualifications for individuals who oversee the following activities:

- Preparations of the FDP;
- Conduct of a vulnerability assessment;
- Identification and explanation of mitigation strategies; and
- Performance of the reanalysis. (21 CFR 121.4(c)(3)).

The Food Defense qualified individual must meet the following two requirements:

1. Education, training, or experience (or a combination thereof) necessary to properly perform the activities
2. Successful completion of training for the specific function that is at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities

Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through a standardized curriculum recognized as adequate by FDA (e.g., the curriculum used in the Food Safety Preventive Controls Alliance (FSPCA) training). (21 CFR 121.4(c)(1) and (2)).

9.3.3 Food Defense Plan Management

The FDP should be reviewed regularly. Food security assessments of the facility should be conducted based on risk of facility or processes by the Food Defense team and management to verify the plan remains relevant. FDA's IA rule requires the FDP to be reanalyzed as a whole, or in its entirety at least once every 3 years. (21 CFR 121.157(a)). There are other circumstances that will necessitate reanalysis of the FDP, or portions thereof, more frequently. These include the following:

1. Whenever a significant change to facility/company activities creates a reasonable potential for a new vulnerability or a significant increase in an existing vulnerability
2. Whenever you become aware of new information about potential vulnerabilities associated with the food operation or your facility
3. Whenever you find that a mitigation strategy or the Food Defense Plan as a whole is not properly implemented
4. Whenever FDA requires reanalysis to respond to new vulnerabilities, credible threats to the food supply, and developments in scientific understanding. (21 CFR 121.157(b))

For reanalysis conducted in response to any of the aforementioned circumstances, you may limit the reanalysis to the affected portions of your FDP. (See 21 CFR 121.157(b)).

9.3.4 Outside, Inside and Processing Security

As an initial step when creating a FDP, the Food Defense team must conduct a risk analysis on the facility's procedures for handling raw materials, ingredients, packaging material, work-in-progress, and finished products and its surrounding security areas to ensure these procedure provide for maximum protection from malicious or intentional contamination while under the control of the site/facility.

9.4 Outside the Processing Areas

When focusing on those areas of the facility outside of the processing area, the Food Defense team should consider the following:

- Whether site premises are clear, secured, and regularly monitored to prevent unauthorized entry

- Whether outside lighting is present and appropriate to facilitate detection of suspicious or unusual activities
- Whether access to the site is minimized to the extent possible
- Whether all access points into the site are secured and monitored, for example: doors, windows, vents, loading doors, tanker truck hatches, bulk storage, silos
- Whether controlled-access measures have been implemented for people and vehicles entering the site or parking lot. The control measures must consider after hours and weekends
- Where practical, can parking areas be separated from entrances to food storage, processing areas, and utilities
- Training all employees to report any suspicious activity to management
- Assuring that management has local law enforcement officials contact information readily available

9.5 Inside the Processing Areas

Regarding the inside of processing areas, the Food Defense team should consider the following:

- Whether restricted areas inside the site are clearly identified and secured;
- Whether restricted ingredients or toxic chemicals are stored in a secured location;
- If access to restricted ingredients or toxic chemicals is limited to authorized and trained personnel;
- If access to utilities such as airflow, water, electricity, gas, and refrigeration is limited to authorized and trained personnel;
- Whether a log is maintained for visitors and non-employees entering the site and a point of contact for visitors has been established;
- If access to computer process control systems and critical data systems is restricted to those with appropriate clearance (for example: using passwords, firewalls); and
- Whether a virus protection system for the computers are available and reviewed regularly.

9.6 Processing Area Security

Processing areas must have the highest security available; the following should be considered:

- Whether access to ingredients and finished product is restricted
- Whether access to process control equipment is restricted to authorized and trained personnel, for example: ovens, mixers
- If employees have been trained and a mechanism implemented for any suspected alteration to the equipment to be immediately reported to management
- Whether ingredients and food contact packaging material are inspected for signs of tampering
- If a traceability program is in place to track ingredients, food contact packaging material, and finished product through the operation from receiving raw materials to shipping finished product

- If inventory irregularities outside a normal range of variability is investigated

9.7 Transportation: Shipping and Receiving

Addressing vulnerabilities associated with the transportation or shipping of materials needed for food processing and the receiving of such materials are essential components of a FDP. It is imperative to monitor closely the integrity of the vehicles that are transporting raw materials, finished products, or other materials used in the food processing.

A risk assessment of shipping and receiving practices should be conducted to identify vulnerable points and potential hazards; mitigation strategies should be identified in the FDP for identified vulnerable points and potential hazards as they pertain to shipping and receiving of materials by the facility.

It is essential that all incoming and outgoing transportation is thoroughly inspected. All designated Food Defense team members should have documented training on the proper unloading and loading procedures for transportation vehicles.

USDA's FSIS has published an industry guidance document titled *FSIS Security Guidelines for Food Processors.* The Food Defense team should consider the following applicable best practices from these guidelines on addressing potential vulnerabilities associated with transportation and specifically shipping and receiving:

- Inspect tanker trucks and/or rail cars to detect the presence of any suspicious material, solids, pests, odors or liquid, in tanks prior to loading liquid products. Load only when appropriate. Report/record results.
- Control access to loading docks to avoid unverified or unauthorized deliveries.
- Require advanced notification from suppliers for all deliveries.
    - Driver's should always sign in and out.
    - When arriving at the plant, whether it's for a unloading or loading, drivers should present a Bill of Lading or Purchased Order (P.O.)
    - All documents should be verified by trained personnel at the plant.
- Immediately investigate suspicious changes in shipping documents.
- Check all deliveries against a roster of scheduled deliveries.
- Hold unscheduled deliveries outside establishment premises pending verification.
- If off-hour delivery is accepted, require prior notice of the delivery and an authorized person to be present to verify and receive the delivery.
- Require incoming shipments of raw product, ingredients, and finished products to be sealed with tamper-evident or numbered, documented seals and verify the seals prior to entry. Reject if seals are broken or missing.
- Minimize the time a truck is unlocked during loading or delivery.
- If dealing with returned products, look for evidence of tampering before salvage or use in rework.
- Maintain records of disposition of returned goods.

The Food Defense team should also consider requiring drivers or delivery personnel to provide identification, preferably with a photo ID.

Lastly, the Food Defense team with company/facility management should consider making transportation companies part of the contractor supplier approval process. During the initial review, trucking companies should be asked to provide the types of security they can provide and what type of sanitation schedules they apply to their containers. When possible, the processing facility should consider creating a specification or agreement that includes explicit expectations such as not simultaneously transporting a second or third client's products or breaking seals without permission, minimum cGMPs that should be required by any food processing plant. Lastly, such specifications or agreements should be signed by the transportation's management representative and processing plant management.

9.8 Storage Security

The Food Defense team should consider the following best practices for addressing vulnerabilities and potential hazards associated with storage:

- Restrict access to product, ingredient, packaging, chemicals (not limited to cleaning chemicals and pest control related chemicals) storage areas to designated employees only (by locked door/gate)
- Maintain an access log for product and ingredient storage areas. If possible, have cameras installed for monitoring
- During off hours, storage areas should be closed. Roll up doors should be kept closed when not in use
- Regularly check the inventory of finished products, packaging, and product on hold
- Restrict access to external storage facilities to designated employees only
- Visitors should not be allowed to wander around without a plant employee

9.9 Water and Ice Supply Security

The Food Defense team should consider the following best practices for addressing vulnerabilities and potential hazards associated with water and ice:

- If water is from a municipally controlled source, check the drinking water analysis reports annually

- If water is from a well, have [a] 3rd party contractor check the water based on the county's required schedules and have all results verified by a preventive control qualified individual
- Inspect water lines for possible tampering (perform visual inspection for integrity of infrastructure, proper connections)
- Include in the FDP, the contact information for applicable local health officials to ensure the establishment can be immediately notified or have questions answered quickly if the potability of the public water supply is compromised
- If ice is supplied from a contractor, evaluate that contractor under the company's/facility's Supplier Approval Program. It is essential that the facility

consider how it uses ice to assure all potential vulnerabilities/hazards are addressed. For example, if the ice comes in contact with food or with food contact surfaces, then the ice should be treated as a food ingredient
- If the ice supply is produced on-site at the facility, the equipment should be inspected regularly and should be scheduled for routine preventive maintenance
- Restrict access to water and ice supply used for food processing to designated employees only (by locked door/gate). When possible, have cameras monitoring those areas where water and ice used for food processing are contained

9.10 Mail Handling Security

The Food Defense team should consider the following best practices for addressing vulnerabilities and potential hazards associated with mail – both physical and electronic:

Physical Mail

Physical mail (letters, packages, etc.) can be used by would-be attackers as a means to transfer a dangerous agent into a facility anonymously. Without proper controls, it may be viewed as an easier way to access the facility than physical entry. One of the most well- known examples is use of mail as a vector for anthrax attacks on public figures in the United States in 2001.

Appropriate controls include:

- Awareness training for employees responsible for receiving or handling mail or packages. Training should include recognizing signs of tampering or suspicious items.
- General mail and package awareness training for all employees, including proper response to any suspicions.
- Mail handling in a dedicated location, away from production and storage areas.

Email, Digital Infrastructure and Cybersecurity

As food processors become increasingly more dependent on technology-based solutions, and computer-operated equipment, the risk of attacks on these devices has become a much greater concern. Malware and hacking can pose a very real risk of data loss, financial loss, processing equipment down-time or damage, improper processing, and even a risk to employees should critical systems within the facility fail. Stolen technology can lead to loss of competitive advantages companies have invested in, and copycat products can outcompete the original product. Attacks are frequently increasing, and the Food Protection and Defense Institute has identified cybersecurity as a critical area of focus for food companies in the coming years.

Measures which should be implemented are the following:

- Secure servers with appropriate, up to date firewall technology. These should be updated with the latest technology frequently.
- Password-protect all systems and devices. Change passwords regularly and make them complex and difficult to hack.
- Anti-virus and anti-malware software are critical. Food processors should research the best providers to use and avoid price-shopping.
- Carefully vet out and manage third-party software and IT vendors, where used, before using their products or services.
- Security training for users may be one of the most important measures to implement. Attackers will use social engineering to appeal to employees' interests or sympathy, to get them to open a file or click on a link. Companies should provide training to employees about the different ways they can be targeted, and why (the purpose), so they can be on the lookout for potential risks and avoid them.
- Systems should frequently be backed up in a secure manner. Food companies will usually identify a vendor that can provide this service.
- Security programs should be reviewed regularly and if possible, a challenge test should be conducted.

9.11 Personnel Security

Personnel are one of the most critical resources a food company has, and as the first line of defense, also one of the most important parts of a company's Food Defense programs. Of particular importance is that employees can become disgruntled and may take action which can pose a risk to consumers and to the company. Recommended measures to take with respect to control of personnel are provided below.

- Before hiring employees, utilize a thorough interview screening process and conduct a background check to identify potential behaviors or personality factors that could be problematic. This is most important for employees working in sensitive areas where product is easily accessible; however, in most establishments all employees have potential access to product.
- Train employees in Food Defense practices and awareness of signs of tampering. Employees should be strongly encouraged to have an attitude of ownership for the safety of the products and taught that food safety is everyone's job. Employees should be encouraged to question any unknown individuals in the facility. A common phrase used in the industry for this type of training is "See Something, Say Something." Related training resources can be found in the Food Defense section of FDA's website. https://www.fda.gov/food/food-defense
- There should be a master list of employees that is maintained.
- There should be a controlled entry process for employees and visitors, through a designated entry door (or doors). These entry points should have clear visibility by staff so that unauthorized entry is easily detected. Each day a list of both employees and visitors present on-site should be maintained and is important for use in an emergency evacuation, as a record for investigations and for monitoring activities.

- Some form of identification (name badges, etc.) should be used as an indicator that each person is authorized to be on-site, particularly when temporary or seasonal employees are employed, and when the company is not a small operation. It is also common for employees to be given unique company-supplied clothing to wear, as an indicator that they are authorized to be present. Visitors generally are provided with uniquely colored hair nets, and smocks or other covering, indicating they are a visitor. As a best practice, it is recommended that designated company attire not be allowed to leave the facility, so that non-employees do not have access to these items. It may be acceptable for employees to take these items home if other access controls, such as an electronic badge entry or similarly robust entry controls are employed.
- Visitors should be escorted whenever possible. For visitors who will be working on- site long term, or will be coming regularly, some form of training should be employed so that they are aware of site policies as they pertain to product. This training should delineate restricted and unrestricted areas, company processes for the approval of chemicals to be used on-site, site cGMPs programs, and any other relevant items.
- Measures should be in place to limit access to restricted processing areas where product is readily accessible and processed in bulk, such as mixing, grinding, roasting, etc. These measures can include locking doors, restricted access signs, and security cameras.
- It is a best practice to have security cameras in place throughout production areas. This functions both as a deterrent and as a record should an investigation be required. Many companies will not have full-time monitoring of camera feeds; in this case there should be at least periodic checks on the feeds to review ongoing activities. Some third-party companies offer monitoring services for camera feeds and will notify the company of any suspicious behavior.
- Personal items should be strictly prohibited in processing areas, and they should be stored in personnel lockers or other designated areas. Lockers should be subject to periodic inspection, both for security reasons and for general cGMPs; for instance, foods stored in lockers can pose a pest control risk and a cross-contamination risk.
- Use of cameras (including cellular phone cameras) on-site should be strictly prohibited for employees or visitors unless authorized by management. Failure to do so could allow photos of the site to become available to potential unauthorized visitors.

9.12 FDA's FSMA International Adulteration Rule

The FDA's Intentional Adulteration Rule, as it is commonly referred to, is fully titled "Mitigation Strategies to Protect Food Against Intentional Adulteration" and can be found by referring to 21 CFR 121. The rule is similar to traditional "Food Defense" programs but goes beyond traditional structures and takes a risk-based, HACCP-like approach.

The purpose of the Intentional Adulteration Rule is to prevent intentional contamination of food with the intent to cause wide-scale harm (illness or death) to consumers. The FDA does recognize that the likelihood of tampering at any single food processor facility may be relatively low, but the potential vulnerability within the food supply as a whole, needs to be addressed because tampering does occur. Addressing this risk starts with each processor taking steps to prevent issues at their own facility.

The unique, new consideration with this rule is that companies have been given a mandate to consider the potential threat from an 'inside attacker', such as an employee who may be disgruntled or have other motivation to tamper with products. This risk has not typically been addressed in traditional Food Defense Plans to the degree that FDA requires in this rule.

For importers, it is also important to note that although foreign suppliers may not be explicitly required to comply with the FSMA Intentional Adulteration rule outlined below, it would be wise to ensure a thorough evaluation of their Food Defense programs is conducted before purchasing products from that supplier.

9.13 What's Required

Key requirements of the rule include the following:

- Develop a documented plan, which may include using some of the elements already in place as part of the Food Safety Plan (FSP) such as the product description, process narrative, process flow diagram, etc.
- Conduct an assessment of potential on-site risks to the product due to intentional adulteration. Adulteration may be committed by trespassers, visitors, or even employees.
    - Companies may either use the "KAT" approach (Key Activity Types); or the "Three Fundamental Elements" approach; or an approach using a hybrid of these two methods; or some other appropriate method such as CARVER+SHOCK.
- Determine mitigation strategies (controls to reduce risk)
- Implement the plan
    - Train employees
    - Implement mitigation strategies/control measures
    - Monitor control measures
    - Apply corrections where needed
    - Verify the plan and its controls
    - Maintain documentation and records
- Reanalyze the plan periodically

Specific processing steps considered higher risk by the FDA, also called "Key Activity Types", are:

- Receiving and storage of bulk liquids
- Liquid storage and handling
- Secondary ingredient handling

- Mixing, grinding, and other bulk handling processes

A second approach is to use the three fundamental elements for the vulnerability assessment. The elements include:

- Element 1: Potential public health impact (e.g., severity and scale) if a contaminant were added. This can be done using the volume of food at risk or using a representative contaminant.
- Element 2: Degree of physical access to the product
- Element 3: Ability of an attacker to successfully contaminate the product

Note: The numerical score is added from the three fundamental elements to determine if there is an actionable process step or not. Vulnerability assessments using the three fundamental elements requires in-person training (Intentional Adulteration Conducting Vulnerability Assessments) through the FSPCA if one is not familiar with this approach.

Another approach that can be used that combines the speed of the Key Activity Types (KATs) method and the in-depth three fundamental elements approach in a hybrid approach. First, the facility would assessment the processing step using the KAT method. If a KAT is identified, the three fundamental elements method can be applied to this step for more in-depth analysis. In some cases, this hybrid approach may determine that certain KATs are process step that may not be an actionable process step or may be an actionable process step that needs one or more mitigation strategies depending on the vulnerability.
This type of vulnerability assessment provides a comprehensive review of vulnerabilities in certain process steps.

Examples of mitigation strategies, as recommended by the FDA, include things like ensuring that raw material silos are secured and locked, using a 'buddy system' for employees in key areas where actionable process steps are located, using access badges for controlling access, assigning an employee to oversee (watch) while materials are unloaded on-site, and using tamper-evident tape to seal hoses that are used for liquid ingredients.

9.14 Vulnerability Assessment

Food operations shall have written procedures at every point or step that must be evaluated to identify significant vulnerabilities and actionable process steps.

9.14.1 Three Fundamental Elements

Minimum elements required to conduct a vulnerability assessment at each point, step or procedure (21 CFR 121.130(a)):

- The potential public health impact (e.g., severity and scale) if a contaminant were added;
- Degree of physical access to the product; and
- The ability of an attacker to successfully contaminate the product.

9.14.2 CARVER + SHOCK Method

A useful tool available on FDA's website, that can be used to assess the vulnerabilities within a system or infrastructure to an attack is called the CARVER plus Shock Primer.

There are six attributes to this tool as follows:

1. **C**riticality – a measure of public health and economic impacts of an attack as a result of the batch size or network of distribution
2. **A**ccessibility – the ability to physically access and egress. This can change over time and as a result of the use of countermeasures
3. **R**ecuperability – the ability of food system to recover from an attack
4. **V**ulnerability – the ease of accomplishing attack. This can change over time and as a result of the use of countermeasures
5. **E**ffect – the amount of direct loss from an attack as measured by loss in production
6. **R**ecognizability – the ease of identifying target

A seventh attribute has been added and is called " **+ SHOCK"** and represents the combined health, economic, and psychological impacts of an attack. This tool can help a company think like an attacker to identify the most attractive targets for an attack.

(Journal of Food Science Vol 81, Nr.4, 2016): https://www.fda.gov/food/food-defense- programs/carver-shock-primer

According to *FDA's Vulnerability Assessments of Food Systems Final Summary Report June 2009-February 2012,* by conducting a CARVER + Shock assessment of a food production facility or process, the user can determine the most vulnerable points in the infrastructure and focus resources on protecting the most susceptible points in the system.

Facilities may identify actionable process steps using the FDA-identified key activity types as described in proposed § 121.130(a) or conduct their own facility-specific vulnerability assessments as provided in proposed § 121.130(b)."

There are five steps to consider.

1. Establish Parameters. To determine the vulnerabilities, questions shall be asked as to what to protect and what to protect from. These will be the scenarios and/or assumptions that need to be analyzed:

    - Assess the supply-chain.
    - What is the final end result from the issue?
    - Who is the attacker and the scope of the attack that needs protection? The attacker can be anyone that wants to cause mass mortality by adding toxic agents to food products or adulterating the food product.
    - What are the agents used in the scenario that will impact the end result of an intentional contamination incident of the assessment (e.g., biological, chemical or radiological)?

2. Establish a team of subject matter experts. These team members will have knowledge to conduct the assessment in food production for the process being evaluated, food science, toxicology, epidemiology, microbiology, veterinarian and human medicine, radiology, and risk assessment. The team will use the information from step 1 and apply to the CARVER + Shock method to each element of food systems structure. The scale value will be graded from one to ten per attribute.

3. Conduct an analysis of the food supply-chain. A process flowchart will be developed of the system to better understand the process. For example, if you are evaluating chocolate nut production, the food system is the chocolate-nut production, which can be broken down into subsystems (production of chocolate subsystem, nut processing subsystem, distribution subsystem). Those subsystems can be further broken down into complexes (e.g., chocolate and nut processing facilities). Those which can be further broken down into components. These components will be looked at from the incoming, storage, process, shipment areas to the equipment(s) used.

4. Score for the CARVER-Shock attributes. To calculate the overall score, the infrastructure of each of the 7 CARVER-Shock attributes has to be simplified to its smallest parts, components and nodes (its smaller structural parts). The node that has the highest overall score is potentially the most vulnerable node, therefore could be an attacker's target.

5. Implement the identified outcome. Based on the scoring and understanding of the critical node(s) of the system, a plan needs to be created to put countermeasure(s) in place. This will help reduce the potential for an attacker to target these critical nodes. Examples of these countermeasures are to strengthen security and limiting access to the product or process.

The following 2 tables are from the CARVER + Shock Method FDA

This appendix provides a table that can be used to total the scores across the CARVER+Shock attributes for each node. The totals can then be compared across the various nodes to determine which nodes are critical. The nodes with the highest scored are the 'critical nodes' and should be the focus for beginning to implement countermeasures.

Table B: Summary sheet for totally scores for nodes across CARVER+Shock attributes.

FOOD:_____

TARGET (Nodes)	CRITICALITY	ACCESSI-BILITY	RECUPER-ABILITY	VULNER-ABILITY	EFFECT	RECOG-NIZABILITY	SHOCK	OVERALL SCORE

This appendix provides a table that can be used to summarize the CARVER+Shock score on each attributes for given node. The table includes a place for a brief narrative of the rational or justification for giving a node a particular score, allowing the thoughts that went into the scoring to be captured.

Table C: Summary sheet for analysis of individual nodes, including the justification for the score given.

Product:		
Target Complex:		
Target Node:		
FACTOR	**SCORE**	**JUSTIFICATION**
CRITICALITY		
ACCESSIBILITY		
RECUPERABILITY		
VULNERABILITY		
EFFECT		
RECOGNIZABILITY		
SHOCK		
OVERALL		
RANK		

APPENDIX B / https://www.fda.gov/food/food-defense-programs/carver-shock-primer

9.15 Mitigation Strategies: Actionable Process Steps

Conducting a Vulnerability/Threat Assessment

Each point/process within the facility must be assessed and if the area is not determined to be an actionable process step a written explanation must be given as to why it was not identified as such, reference 21CFR121.130.

Under the IA rule, this assessment must additionally consider the threat of an insider (e.g., disgruntled employee) and the potential to cause wide scale public harm for all acts.

The *Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry, March 2019*, provides the following examples:

Table 3-2. Scenario 2.
Worksheet 1-H: Mitigation Strategies

PRODUCT(S): FOOD XYZ
FACILITY NAME: Anytown #12345
ADDRESS: 1245 Washington Street, Anytown, USA
SIGNED DATE: March 7, 2018

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Explanation
	Bulk liquid receiving	Use tamper-evident seals on inbound shipping conveyances. Match the numbers on the seals with the numbers provided on the shipping documentation from the supplier. If the seals do not match, the load will be rejected to prevent potentially adulterated ingredient from entering the facility.	Using numbered wire or plastic seals to secure hatches, ports, and other access points to the transport conveyance significantly reduces the ability of an attacker to successfully contaminate the product without being detected. Tamper-evident seals will indicate if the product has been interfered with during transport.
	Bulk liquid receiving	Use tamper-evident tape on hose ends after capping.	Using tamper-evident tape to seal the hose caps when not in use limits the ability of an attacker to successfully contaminate the product without being detected.

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Explanation
	Bulk liquid receiving	Use authorized personnel for visual observation of the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment.	Having the employee responsible for reviewing shipping documentation visually observe the opening of venting and sampling hatches as well as the hooking up of hoses and pumping equipment significantly reduces the ability of an attacker to introduce a contaminant either to the conveyance via the venting or sampling hatches, or into the hoses prior to unloading without being detected.

Table 3-3. Scenario 3.
Worksheet 1-H: Mitigation Strategies

PRODUCT(S): FOOD XYZ
FACILITY NAME: Anytown #12345
ADDRESS: 1245 Washington Street, Anytown, USA
SIGNED DATE: March 7, 2018

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Explanation
	Liquid food storage tank	Inspect liquid food storage tank prior to use. Immediately prior to reintroducing food, the tank will be visually inspected by the quality control manager using high intensity flashlights and ultraviolet lights to ensure that no contaminant has been added to the tank while it was open and accessible after cleaning.	The use of both high intensity flashlights and ultraviolet lights will enable the quality control manager to make a thorough inspection of the tank to ensure no contamination occurred. The hatch is wide enough to provide a clear view of both the walls and floor of the tank, enabling inspection of all surfaces of the tank interior.

Table 3-4. Scenario 4.
Worksheet 1-H: Mitigation Strategies

PRODUCT(S): FOOD XYZ
FACILITY NAME: Anytown #12345
ADDRESS: 1245 Washington Street, Anytown, USA
SIGNED DATE: March 7, 2018

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Explanation
	Breader	Restrict access to breader to authorized personnel. The facility issues these employees special red caps and identifies their job function on their employee identification badges. Workers authorized to work at the breader will have attained at least the position of "Food Safety Technician Level 3" with at least 4 years of employment and be in good standing with human resources with no pending or previous disciplinary actions. Employees working at the breader will immediately escort out of the area anyone not authorized to be in the area surrounding the breader.	This mitigation strategy significantly reduces the ability of an attacker to enter the area to contaminate the food. Restricting this area to only Food Safety Technician Level 3 workers significantly reduces the number of people who are authorized to be in the area and significantly minimizes the vulnerability posed by an attacker, including an inside attacker. Food Safety Technician Level 3 workers in good standing and with more than 4 years of employment have demonstrated their level of responsibility and trustworthiness to work in this highly vulnerable area and to restrict access to the area.

9.16 Mitigation Strategies: Management Components

Mitigation strategies include risk based, reasonably appropriate measures that an individual knowledgeable about Food Defense would employ to significantly minimize or prevent significant vulnerabilities identified at actionable process steps, and that are consistent with the current scientific understanding of Food Defense at the time of the analysis 21 CFR 121.3.

Food Defense Verification Activities

Food Defense verification activities include the following:

- Verification activities to assure that Food Defense monitoring is being conducted as required
- Verification activities to assure appropriate decisions about Food Defense corrective actions are being made

- Verification activities to assure mitigations strategies are being properly implemented and are effective in minimizing significant vulnerabilities

Table 4-5. Scenario 1.
Worksheet 1-I: Mitigation Strategies Management Components

PRODUCT(S): FOOD XYZ
FACILITY NAME: Anytown #12345
ADDRESS: 1245 Washington Street, Anytown, USA
SIGNED DATE: March 7, 2018

(1) #	(2) Actionable Process Step	(3) Mitigation Strategy	(4) Food Defense Monitoring Procedure and Frequency	(5) Food Defense Corrective Action Procedures	(6) Food Defense Verification Procedures	(7) Food Defense Records
	Liquid ingredient storage tank	Use a lock to secure access hatch on ingredient storage tank. Keys to the lock are held in the security office and can only be retrieved with good reason and approval from the facility security manager or food defense coordinator.	Employee assigned to ingredient storage observes whether the lock is in place and locked at the beginning and end of the tank's 48-hour cleaning cycle.	*Guidance forthcoming*	*Guidance forthcoming*	Liquid storage tank observations record
	Bulk liquid receiving	Use tamper-evident seals on inbound shipping conveyances. Match the numbers on the seals with the numbers provided on the shipping documentation from the supplier. If the seals do not match, the load will be rejected to prevent potentially adulterated ingredient from entering the facility.	Technician assesses whether the seal is intact and matches seal or documentation numbers upon arrival of the load, before hooking up the hose for each delivery.	*Guidance forthcoming*	*Guidance forthcoming*	Receiving/delivery paperwork that includes additional information to indicate monitoring was completed
	Bulk liquid receiving	Use tamper-evident tape on hose ends after capping.	After daily operations, supply chain supervisor confirms that the hose cap is on and taped.	*Guidance forthcoming*	*Guidance forthcoming*	Food defense monitoring log
	Bulk liquid receiving	Use authorized personnel for visual observation of the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment.	On a periodic basis (but at least twice weekly), a manager observes whether personnel are visually observing the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment.	*Guidance forthcoming*	*Guidance forthcoming*	Food defense monitoring log

Source: Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry, March 2019

9.17 Monitoring and Verification Procedure

Verification Activities/Records

An effective FDP must consist of verification activities that are appropriate to the mitigation strategy and how it fits into the facility's Food Defense system. It must be verified that a facility's Food Defense monitoring is being conducted as required by 21 CFR 121.138 (and in accordance with 21 CFR 121.140).

Next, it must be verified that appropriate decisions about Food Defense corrective actions are being made as required by 21 CFR 121.138. Also, mitigation strategies must be verified to assure that they are properly implemented and are significantly minimizing or preventing significant vulnerabilities.

This is accomplished by assuring the activities include a timely review of the Food Defense corrective actions records for completeness of records, that the activities noted in the records occurred in accordance with the FDP, that the mitigation strategies have been properly implemented, and that appropriate decisions were made about Food Defense corrective actions. Also, any other activities for verification of proper mitigation strategies may also be included.

Importantly, these activities must be appropriate to the facility, the food, and the nature of the mitigation strategy and its role in the Food Defense system.

A verification of the reanalysis of the FDP must be done in accordance with 21 CFR 121.157. All verification activities must have established and written procedures that include the frequency for which they are to be performed for Section 9.18. Finally, all verification activities must be documented in records.

All monitoring records, corrective actions and other verification activities must be verified and reviewed within 7 calendar days of their completion. All records must include the following:

- Date, time, signature of person responsible for monitoring
- Must be verified by an authorized person (e.g., FDQI/Certified Food Defense Coordinator)

Please note: Records must not be monitored and verified by the same individual.

All Monitoring/Verification/Activity records are to be maintained by the Document Control designee at your facility.

9.18 Corrective Action Procedures

Establishment and implementation of written Food Defense corrective action procedures that must be taken if mitigation strategies are not properly implemented or effective is a key component of a robust Food Defense system. Food defense

corrective action procedures must be designed such that they are appropriate to actionable process step and the associated mitigation strategy. The Food Defense corrective action procedures must describe steps to be taken to ensure that the action taken to correct a problem is effective in reducing the likelihood that the problem will reoccur. Finally, all Food Defense corrective actions taken in accordance with the scope of section 9.17 must be documented in records that are subject to Food Defense verification and records review in accordance with section 9.17 of this document.

9.19 Appropriate Signatures

The owner, operator, or agent in charge of the facility must sign and date the FDP upon initial completion and upon any subsequent modification.

9.20 Re-Analysis of the FDP

Areas where a significant risk is identified must be defined, monitored and controlled (e.g., external storage, intake points for product and raw materials (including packaging). The FDP must be formally reviewed whenever:

- A new risk emerges (e.g., a new threat is publicized or identified) [21 CFR 121.157(d)]
- An incident occurs, or where product security or Food Defense is implicated
- Where there are changes to the site or building

Note: GFSI requires FDP to be reviewed annually.

Records Requirements

The FDP, assessment, actionable points, corrective action, and verification procedures must be written, stored in a safe area and readily available upon FDA request.

9.21 Education, Training and Qualifications

9.22.1 Food Defense Team

The table below is an example of education, training, and qualification for some members of the Food Defense team:

Name	Position	Roles and Responsibilities	Training **
	Food Quality and Safety Manager*	Food Defense Coordinator (FDQI) Manages food defense program. Evaluates testing and sampling program to monitor for intentional contaminants. Coordinates with outside laboratories for analysis. Ensures that food defense team is aware of customer complaints. Establishes procedures for managing samples and documenting testing.	Certified Food Defense Coordinator; FSPCA Food Defense Awareness
	Supply-chain Manager	Helps develop food defense plan. Enforces plan with supply-chain.	FSPCA Food Defense Awareness
	Director of Operations	Supports a culture of commitment to food defense. Provides appropriate resources (people and capital). Approves changes or recommendations to program	Food Defense Coordinator; FSPCA Food Defense Awareness
	Manager	Helps develop food defense plan. Ensures the food defense plan is enforced with all employees. Educates other members of the food defense team on findings during monitoring of CCTV.	Food Defense Coordinator; FSPCA Food Defense Awareness

*FDQI/Certified Food Defense Coordinator

**Certificates and training records are maintained in the Document Control office

Employee Training

Employees are trained on the following at the time of hire, then additionally given refresher training on an annual basis.

Training records are kept:

- New Hire See Something Say Something/ FIRST Line of Defense
- Annual Refresher – See Something Say Something

See Something Say Something – Threat Awareness

- Threat Awareness training is provided to help employees recognize and report potential threats.
- Employees are encouraged to immediately report any suspicious activity to their manager/supervisor

Supervisors/Managers of those individuals assigned to actionable process steps (including temporary and seasonal personnel) are additionally trained on Food Defense Awareness:

- A Food Defense qualified individual (e.g., have appropriate education, training or experience) or combination thereof necessary to properly implement the mitigation strategy or combination of mitigation strategies at the actionable process step Training/certificates are kept on file in the facility or company document control office

Chapter 10

FOOD FRAUD PREVENTION (UPDATED)

10.1 Introduction

Food fraud is one of the most urgent and active food marketplace concerns. Though food fraud has probably occurred since the start of food commerce, only recently has an interdisciplinary approach been applied to focus efficiently and effectively on prevention. The nut industry may seem like a lower food risk, especially considering using whole nuts. Still, many other vulnerabilities can lead to a recall, loss of consumer confidence, or concern for entire categories of products. Regardless of the level of concern or vulnerability, addressing food fraud is a requirement for most regulatory compliance and industry standards.

From Spink, 2019, there are several types of food fraud risks:

- Direct food fraud risk occurs when the consumer is put in immediate or imminent danger, including an acutely toxic or lethal contaminant; that is, one exposure can cause adverse effects in the whole or a smaller at-risk population.
- Indirect food fraud risk occurs when the consumer is put at risk through long-term exposure, such as the buildup of a chronically toxic contaminant in the body, through the ingestion of low doses. Indirect risk also includes the omission of beneficial ingredients, such as preservatives or vitamins.
- Technical food fraud risk is nonmaterial in nature. For example, food documentation fraud occurs when product content or country-of-origin information is deliberately misrepresented.

Before the Food Safety Modernization Act (FSMA), all intentional acts, including Food Defense and food fraud, were combined under the “intentional adulteration” or “intentional contamination” term. Based on this categorization, food fraud was previously included by the FDA as a sub-category of Food Defense. After the FSMA Intentional Adulteration rule (FSMA-IA) was finalized, the Food Defense concept was narrowed to only intentional acts with the motivation to harm. Also, FSMA-IA further narrowed the FDA focus to only actions that resulted in “wide-scale public health harms.” The FSMA-IA rule stated that economically motivated hazards (e.g., food fraud) were addressed in the FSMA Preventive Controls rule (FSMA-PC). Thus, the FDA does not include food fraud under the Food Defense umbrella. This is consistent with the Global Food Safety Initiative (GFSI), the International Standards Organization (ISO), the Codex Alimentarius draft documents, and other global regulatory agencies and industries.

DEFINITIONS

The general definition of **food fraud** – including the sub-category of economically motivated adulteration (EMA) – is intentional deception for economic gain using food, including ingredients, through finished goods in the marketplace. A more formal definition is the following:

- **Food fraud** as defined by the GFSI is "A collective term encompassing the deliberate and intentional substitution, addition, tampering or misrepresentation of food, food ingredients or food packaging, labeling, product information or false or misleading statements made about a product for economic gain that could impact consumer health."

The food risk matrix is a simple way to explain how food fraud is related to food safety, food quality, and Food Defense (Figure A).

- Food Defense: an intentional act with the intent to harm as defined in terms of psychological terror, economic harm, or a public health threat.
- Food Defense in relation to FSMA-IA: the FSMA includes an Intentional Adulteration Final Rule that narrows the focus of Food Defense to "wide-scale human health harms." When addressing Food Defense, it is CRITICAL to state the definition and scope of the project to avoid confusion related to regulatory or certification compliance.
- Food Safety: product causes a health hazard. This is an unintentional act with a health hazard.
- Food Quality: product meets the specification. This is an unintentional act with no intent to harm.

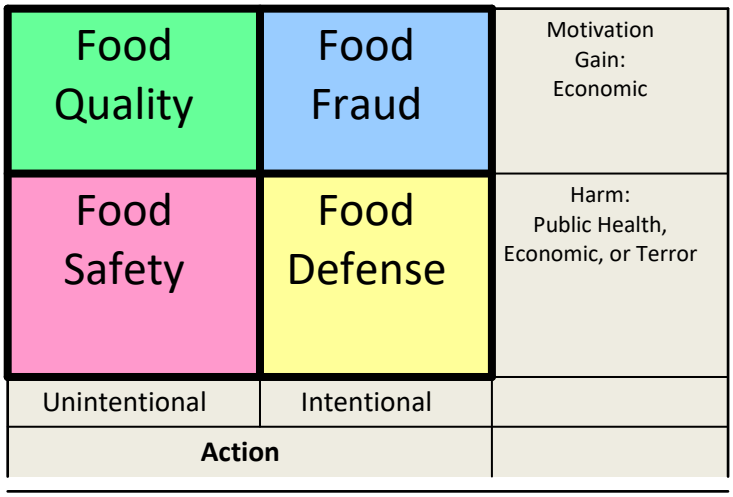


Figure A: The Food Risk Matrix from Spink and Moyer, 2011

Other related key definitions are included here and include a figure to explain the relationships (Figure B) visually:

- Food Authenticity, citing the Elliott Review, “is about ensuring that food offered for sale or sold is of the nature, substance, and quality expected by the purchaser.”
- Food Integrity, citing the Elliott Review, “can be seen as ensuring that food which is offered for sale or sold is not only safe and of the nature, substance, and quality expected by the purchaser but also captures other aspects of food production, such as the way it has been sourced, procured and distributed and being honest about those elements to consumers.”
- Intentional Adulteration, especially when referring to FDA-related compliance such as to the FSMA Intentional Adulteration rule (FSMA-IA), applies to intentional acts with the intent to harm or Food Defense.
- Economically motivated adulteration, especially when referring to FDA-related compliance such as to the FSMA Preventive Controls rule (FSMA-PC) and FDA’s working definition, is a “substance” added or excluded “for economic gain” that has a “health hazard.” EMA is a sub-category of food fraud.
- Food Security, as defined by the World Health Organization (WHO) and universally adopted, is “…the access to safe, continuous, nutritious, and economical supply of food.”
- Food Protection, from the FDA, is “A Food Protection Plan (the Plan) that addresses food safety and defense for domestic and imported products.… Address both unintentional and deliberate contamination.”

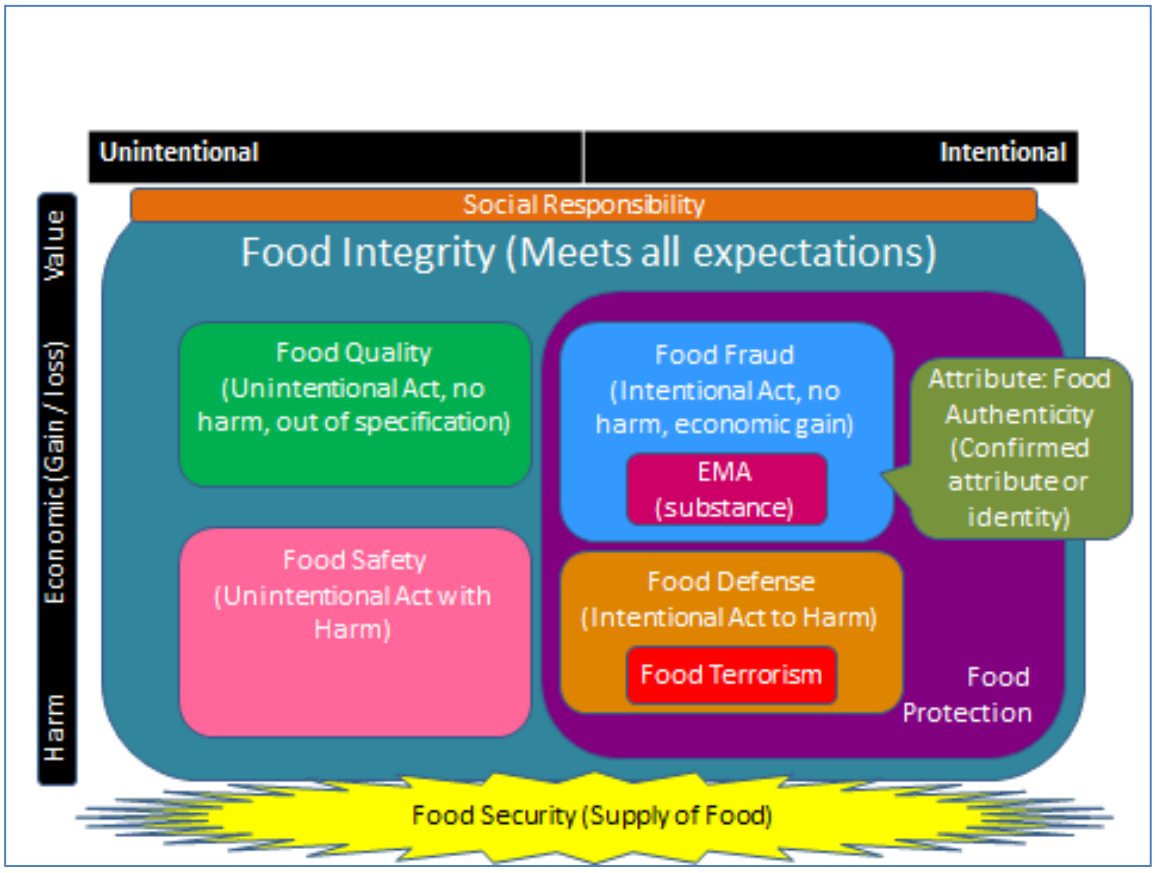


Figure B: Hierarchy and Relationship of Food Fraud Related Terms with the Addition of Food Protection, Food Integrity, Food Authenticity, Social Responsibility, and Food Security

Other important related terms are the following:

- Vulnerability Assessment, from the ISO, is "…a process of identifying and quantifying something that creates susceptibility to a source of risk that can lead to a consequence."
- Food Fraud Prevention Strategy (Food Fraud Mitigation plan), from the GFSI, is "[A] documented plan in place that specifies the measures the organization has implemented to mitigate the public health risks from the identified food fraud vulnerabilities."
- Vulnerability Assessment and Critical Control Point Plan (VACCP), from the GFSI, is the "…prevention of intentional adulteration, economically motivated." One of three components under the GFSI Food Safety Management system includes Hazard Analysis and Critical Control Point (HACCP), Threat Assessment Critical Control Panel (TACCP), and VACCP. Food Fraud assessments focus on "vulnerabilities" rather than "risks." This provides consistent wording for referring to the different assessments.
- Food Fraud Vulnerability Assessment, from the GFSI, is "The standard shall require that the organization have a documented food fraud vulnerability assessment in place to identify potential vulnerability and prioritize food fraud vulnerability control measures." From the GFSI Guidance Document is the following: "…in which information is collected at the appropriate points along the supply chain (including raw materials, ingredients, products, packaging) and evaluated to identify and prioritize significant vulnerabilities for food fraud."
- Economically motivated adulteration (EMA) is a sub-type of food fraud that includes an adulterant-substance. The definition is based on the FDA working definition; thus, the key definition in relation to regulatory compliance requires a "substance" for "economic gain" and a "food safety hazard." The EMA term is often incorrectly used interchangeably with food fraud. From the FDA is the following: "Fraudulent, intentional substitution or addition of a substance in a product to increase the apparent value of the product or reduce the cost of its production, i.e., for economic gain."

The types of food fraud were first defined in a scholarly journal by Spink and Moyer in 2011, codified in an ISO standard in 2018, and expanded upon by the GFSI and Safe and Secure Food for Everyone Association (SSAFE), and they include the following:

- Adulterant-Substance (Adulterate, Adulterated, etc.): A component of the finished product is fraudulent
    - Dilution: The process of mixing a liquid ingredient with a high value with a liquid of a lower value.
    - Substitution: The process of replacing an ingredient or part of a high-value product with another ingredient or part of a lower-value product.

    - Concealment: The process of hiding low-quality food ingredients or products.
    - Unapproved enhancements: The process of adding unknown and undeclared materials to food products to enhance their quality attributes.
    - Note: this type also includes economically motivated adulteration (EMA).
- Tamper: Legitimate products and packaging are used in a fraudulent way.
    - Mislabeling and Misbranding: The process of placing false claims on packaging for economic gain.
- Over-run: Legitimate product is made in excess of production agreements
- Theft: Legitimate product is stolen and passed off as legitimately procured
- Diversion: The sale or distribution of legitimate products outside of intended markets. This is not necessarily illegal or a violation of a contractual agreement, but it identifies a lack of transparency in the supply chain and potential vulnerability.
- Simulation: Illegitimate product is designed to look like the legitimate product but not is an exact copy. This act is not necessarily illegal and, in most cases is lawful, but it can be confusing and create a potential vulnerability.
- Counterfeit (Intellectual Property Rights (IPR) infringement): All fraudulent product and packaging aspects are fully replicated.

COMPLIANCE REQUIREMENTS

All types of food fraud are usually illegal under one or several regulations. For example, the Federal Food, Drug, and Cosmetics Act (FD&C Act), supplemented by the Food Safety Modernization Act (FSMA), requires "…a hazard analysis, regardless of the outcome." A hazard analysis must be conducted and written to meet compliance if you think an issue like stolen goods is not applicable. Also, all types of food fraud are a violation of either (or both) the FD&C Act's Adulterated Foods or the Misbranded Foods sections.

Building upon the broader range of international, public, and private requirements, the GFSI has summarized them in its guidance document. The requirements include the following:

- Conduct an incident review
- Conduct, document, and update a Food Fraud Vulnerability Assessment (FFVA). This is often supported by a corporate risk map or a risk heat map.
- Conduct, document, and update a Food Fraud Prevention Strategy (FFPS). This is often supported by a presentation of the management system or workflow, such as the Food Fraud Prevention Cycle (FFPC).
- Incorporate and calibrate the FFVA and FFPS with the Food Safety Management System (My Food Safety Plan).

One of the most important steps is calibrating the FFVA with all other food safety and enterprise-wide risks. The food fraud problems should not be ranked only versus the other food fraud problems. The same likelihood and consequence ranks, and the same enterprise-wide risk tolerance should be used. It is possible that most of the food fraud problems fall below the enterprise-wide risk tolerance.

10.2 Understanding the Risk and Vulnerability

Food fraud is a unique food risk because the root cause is an intentional act by a human adversary. The fraudster is often intelligent, resilient, patient, stealthy, and often sell-funded. The field of social science focuses on human behavior, and specifically, criminology focuses on crimes. The goal of crime prevention is to reduce the opportunities so fewer crimes occur. Building on crime prevention theory, the focus is to detect, deter, and prevent. Crime prevention is most efficient when identifying and reducing system weaknesses or vulnerabilities.

Key terms from ISO 31000 Risk Management are the following:

- Risk: "…is an uncertainty of an outcome that is assessed in terms of likelihood and consequence" that is usually presented in a quantitative probability, such as a 55% probability with an assumed 95% confidence in the statistical accuracy of the statement (the 95% confidence interval).
- Vulnerability is "…a weakness or flaw that creates opportunities for undesirable events related to the system ("system design")" and is usually presented in a qualitative statement, such as very high, medium, or low, or very low though each rank can be based on numbers, such as "$100k to $1 million in loss".

- Prevention: "intended to reduce or eliminate the likelihood of the event occurring."

- Mitigation: "intended to reduce the consequence of the event"

To define the situation:

- Problem (based on criminology scholarship): "…the basic unit of police works rather than a crime, a case, calls, or incidents. A problem is something that concerns or causes harm to citizens, not just the police."
- Event: an "occurrence or change of a particular set of circumstances."
- Hazard: "…is an event that has not occurred and could cause harm if not addressed."
- Threat: "…the cause of an unwanted event that includes generally known variables or attributes of the source of the negative consequence."

Building on the ISO 31000 foundation, a likelihood and consequence define the risk assessment. Each of these factors can be further defined by characteristics, such as the likelihood of occurrence and likelihood of detection. The consequence can be further defined by the speed of onset, length of warning, length of impact, recoverability of the system, and time to recover. The findings are present in a matrix that is referred to as a corporate risk map or a risk heat map (Figure C).

The two axes are identified with these elements:

- Likelihood: from the ISO is "In risk management terminology, the word 'likelihood' is used to refer to the chance of something happening, whether

defined, measured or determined objectively or subjectively, qualitatively or quantitatively, and described using general terms or mathematically (such as a probability or a frequency over a given time period)."

- Consequence: from the ISO is the "…outcome of an event affecting objectives," including "a consequence can be certain or uncertain and can have positive or negative effects on objectives."

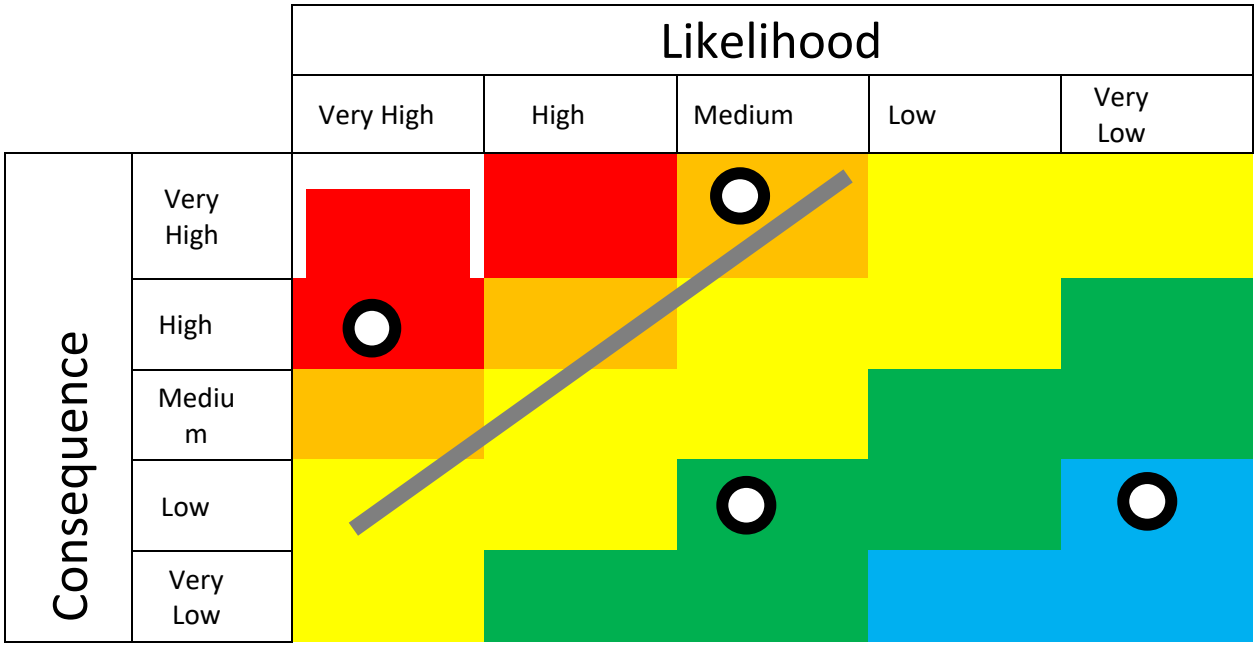


Figure C. Corporate Risk Map Matrix with the estimated risk tolerance line and four identified problems.

A vulnerability assessment can be qualitative or quantitative.

A vulnerability assessment, as recognized by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) managerial accounting practice in Enterprise Risk Management (ERM or COSO/ERM), can take a two-stage approach, including an "initial screening" and then a "detailed assessment." An initial screening is sometimes referred to as a "pre-filter." The guidance from the managerial accounting perspective is first to conduct a quick and straightforward assessment that covers the entire enterprise and addresses all products and sources for all incoming and outgoing goods. This initial screening helps reduce the amount and intensity of the first activities and narrow the focus to the most important problems and is used to identify where there should be more research or where more data are needed to understand the problem entirely.

Once the initial screening is completed, the following more detailed assessment is conducted. The process is repeated in more detail until a decision can be made regarding resource allocation for countermeasures and control systems. The

assessment should be conducted for specific problems until one decision can change a vulnerability from unacceptable to acceptable.

The goal is not to get to ‘zero risk’, which is not only impractical but often impossible, but to understand the risk in relation to the enterprise's risk tolerance. Some compliance requirements clearly state risk tolerance levels for an item (e.g., a food safety test for parts per million of a chemical) or the need for a process (e.g., a Food Defense Plan).

Regarding ‘zero tolerance’ or ‘zero risk,’ consider employee safety versus a meteor strike. Yes, a meteor could hit your facility, and the incident would be catastrophic, so it is a known system weakness. The consequence is extremely high. The likelihood is extremely low. Another consideration is the cost and ability to mitigate the risk (preventing a meteor strike is the in the category of a Star Trek television show episode). Protecting the employees from this vulnerability would be extremely costly, such as moving your operations into an underground bunker. Thus, this is a known extremely high consequence incident that is accepted and within the enterprise's risk tolerance.

Common examples include extra-virgin olive oil diluted with cheaper oil or honey diluted with corn syrup. Unfortunately, not all scenarios are as innocuous as these; some types of food fraud pose a real health risk to consumers. Potential food fraud risks in the nut industry, although uncommon, may include the following:

- Labeling nonorganic products as organic.
- Labeling products as being grown in a specific geographical region, allowing sale at a higher price than the region in which the nuts are grown.
- Mixing a less expensive nut with a more expensive product, such as adding peanuts or peanut pieces to cashew products or to blanched almond products.
- Inclusion of inferior products (nuts which do not meet specification) or nonfood products, such as cellulose powder, to processed items like nut meals or nut butters. Examples from other food items include peanut or almond added to ground cumin, melamine added to dairy products, use of cheaper oils in extra virgin olive oil, and addition of sugar syrups to honey.
- Coloring, painting, or dying defective or inferior nuts for sale at a higher price. Examples from other industries include various illegal dyes used to color chili pepper products, turmeric, saffron, and other spices.

VULNERABILITY CRITERIA AND THE MANAGEMENT SYSTEM (VACCP)

The Food Fraud Prevention Strategy (FFPS) provides a decision-making process for selecting, implementing, and managing the responses. The food fraud prevention activities are all centered around the food fraud vulnerability assessment. The new incident information is fed into the vulnerability assessment to identify the level of concern. Collectively, this is referred to as the Vulnerability Assessment and Critical Control Point Plan (VACCP). The core activities are based on quality management, such as the food safety HACCP plan. Essentially, VACCP is like HACCP but for food fraud prevention.

Gather Incident Review Data

The first step is to gather food fraud incident review data. A key is gathering a wide range of information from detailed incident review laboratory tests to even informal suspicious activity concerns. The next step of the vulnerability assessment will process and rank the problems. In some situations, the process may identify that more information or details are required.

It is helpful to keep a list of all the possible vulnerabilities and the conclusion to act or not, so they can be periodically reviewed.

There is sometimes a concern that by identifying many vulnerabilities, there will need to be many new control plans. This is not true. Not every vulnerability is a risk, not every risk is a hazard, and not all hazards require preventive control. From Spink, 2016:

- Sources of data for the Food Fraud Initial Screening (FFIS) and Food Fraud Vulnerability Assessment (FFVA):
  - Subject matter expert insight
  - Known incidents within the company (i.e., internal sources)
    - List incidents
    - List details and costs if known
  - Databases (i.e., static external sources)
    - Review product recall information (i.e., company, product group, industry, etc.)
    - Review Food Fraud or related databases
  - Internet searches (i.e., dynamic external sources)
    - General Internet searches (i.e., by individual products, etc.)
    - Set up automated Internet keyword alerts, for example, ongoing Google Alerts

There is extensive guidance from the criminology perspective on assessing data sources (all sources of information are not equal) and reviewing the suspicious behavior details (not all suspicious behavior is a problem).

Food Fraud Initial Screening and Vulnerability Assessment

The next step is to conduct the vulnerability assessment. Each new data point should be assessed in terms of the likelihood and consequence. While all food fraud is “bad,” every incident is not above the risk tolerance.

Regarding accepting criminal activity, consider jaywalking (not crossing a street at an identified crosswalk). In many locations, jaywalking is illegal. This is clearly a violation, but it is rarely enforced. The law enforcement priority-setting continues to apply the resources to higher problems. In other situations, such as where there may be many injuries or deaths (such as late on weekend nights along a busy street next to bars and nightclubs), the law enforcement priority may be to enforce jaywalking laws more strictly.

Following the guidance, such as in the Food Fraud Initial Screening (FFIS) tool:

- Consider separately incoming and outgoing goods.
- Identify and define the factors, such as in these two groups (see Figure D):
    - Product/Groups (dairy, meat, dry goods, bulk, branded, etc.) and
    - Supply/Customers (countries, companies, types of products, etc.)
- Develop assessment criteria. (This is often a difficult first step, but fortunately there is guidance.) This step defines the details for very low, low, medium, high, and very high.
- Conduct the assessment. Review the list of incidents and select likelihood and consequence ranks as well as the overall vulnerability rank.
- Plot the final vulnerability rank on the corporate risk map. This step provides a visual summary of the specific problems that are above the risk tolerance.

		Market/ Region				
			x	x	x	x
Product/ Group		A	B	C	D	E
Spices	1	VH				
x	2					
x	3					
x	4					
x	5					

Figure D. Food Fraud Initial Screening (FFIS) Risk Matrix for Incoming or Outgoing Goods.

To complete the process, it is recommended to create a one-page summary. This summary helps identify gaps in the findings. This also provides a simple summary to present to management, auditors, or customers.

FOOD FRAUD PREVENTION STRATEGY AND MANAGEMENT SYSTEM

The implementation is presented in three parts: the Food Fraud Prevention Strategy (FFPS), implementing a management system, and then integrating it into the Food Safety Management System.

Food Fraud Prevention Strategy

The strategy is the working document or process to receive new information and direct the activities.

The set of activities and methods could be defined as a system such as in the Food Fraud Prevention Cycle (FFPC) (Figure E). The FFPC activities include the following steps:

1. gathering new or changing information
2. reviewing the fraud opportunity
3. conducting a Vulnerability Assessment

4. Using the Enterprise Risk Rank Calibration
5. ranking on the Corporate Risk Map, and
6. considering and managing Countermeasures and Control Systems. As with any risk management or continuous improvement system, the cycle should be repeated.

By identifying each activity, there can be an assurance that each step is taken. Also, the further review can develop and refine each activity's process and sub-processes.

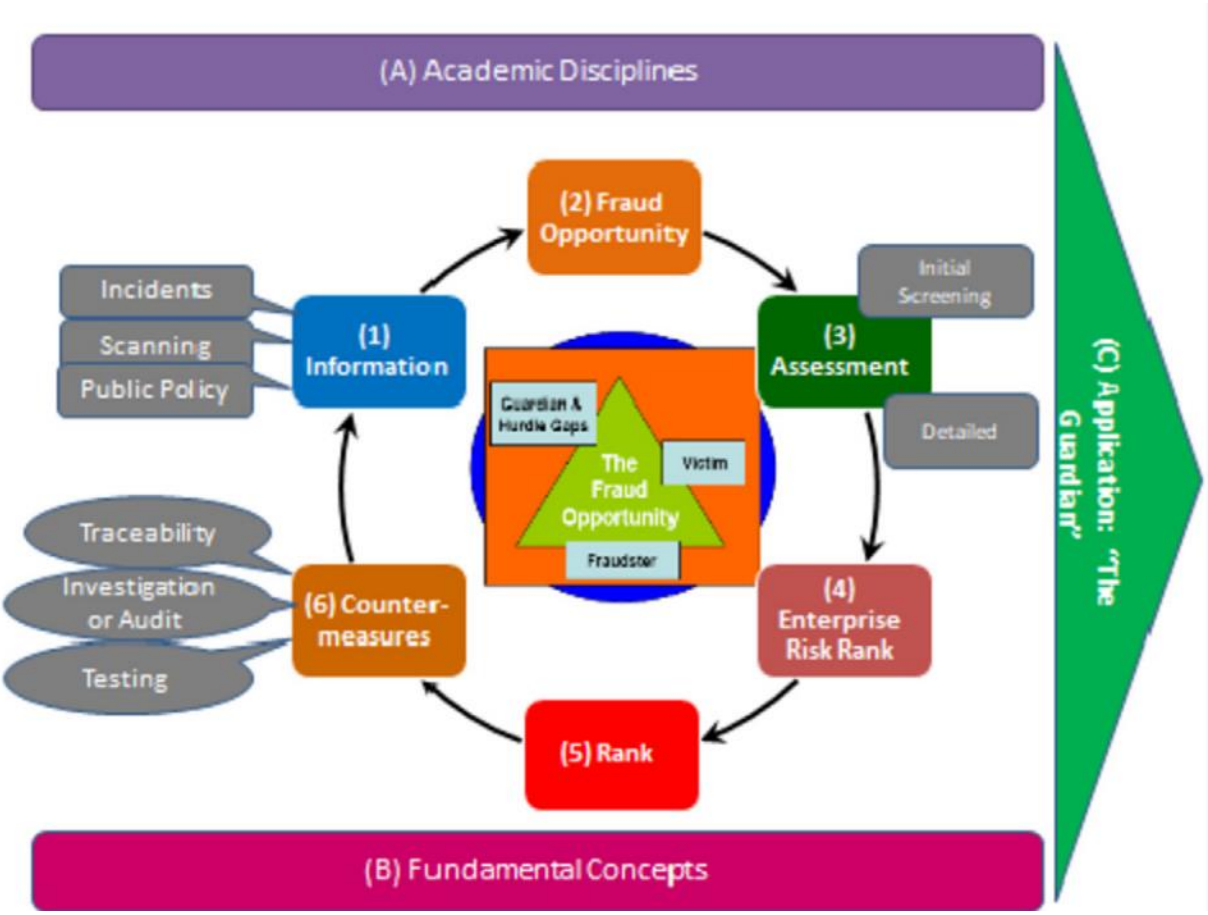


Figure E. Food Fraud Prevention Cycle (FFPC) (Spink, 2016)

Implementing a Management System

A strategy is often just a plan on a piece of paper. As defined by ISO for quality management, a management system is "…a set of policies, processes, and procedures required for planning and execution (production/development/ service) in the core business area of an organization."

Consider the formality of quality management or food safety system. In application, a management system is demonstrated by identifying a leader and a team, defined team goals and objectives, a regular meeting schedule, a method to define when special meetings or actions take place, and the related support documentation. Remember, VACCP is like HACCP but for food fraud.

Though this may seem to add a tremendous amount of activity and formality, in reality, a holistic and all-encompassing Food Fraud Prevention Strategy could streamline and lessen the amount and intensity of activity while simultaneously more effectively and efficiently protecting the company and consumers. Without a comprehensive plan, there may be no clear support to define 'how much is enough or, more importantly, 'how much is too much.'

Integration into the Food Safety Management System

Finally, to complete the integration into the enterprise and to meet GFSI requirements, there must be an explanation of how the food fraud vulnerability assessment and the prevention strategy fit into the overall Food Safety Management System. The Food Safety Management System is synchronized and calibrated to the enterprise's overall quality management and risk management systems.

10.3 Addressing Food Fraud in My Food Safety Plan

The risk of food fraud in a company's supply-chain, when it bears a potential health risk, may be addressed within the company's food safety (or HACCP) plan. If the company has implemented a GFSI-compliant program, an additional, more detailed assessment of the potential for food fraud is also conducted in a separate program per requirements laid out in the respective GFSI program. Regardless of approach, there are several risk factors that should be considered as part of the assessment:

- High cost of the item, such as with spices
- Low supply (rarity) of the item, either as a matter of course or due to other factors, such as weather events or political crises
- Ease of contamination, for instance, a ground, liquid, or powdered item that would be easier to add foreign material to, without detection, than a whole natural nut
- Likelihood of detection, if contamination did occur
- Ease of access to the item within the supply-chain; this can be limited by security measures at your supplier and activities, such as transportation security measures
- Country of origin (food companies may refer to the "Corruption Perceptions Index" as a gauge of risk)
- Confidence level in the specific vendor, due to established company history, past performance, any past FDA enforcement activities, and any recent changes in ownership

Appropriate control measures can include programs, such as the following:

- Thorough vetting of suppliers prior to product purchase and receipt, including checking the Food and Drug Administration (FDA) website for any past issues the company has had, such as import alerts, warning letters. This can be done using the FDA's Supplier Evaluation Resources page, https://datadashboard.fda.gov/ora/fd/fser.htm.
- Security measures in the supply-chain, such as a truck or container sealing
- Inspection of the load upon arrival including verification of the seal or lock, and general condition of the load and container
- Inspection and on-site testing of raw materials upon receiving, potentially to include specialized testing at a third-party laboratory as appropriate

Protecting the product does not stop with the supply-chain. Once the product arrives, measures must be taken on-site to prevent any intentional tampering with the product. This is outlined in the Food Defense section of this manual, as well as in the section addressing FDA's Intentional Adulteration Rule, which is part of the FSMA Rules

10.4 Training

A selection of free training resources is reviewed here. Fee-based or commercial training is not included because the updated offerings can be found in Internet searches.

Food Fraud Prevention Academy (FFPA), free, on-demand, Massive Open Online Courses (MOOCs): Food Fraud Prevention Overview, Food Fraud Prevention Audit Guide, Food Fraud Vulnerability Assessment (FFVA) and VACCP, Food Fraud and Enterprise Risk Management, and others. URL: www.FoodFraudMOOC.com

- The FFPA courses were developed to provide a holistic and all-encompassing program. The focus is on capacity building and capability building for an internal food fraud team as well as others such as internal auditors. The courses have been offered since 2013 and are continually updated and expanded to meet emerging needs.

Global Food Safety Initiative (GFSI), Food Fraud Technical Document Support Training (Tackling Food Fraud Through Food Safety Management Systems). URL: https://mygfsi.com/wp-content/uploads/2019/09/Food-Fraud-GFSI-Technical-Document.pdf.

- This is the official guidance from GFSI regarding GFSI compliance. The technical document is supplemented by free training videos on the GFSI Food Fraud Requirements and an overview of the terminology and compliance requirements.

International Association for Food Protection (IAFP), Professional Development Group on Food Fraud Prevention (PDG-FF), free online training for the application on the role of science and technology in food fraud prevention. URL:

https://www.foodprotection.org/get-involved/professional-development-groups/food-fraud-pdg/.

- The IAFP is a professional organization, and the PDG-FF has created a foundation for its members to support the development, selection, and use of science and technology. Specifically, the IAFP membership is focused on detection activities for the adulterant-substances.

SSAFE Organization (formerly the Safe and Secure Food for Everyone Association), Food Fraud Vulnerability Assessment Tool and video training. URL: https://www.ssafe-food.org/tools/food-fraud-vulnerability-assessment-training-modules.

- SSAFE is a group of food industry thought leaders from thought leader companies. This is an industry and academia-created tool and training video created to meet the GFSI food fraud prevention requirements. This resource includes an online survey tool that makes a results report.

U.S. Department of Agriculture (USDA), National Organic Program (NOP), Organic Integrity Learning Center (OILC), free, on-demand video training on Organic Fraud and the Criminal Mind and Prevention Organic Fraud. URL: https://www.ams.usda.gov/reports/organic-integrity-learning-center.

- This is the official USDA NOP guidance for USDA NOP compliance. The USDA NOP funded this project to create training for their USDA Organic Inspectors. This training includes a comprehensive background on system weakness situations and scenarios. This applies to all product fraud, not just organics.

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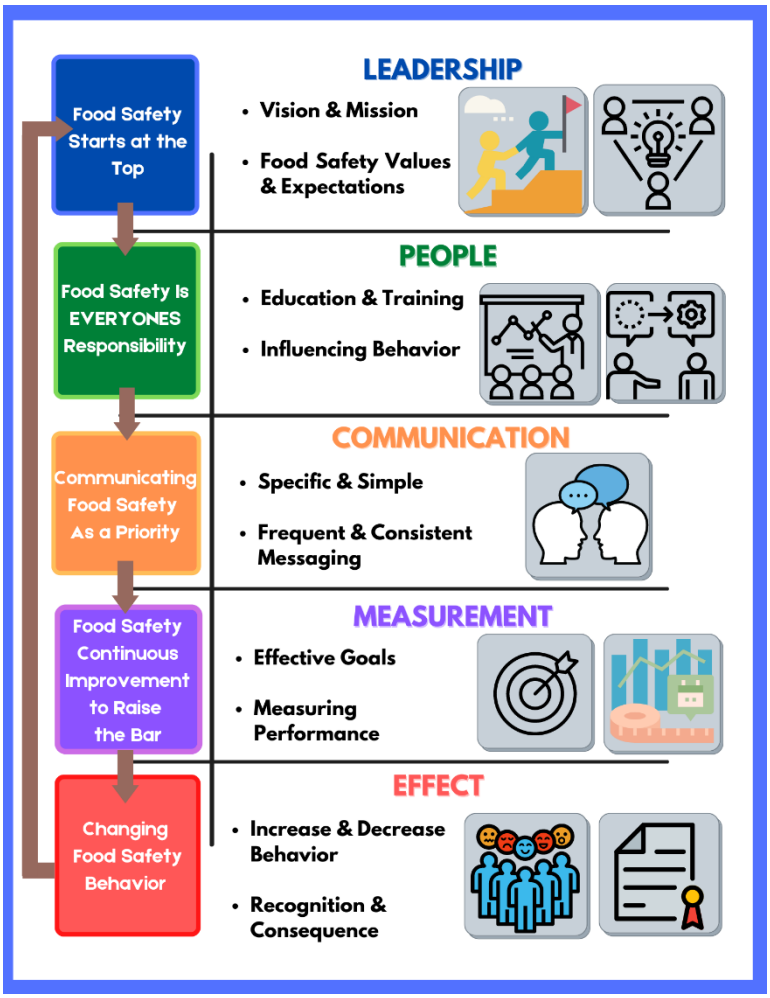
Chapter 11

FOOD SAFETY CULTURE (NEW)

11.1 Introduction

Food Safety Culture is a new initiative undertaken by the Global Food Safety Initiative (GFSI) and the Food and Drug Administration (FDA) (GFSI, 2018; FDA, 2020). Facilities that have a strong Food Safety Culture are ones where food safety and quality are a shared responsibility among all employees and are not deemed just a function of one department. These facilities have empowered and encouraged employees to act when they see any deficiencies and have a management team that supports addressing concerns or potential issues as they arise.

The GFSI have identified five dimensions of Food Safety Culture (GFSI, 2018). Each dimension is important to advancing food safety to become part of the business culture and core value. Culture is more than a written set of programs or rules but rather the behaviors and actions of a group.



11.2 Definitions

Food Safety Culture: “Shared values, beliefs, and norms that affect mindset and behavior toward food safety in, across, and throughout an organization” (GFSI, 2018). Another definition is “How an organization or group does food safety” (Yiannas,2009).

Figure 1 summarizes the five components of Food Safety Culture. The components include the following:

1. Leadership through established vision and mission as well as food safety values and expectations;
2. Ensuring that people in your organization receive the appropriate education and training to influence behavior;
3. Having specific and simple communication with frequent and consistent messaging;
4. Establishing effective goals and measuring performance; and

5. Effect food safety behavior in the organization. The arrows indicate that it is a continuous cycle to improve on Food Safety Culture.

11.3 Leadership – Food Safety Starts at the Top

Leaders of an organization can influence a company's culture. Therefore, it is of great importance that leaders: 1) establish a clear vision and mission for a company, 2) set the direction including food safety values and expectations for all employees, and 3) have leadership commitment for food safety and appropriate messaging that goes along with that commitment.

11.3.1 Vision and Mission

Vision and mission statements are generally established by the Senior Leadership team of a company and communicate the business's expectations. These statements have specific messaging for how it translates to all stakeholders and communicates the values of the company. Though not required to specifically mention food safety, the importance of food safety should be clearly reflected in the company's communications.

11.3.2 Setting Food Safety Values and Expectations

Leaders set directions by identifying clear paths to success. Goals, milestones, and set expectations for measuring success and failure are included when setting clear direction for the company. Food Safety Culture should be a core value and integral in direction-setting.

Circumstances to include that can alter direction-setting may include the following:

- Changes in regulatory requirements
- Acquisitions and divestments
- Product innovation and new product development
- Entry into new markets
- Serious food safety incidents (e.g., recalls, market withdrawals, internal incidents)
- New information from science, technology, and analytical advances
- New knowledge regarding food safety or quality hazards

Leadership sets the tone and direction for the Food Safety Culture in ways that support, align, and contribute to the overall vision and mission. Leaders throughout the business organizational chart from executives to plant supervision have an impact on the organizational culture. A leader's commitment to food safety can significantly influence the development of a strong Food Safety Culture.

A food safety policy signed by the Senior Leadership team is a foundational element of establishing and cultivating a Food Safety Culture. The signed policy should align with the company's overall strategic direction and address food safety ownership at all organization levels.

One of the most important ways to demonstrate a leadership commitment to Food Safety Culture is by allocation of resources, including financial, people, and time. A capital plan or budget available that prioritizes food safety and clearly communicating that plan helps enforce that food safety is a top priority for the company.

Clear and concise messaging regarding the company's food safety expectations is crucial for a successful Food Safety Culture. The goal of communication is to educate, inform, and raise awareness among all employees in the company. Tailoring the message to each group ensures all individuals in the company as a whole take ownership of their role in food safety.

Including food safety in leadership meetings and personal growth goals ensures a strong focus and commitment across the entire leadership team. Leaders should be trained to "lead by example" and demonstrate a commitment to food safety as well as listening to and addressing concerns of employees.

11.4 People – Food Safety Is Everyone's Responsibility

People are the most critical element in establishing a Food Safety Culture. Every person within an organization has an impact on food safety. From the sales team, to marketing, to each individual in the production facility, everyone's behavior has an impact on the overall Food Safety Culture of an organization.

The People dimension focuses on providing the tools to all employees to understand how their actions impact the overall safety of the food produced. Tools include knowledge, standards, metrics, and accountability. There is also an element of empowering employees to act and use their knowledge to maintain or enhance food safety practices.

To have a mature Food Safety Culture, organizations have educated and empowered all employees throughout the organization to understand food safety. To that extent, all employees from field workers, maintenance crews, and forklift drivers, to production workers must understand their role in ensuring all products are safely produced, processed, handled, and shipped.

Cross-functional teams drive engagement of all stakeholders and build a foundation for a strong Food Safety Culture. The end goal of a mature Food Safety Culture is for every employee to understand that food safety is a shared responsibility.

11.4.1 Education and Training to Influence Behavior

Similar to the company's mission and values, food safety should be embedded within the organization's governance structure and should be an important piece of continuing education. Food safety governance should be included in the following:

- Strategic direction
- Organizational structure and accountability
- Policies and standards

- Risk and issues management
- Culture and behaviors

Companies should establish a formal food safety structure with clearly defined responsibilities. Direct communication or processes empowers employees to escalate food safety concerns or issues to Senior Leadership in a timely manner. A "see something, say something" mentality is important part of the Food Safety Culture of an organization.

A large part of a Food Safety Culture is empowering the workforce with knowledge and authority to act on any concerns or issues. This ensures the company has an ability to adapt, improve, and sustain the culture. Part of the Food Safety Governance is to empower employees and ensure they can lead or initiate positive change through positive education and re-enforcement.

Developing employee understanding and competency of food safety ensures the employee base can swiftly identify concerns or issues. Education is critical in ensuring that employees understand food safety as it pertains to them. Food safety should be included in Internal Development Plans (IDPs) and the developmental training paths for all employees across an organization. Training topics should include the following:

- Technical food safety aspects per position
- Broader food safety understanding
- Communication and problem-solving skills
- Change management

In a food safety training program, consider whom you are training (i.e., frontline workers, plant management, Senior Leadership) because that will determine what type of information or message is part of that training. For example, if training Senior Leadership, convey how food safety affects business results or how certain business decisions they make affect food safety. For training frontline workers and plant management, a clear, straightforward message with graphics, video, or on-the-job demonstration may work better than detailed text and technical wording. Work with Human Resources (HR) to determine if employees from varying regions or different cultural backgrounds have a preferred language for training and/or communication. At the end of the training, an acknowledgement question for employees to answer if they will commit to follow the food safety practices outlined in the training can help engage employees to follow those practices.

Tools for ensuring competency and retention after training is essential. These tools help determine employee's level of understanding and confidence in the training received. By evaluating competency and confidence of employees for identifying and communicating concerns, companies can tailor approaches to ensure all individuals understand their role and responsibilities.

11.5 Communication – Communicating Food Safety as a Priority

Communication is essential in developing and sustaining a culture. Good communication ensures all employees are communicated to in a method they understand. Messaging should be specific and simple. The communication should occur on a regular basis (see Table 1 for important food safety and nut industry dates through the calendar year) and be tailored to the audiences, accessible, and measured for effectiveness.

Table 1. Food Safety and Nut Industry Calendar Dates.

Month	Date	Description
February	National Snack Food Month	
	16th	National Almond Day
	25th	National Chocolate Covered Nut Day
	26th	National Pistachio Day
March	National Peanut Month	
	1st	National Peanut Butter Lover's Day
April	National Pecan Month	
	14th	National Pecan Day
	21st	National Chocolate Covered Cashew Day
May	Food Allergy Awareness Month	
	17th	National Walnut Day
June		
	1st	National Hazelnut Cake Day
	7th	World Food Safety Day
	Food Allergy Awareness Week	
July		
	8th	Chocolate with Almonds Day
August		
	3rd	National Grab Some Nuts Day
	31st	Trail Mix Day
September	Food Safety Education Month	
	4th	National Macadamia Nut Day
	13th	National Peanut Day
October		
	15th	Global Handwashing Day
	22nd	National Nut Day

November	National Peanut Butter Lovers Month	
	15th	National Clean Your Refrigerator Day
	23rd	National Cashew Day
December		
	14th	National Roast Chestnuts Day

Communication of any identified food safety risks is also important in ensuring a shared understanding of food safety. High-level communication of risk includes ensuring cross-functional understanding of potential crises. Driving risk-based decision making and having training scenarios with Senior Leadership commitment of financial resources ensures that in the event of a crises, all teams are prepared and understand the impact of their actions. Consistent messaging and alignment across the organization reinforces a culture of food safety. Consistency in actions as well as decisions from top management to plant supervisors strengthens the communications received by employees.

Written policies, procedures, trainings, Key Performance Indicators (KPIs), and communications are essential in building a Food Safety Culture. However, understanding and encouraging employee engagement is what really drives the behavior aspect of a Food Safety Culture.

In addition to training and ensuring employees understand food safety, companies should engage employees on how to enhance and correct any deficiencies noted. A two-way street for communication and responding to feedback creates a culture where employees feel empowered and engaged.

Documentation provides a single source of information to share knowledge of a company's processes and policies. Documenting procedures eliminates the practice of relying on individual and tribal knowledge sharing. Documentation must be accessible and maintained as current.

Adequate and accurate documentation is essential in keeping employees informed of changes, expectations, and responsibilities. Any major changes to the documented policies and procedures should be communicated to employees who are affected by the change. Employees must understand why the change was necessary and important to food safety. This helps an organization to get a "buy in" from employees and to get feedback from employees on how the change may affect their work.

11.6 Measurement – Food Safety Continuous Improvement to Raise the Bar

Measuring performance enables a company to make improvements and allocate resources accordingly. Strong connections exist between what a company measures and how employees behave. Defined and routine measurements or KPIs ensures employees remain focused on food safety.

Food safety performance measurements should not only address product and process performance of the employees on the production line but also address decisions, actions, and behaviors of all employees throughout the organization. Measurements should include overall organizational information, departmental measurements, and individual performer output. Goals and KPIs should be developed for each of the above.

Metrics should be developed carefully and cascaded through the organization. Things to consider are reactive measurements (lagging) and proactive measurements (leading) that may have separate impacts when measured. Review with the leadership team what the goal of each metric will be, how success will be measured, and what actions will be taken to address deficiencies identified.

11.7 Effect – Changing Food Safety Behavior

A company with a strong Food Safety Culture can adapt to changing circumstances and conditions in a timely manner. This is essential when managing through events or crises.

Empowering employees to make decisions after quickly reviewing data is a key element of adaptability. Setting expectations and having clearly documented responsibilities and communication decision trees ensure the right people make the key decisions in a timely manner rather than having a lagging period of fact-finding.

Companies should identify an effective and efficient communication procedure for communicating changes in the facility and regulations or when in times of crises. In addition to communication, the company should take time to review and learn from any crisis and update policies and procedures for any gaps identified. A crisis management team is essential during times of crises. This team should consist of a cross-functional members (i.e., recall coordinator, consumer/customer communications, social/news media communications, Senior Leadership, backups) and know their role on the team. The crisis management team should be challenged on some frequency by a mock or simulated crisis event so the team is ready in case there is a potential crisis event.

The company should recognize actual and potential food safety hazards and risks at all levels across the company for a strong Food Safety Culture. Risks are associated with each department from purchasing to marketing to sales and production. All employees should understand food safety risks associated with their tasks and how to mitigate and/or communicate those risks. An example is using a change management system to document major changes and have a workflow with the key cross-functional stakeholders to approve those changes.

All companies have expectations and rules for food safety (for example, supplier approval requirements) and having all individuals understand the “why” associated with their job functions ensures food safety is a fundamental element of all tasks. All employees throughout an organization must have clearly defined accountabilities for food safety. This empowers individuals to take responsibility for food safety-related decisions and actions and any consequences for those decisions.

Consistent individual accountability up to and including termination enforces the company's overall commitment to ensuring a consistent Food Safety Culture.

Individual accountability includes acknowledgement of responsibility for actions, products produced, decisions, and policies. Accountability must be consistent with levels of authority and must be understood by all involved.

Recognition is often part of successful communication plans. Formal and informal recognition systems in place throughout all levels of an organization can empower team members to recognize the impact of their colleagues. In addition, a formal recognition process shows the commitment of Senior Leadership in understanding and supporting food safety actions.

11.8 Appendix:

11.8.1 Communicating Food Safety Vision and Values

Include these on the company website and annual reports, or include food safety topics and discussion points at all executive-level meetings

- Review food safety KPIs at established intervals across the organization
- Create a food safety logo for your company

11.8.2 Leadership Commitment

Food safety policies signed by the Senior Leadership and Plant Management, and ensure they are communicated to all levels of employees.
Some companies have multiple food safety policies that are signed at various levels across the supply chain (from Product Development to Shipping) to ensure food safety is engrained in each department.

With capital budgets, prioritizing certain capital projects that improve food safety and plans that include food safety aspect of projects are important.

Leading by example (e.g., picking up trash during a manufacturing plant walkthrough, proper hand washing) is also important.

11.8.3 Messaging

Company emails that outline importance of food safety and commitment to food safety
Intranet homepages
Worksite bulletin boards
Team meetings
Posters and table tents
Television monitors
Company-wide messaging system (e.g., text messages, email distribution lists)

11.8.4 Food Safety Education, Training, and Governance

Organizational charts that include responsibility for food safety at all levels
Job descriptions that outline food safety responsibilities

Escalation route process for reporting concerns direction to Senior Leadership
Whistleblower hotline for food safety issues
Suggestion boxes
Routine training and education topics
Toolbox talks

11.8.5 Food Safety Communication

Posters
Routine meetings
Videos
Newsletters
Shift huddles
TV monitors
Recognition Programs / Recognition Cards
Rewards/Incentives (formal and informal)
Prizes (e.g., gift cards, vend bucks), giveaways (e.g., t-shirts, hats, coffee travel mugs), and raffles (e.g., television, grill, entertainment tickets)
Employee feedback surveys
Gemba Kaizen meetings (e.g., with Senior Leadership, employees)
Mentorship or “buddy” programs
Competitions and gamifications
Message boards
Social media and networking
Crisis Management Plan tests and scenarios
Email distribution lists
Consumer complaint system and notifications
Hold system and notifications
Supplier approvals and supplier notification system
Management reviews (e.g., Board of Directors, Executive/Senior Leadership, Plant Management)
See Something, Say Something
Food Safety Heroes
Food Safety in a Nutshell

11.8.6 Performance Measurement

Key Performance Indictors (KPIs)
Audit scores (e.g., third-party, customer, internal)
First-pass quality reports
Weekly/monthly food safety and quality reports
Food safety maturity model

11.8.7 Documentation

Standard Operating Procedures (SOPs) and Work Instructions
Sanitation Standard Operating Procedures (SSOPs)
Food Safety Plans (FSPs) (HACCP) (See Appendix D for examples)
Food safety records (e.g., Preventive Controls/CCP Documentation)
Current Good Manufacturing Practices (CGMPs) Illustrated Guide
One-point lessons
Job safety analysis

11.8.8 Accountability

Crisis Communication Plan (Communication decision trees for employees)
Program Tests (Food Defense, Food Fraud, Food Security, Mock Recall, etc.)
Internal audits
Food safety incidents and Near misses review
Behavior-based observations

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Chapter 12

TRACEABILITY (NEW)

12.1 Introduction

Traceability is an essential component of every Food Safety Plan. An effective traceability system enables manufacturers to quickly locate and recall/withdraw unsafe food from market before consumption by consumers. This system is necessary for regulatory compliance to 21 CFR 117.3 and ensures food safety and quality assurance of food. Historically, food manufacturers were only expected to trace product one step forward and one step back; this practice is no longer acceptable. Major recalls in the years leading up the Food Safety Modernization Act (FSMA) led to requirements for more effective traceability of food products.

Today, the Food and Drug Administration (FDA) includes food traceability as one of four key components that make up the New Era of Smarter Food Safety Blueprint (https://www.fda.gov/food/new-era-smarter-food-safety/new-era-smarter-food-safety-blueprint), which falls under the FSMA. Under the proposed rule, FDA defines food traceability as "…the ability to follow the movement of a food product and its ingredients through all steps in the supply-chain, backward and forward. Traceability involves documenting and linking the production, processing, and distribution chain of food products and ingredients" (FSMA Proposed Rule for Food Traceability: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-food-traceability). The final rule will be submitted on November 7, 2022. Sections regarding this rule will be added to this chapter after the final rule.

This chapter will focus on the traceability of peanuts and tree nuts.

12.2. Traceability Plan

Traceability is the ability to trace the history, application, or location of an entity by means of recorded identifications (ISO, 1994). This is the origin, processing history, distribution, and location of the product. Effective traceability and recall procedures should improve food safety by shortening the time consumers are exposed to contaminated products and can minimize economic loss to manufacturers.

The essential components of an effective traceability system are explained in the next nine labeled paragraphs (Ruiz-Garcia et al., 2010; Schwägele, 2005; Pettitt, 2001; Food-Standards-Agency, 2002; Manikas and Manos, 2009; Van der Vorst, 2004; Daives, 2004; Kelepouris et al., 2007; Wilson and Clarke, 1998).

1. Supply-chain structure and organization

An organization's supply-chain structure has a direct impact on the complexity of the traceability system. This is especially true in environments where the supply of materials is limited. Tracing product is easier for vertically integrated supply chains

where data are not restricted. This is also true for simple supply-chains with few inputs and outputs of materials. Supply chains with numerous suppliers and/or international suppliers are more complicated. Organizations must work diligently with providers of goods that lack the robust traceability systems necessary to ensure efficient data recording and transfer. An example of data that must be recorded and easily accessible includes origin of goods and subsequent transportation information.

It is important to understand the role of each company in the supply chain when establishing a traceability plan. A company must evaluate the risk of the ingredients and the history of the supplier. This risk-based approach will aid in determining which documents are necessary for approving each supplier. (Refer to the Chapter Five for more information.)

2. Product destination

A traceability system must be able to identify every location all the components of a product from origin, to manufacture, receiving, processing, storage, and finished product point of purchase. The challenges associated with tracking of these components depend on the complexity of an organization's supply-chain. As stated in the previous section, it is usually easier for vertically integrated and product with few components to access the needed information than for products with numerous and/or imported components. Additional complications arise with the use of brokers.

Brokers may be unaware of the documentation required by an organization to effectively manage the risk of a supplier. Often, if a supplier is unable to deliver a product to brokers for distribution, they may hastily use an alternate supplier without informing the organization of the change. Brokers must be provided with a supplier expectations manual (or an equivalent document) defining the organization's requirements.

Thorough documentation is critical to demonstrate proper chain of custody during transport and that only approved materials from approved suppliers are in the final product. This is also necessary for any waste products purchased by other organizations for animal feed.

3. Traceability lot identification

To trace a lot or batch, one must understand what defines the lot. Each lot is assigned a unique identifier number. It is critical to know every input for internal and external suppliers with all contributing factors being accounted for at every step. Depending on what is being tracked, a finished product may have multiple lot numbers. Unique identifiers are often assigned to indicate a lethality treatment, pesticide application, or packaging. This is necessary because a recall may be due to a biological, chemical, physical, or radiological hazard as well as incorrect packaging or labeling.

The FDA proposed rule requires the first product identification to be applied at the grower or field. Grower tags have U.S. Department of Agriculture (USDA) specific information. The USDA field reports may show crop grade as well as indicate if a

commodity has been deemed inedible. Other than the ABC, no other tree nut or peanut industry has reporting requirements. The ABC also requires manufacturers to report the number of pounds received at the facility. Due to the lack of standard industry reporting requirements, USDA field reports should be included with the certificate of analysis (COA) of any peanut or tree nuts received into an organization. The information may assist in the traceability of product and should be kept readily available.

At minimum, labels must identify the commodity and provide a lot number, net content, as well as the name and address of the manufacturer, packer, or distributor. The COAs and any other documentation provided with load must match the label's product identification and lot number. Per the FDA proposed rule, lot codes must be created to uniquely identify the product throughout the supply-chain. The organization's responsibility is to describe how lots are established and assigned. The product must always be labelled with a lot number. This means the product must receive a unique identification number at receiving, and it may receive a unique lot number at processing that must be carried through to the finished product, storage, and shipping.

Below is an example of what a lot may contain:

Product Description must contain

- Type of nut (almond, peanut, pistachio, hazelnut, walnut, etc.)
- Configuration of nut (whole, broken, pieces, dice, etc.)
- Any process (steam treatment, dry roasted, oil cooked, etc.)

Production Code may contain

- Work shift or times
- Julian date
- Crop year
- Facility location (if multiple)
- Production line – any time of identification for example
    - Pasteurizer/kills step (if there are multiple validated lines, each must have a unique code)
    - Sizing
    - Sorting
    - Packing

A simple example of a label may be the following:

Blanched Almond Whole Lot#: 142202221XZPT

In the example above, note the following:

- 1422022 stands for May 22, 2022
- 21 stands for Crop Year
- XZ stands for facility unique location identifier
- PT stands for production line, in this case, pasteurization

The proper assignment of unique identifiers should be tested regularly by audits to ensure the speed and effectiveness in the event of a recall. Below are some examples of what a company may track at different points in the supply chain.

Possible ranch/farm checklist (all items may not be applicable):

- Seed lot
- Water
- Soil amendments
- Pesticides
- Herbicides
- Antimicrobials
- Other chemicals (e.g.: ripening agents)
- Equipment
- Harvest personnel
- Harvest equipment (record full sanitations)
- Transportation

Possible huller/sheller list:

- Line used (if more than one line)
- Hulling equipment
- Shelling equipment
- Wash area
- Driers
- Transfer
- Storage area
- Transportation

Possible processing or manufacturing facility list:

- Storage area
- Raw materials (the product and an added ingredients/product contact packaging)
    - Brokers
- Weight out area
- Processing equipment
- Piping
- Lethality treatment
- Rework/work in process
- Transfer to packaging (if not treated in finished packaging)
- Pallets
- Transportation

4. Time requirements to complete a product trace

A smaller batch size does not always mean a smaller recall. For example, if an ingredient on seasoned nuts, such as non-fat dried milk (NFDM), which is a component of many seasonings, is recalled, then all the products using a seasoning containing the NFDM will be recalled, too.

Differences in traceability systems, such as reliance on paper records versus electronic records, present challenges. For example, one organization's data cannot always be used by another even in the same industry due to data storage differences or different methodologies of keeping records. As part of the FDA's New Era of Smarter Food Safety, "…a new approach to food safety leveraging technology and other tools to create a safer and more digital, traceable food system…." is being explored. The FDA's proposed rule on traceability requires documents to be maintained in their original state, such as in paper form or electronic form (sortable spreadsheet required), and they must be made available within 24 hours after a request. This is necessary for providing the FDA with assistance during an outbreak or a recall. Depending on which Global Food Safety Initiative (GFSI) scheme is used by the organization, the time limits required to perform a full trace may vary. For example, per issue 7, Clause 3.9.2 from the British Retail Consortium Global Standard (BRCGS) standard, traceability must be completed within four hours.

5. Integrity of the traceability method

A traceability system must account for different lot defining scenarios, such as microbial lethality, growing location [pesticides, mycotoxins, and heavy metals], packaging, and rework. These scenarios make it possible to have numerous lot designations assigned to a single batch of nuts. To develop an appropriate traceability program, a thorough hazard analysis must be performed first. This is necessary for all known hazards to be identified and addressed.

Traceability begins at the crop or field at the ranch/farm for the following reasons:

- Pathogens
- Heavy metals
- Pesticide residues
- Other chemicals (insecticides, herbicides, and antimicrobials)
- Potential allergen cross-contamination from crop rotations

For many nuts, segregating lots by the growing block is easier because many truckloads are filled by growing block, which the first processor (huller/sheller) maintains as a lot.

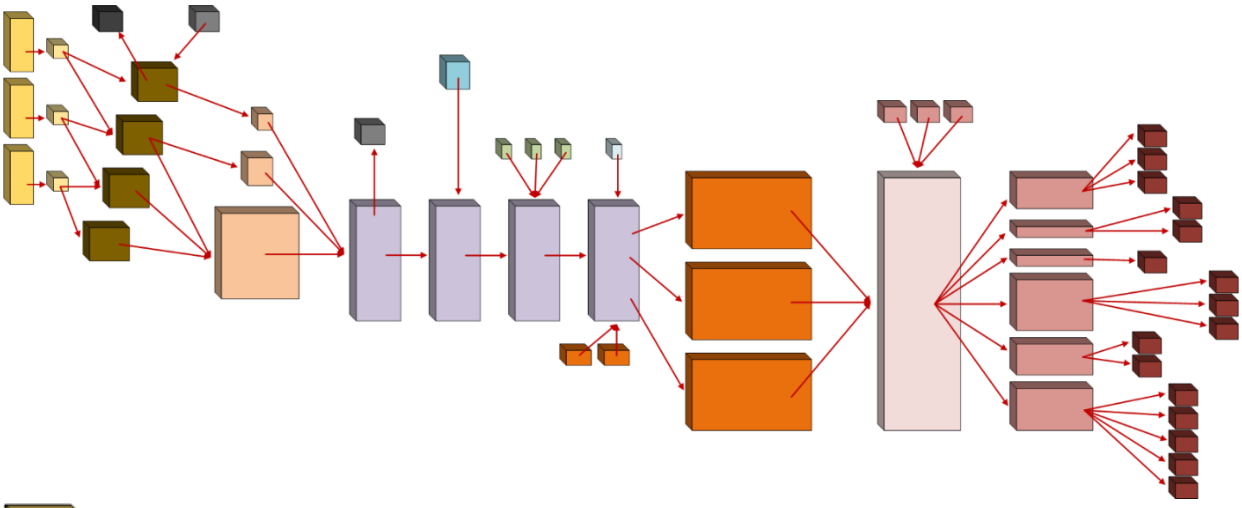
The challenge of preserving these separations often begins at the processor. Small and medium-sized processors use small holding units that often only hold nuts from one field block or one ranch. Processors with larger holding units (up to two million pounds) can rarely segregate by ranch or field block. Additionally, many processors handle more than one type of nut, which also requires allergen tracking and segregation.

In some cases, large bays with capacities of ten to 15 million pounds are continuously filled as they empty, resulting in no definitive way to know where nuts

from one field begin and another ends due to commingling. In other cases, suppliers use larger storage locations that can house multiple grower inputs that can be depleted and refilled during harvest/processing season. Keeping track of which fields, growers, and lots were commingled for the sake of traceability is important even if narrowing to one specific grower is difficult. A more effective practice is to incorporate clean breaks that help limit the total number of lots that are commingled through batch merge practices.

Complications continue at facilities that process nuts into other matrices. These include cut nuts (diced, chopped, slivers, and pieces), nut butters, milks, pastes, and oils because these often consist of rejects from numerous whole nut batches and any rework adds an additional layer of complexity. The convergence of different lots makes traceability a challenge, not usually due to information systems' limitations but the human component. On a production floor, a raw material may be designated for use in a batch, but another material may accidentally be used. In such cases, having verification of tags is important by having supervisors or employees handwrite the lots used for a batch. This is in addition to real-time scanning of materials wherever possible. Traceability is not only applicable for ingredients and additives but is also required for packaging materials. Keeping track of the amount of packaging and the lots used is also part of the traceability.

The flowchart below gives a visual demonstration as to the degree of trace complexity. It may be helpful for companies to create a flowchart, such as below, to understand where their products come from and the path to their final destination. This could become a tool for training all employees.



Orchard

Grower Delivery

Huller/Sheller

Oilstock

Storage Warehouse / Silo

Manufacturing Steps

Byproducts

Processing Aide

Ingredient

Packaging

Manufacturer Finished Goods

Industrial Customer

Industrial Customer Finished Goods

Consumer

6. Data standardization

The information required to perform a trace becomes clearer upon the completion of the Food Safety Plan (FSP), which includes the Hazard Analysis (risk analysis) and the Recall Plan. The exercise should be performed upstream and downstream of a product. Documentation of the root cause analysis on all gaps identified and the corrective actions issued, needs to be maintained. It is recommended that a traceability exercise be completed at least annually to ensure the program functions as intended. In addition, depending on the GFSI scheme utilized by the organization, standards, such as Safe Quality Foods (SQF) and BRCGS, require at least one annual Mock Recall. Documentation collection can be extensive; thus, below is a general idea of documents that can assist in traceability and in recall/withdrawal.

Example of record-keeping for nut butter:

- Lot number or process order
- Date of production
- Input product list and quantities
- Output quantities (includes but not limited to)
    - Intermediates not consumed
    - Holds
    - Rework
    - Rejects
    - Oil(s) stock waste
    - Animal feed
- Packaging material
- Quality checks
- Pre-operations (pre-ops) and post-operations (post-ops)
- Sanitation records

7. Data identification methods

Data identification is the process by which product inputs (e.g., packaging, processing aids, ingredients) and outputs (e.g., by-products, finished goods) are identified with a unique marking. Traceability utilizes these unique markings to obtain data information on the product's history, current state, and possible future state. Data identification can be as simple as a pallet tag or product label, or more complex, such as a barcode or Quick Response (QR) code. Regardless of the identification method, the unique marking must establish and maintain the identity of the product and relevant product job, batch, or lot information.

8. Degree that the traceability system is integrated with the information management system

All businesses must assess their needs for developing a traceability system and determine whether to incorporate an information management system as an

element with the traceability system. Smaller processors may be efficient with maintaining paper records for substantiating traceability of their product though the complexity of larger, vertically integrated processors may require a commercial information management system to organize all their data records from receipt to outbound shipment. Other processors may find their traceability efficiency aligns with a hybrid method of paper records combined with an information management system. Regardless of the choice in managing the data records, the system must have the ability to perform a traceability exercise in as little time as possible to prevent a potential food safety hazard from expanding out of control.

9. Legislation on traceability

Traceability standards are primarily influenced by GFSI standards and customer expectations. Regulatory standards associated with traceability are minimal and more align with having a validated traceability system that will provide the needed data in the event of a food safety recall. However, the FDA is currently working on a proposed traceability rule that will require entities who manufacture, process, pack, or hold certain identified foods to establish and maintain records on Key Data Elements (KDEs) associated with the food's Critical Tracking Events (CTEs). Every commodity can have a different set of CTEs, but the more common CTEs include growing, receiving, creating, transforming, and shipping of an identified food. Within each CTE, KDE records help identify the condition of the food product at that CTE. Records include data, such as growing conditions, location identifier, location description, data identification (lot coding), quantity and unit of measure, business entity information, processing records, transportation records, and other reference records. Please refer to the following link for specifics on the proposed rule and for Food Traceability List of identified foods: FSMA Proposed Rule for Food Traceability (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-food-traceability).

12.3 Conclusion

All these components must be considered for effective traceability systems. Because data exchange is critical for a traceability system to work, companies need to work together to ensure data exchange is possible and expedient. Complete traceability is now expected by governments and industry because it provides better food safety.

BATCH MANAGEMENT AND TRACEABILITY

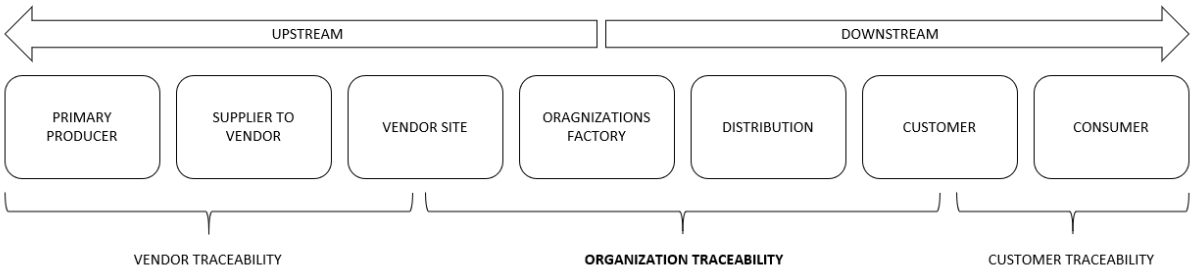
Batch Management – All materials which can affect the food safety or quality of a finished product must be batch managed.

Batch Size

- Raw and packaging materials should be from approved suppliers prior to the first delivery and must be considered during a trace.
- A finished product can be defined by the organization, but it is recommended not to exceed 24 hours.

Batch Traceability – Keeping of records for each material handling of material number, batch code, and quantity.

- Raw and packaging material used in finished product up to the vendor site supplying the organization.
- Finished products to the customers, trade partners, and food service operators until chain of custody leaves the organization.



Vendor upstream traceability – Raw and packaging materials traceability may be verified during vendor audits. Vendors should have proper systems in place for the traceability of their products to the origin of the raw and packaging materials delivered to the organization.

Upstream traceability – The following information must be known for each delivered material:

- Information about the delivered material from the vendor (i.e., vendor manufacturing site, vendor batch code, material delivered) should be available.
- The vendor batch code should be used for correct batch identification.
- How the incoming batches are handled at receiving (e.g., separation, mixing into silos) must be identified
- The identification scheme of the material units should be defined (scanning, manual batch recording, or re-labelling).
- The impact of the vendor batch size on the finished product traceability window should be identified.
- The storage location must be assigned.

Production traceability should be ensured by the following:

Understanding the impact that the production process has on the traceability.

- Ensuring each finished product must have an approved recipe and Bill of Materials.
- Ensuring all finished products and materials used to produce finished products must follow a batch coding scheme.

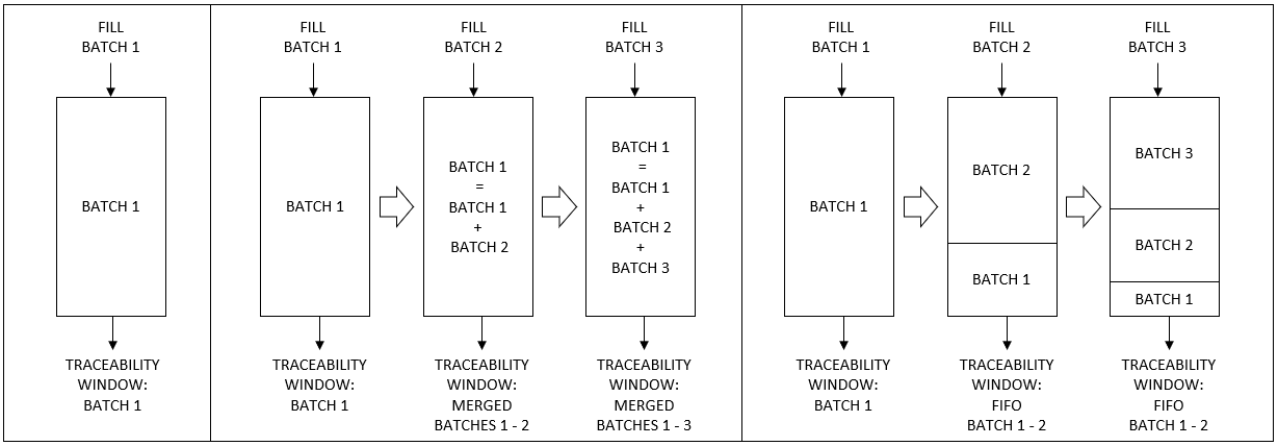
Recording traceability information during the production process.

Records of material handling transactions containing the batch material quantity should be kept and be available for all finished products and materials used to produce them (raw and packaging materials, rework, and semi-finished products). Records may include the following:

- Staging to production
- Consumption to a process order
- Receipt of goods from production
- Transport and storage within the factory
- Batch transfers (i.e., write-offs)

Silo Traceability should be ensured by using one of the recommendations below:

- Every batch physically separated into a silo
  - No continuous filling
  - Limits traceability window to individual batches
- Batches mixed in silo (typically applicable for liquid silos, oil, etc.)
  - Emptied and filled on a continuous basis, no physical batch separation
  - Batches are merged during inbound receipt of the new batch
  - Traceability window is based on a group of merged batches
  - A cut-off point should be identified between two complete emptying of the silo or based on a calculation dilution factor of remaining batch quantity upon filling of a new batch.
- Limited silo mixing during batching (typically applicable for free-flowing materials with negligible mixing, such as salt
  - No physical batch separation. Fill and empty on a continuous basis
  - Multiple batches co-exist in the silo. Batches are NOT merged at receiving.
  - Traceability is based on first in, first out (FIFO) use of the inventory.



Traceability window should be defined using the elements below:

- The batch size of the finished product and the materials used to manufacture it result in the quantity of materials that need to be considered.
- Batch separation inaccuracies arise when continuous production processes are utilized because clear batch separation is not always possible. These inaccuracies may arise from the following:
  - Use of rework
  - Semi-finished product changes
  - Mixed pallet production
  - Use of silo materials in production process

Downstream traceability with customers – should be ensured until the change of ownership by:

- Keeping records of material handling transactions. These records should contain the material number, the batch code, and the quantity, should be readily available for all finished products, and can be used to describe the following situations:
  - Finished products shipped to distribution centers
  - Finished products received in distribution centers
  - Storage and further shipments to interim distribution points (until the change of ownership)
  - Delivery to customers of finished products
  - Returns and refusal of finished products
  - Batch to batch transfers (e.g.: write-offs)
  - Samples and donations, staff sales

The effectiveness of the traceability system should be verified at least annually by executing a Mock Recall.

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Appendix A. Historical Acknowledgements (2010 – 2020)

The Peanut and Tree Nut Processors Association (PTNPA) and the Consumer Brands Association (CBA) would like to acknowledge the 2020 Handbook Task Force and their affiliations at the time when the latest update was based.

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Principles of Equipment Design:
Joe Stout (sub-group lead), Warren Stone and other members of the GMA Sanitary Equipment Design Working Group.

Appendix B. Considerations for Sampling and Testing Nuts and Nut Products

Microbiological testing of finished product, processed nuts and nut products may be conducted under some circumstances as part of an overall verification of *Salmonella* control. However, testing conducted on any sample is inadequate to assess the microbiological quality of a product without an acceptable sampling plan. Finished product testing should be one of several steps used to implement a food safety program. Conducting periodic product testing will be useful in verifying the food safety system for controlling *Salmonella* is working. However, there may be situations in which the testing frequency may be influenced by requests or requirements that differ from the nut processor's testing program, e.g., customer requirements. A customer may require a certificate of analysis (COA) that represents specified testing on each lot of nuts.

Each nut processor should develop Standard Operating Procedures (SOP) that describe the testing program, frequency at which testing occurs, sample size and other essential information. The SOPs should clearly state that all product lots being tested for *Salmonella* should be placed "ON HOLD" and only released if the product tests negative for *Salmonella*.

In addition, the SOPs should clearly stress that finished product testing is not a control measure but a verification tool. Finished product testing should be selected and applied with the understanding limitations and benefits exist. The

sampling levels routinely used have a low probability of detecting defective lots when the level of pathogen contamination within the lot is low. The absence of *Salmonella* in finished product cannot be guaranteed using testing alone (FAO/WHO, 2006; EFSA, 2008). The absence of *Salmonella* cannot be assured by using acceptance or rejection of a lot based on requirements listed in a specification.

A food safety system should consist of several components to ensure food safety; end product testing is only one of those components. A combination of approaches, e.g., implementation of a Food Safety Plan (FSP) inclusive of a Hazard Analysis and Critical Control Point (HACCP), current Good Manufacturing Process (cGMPs) and other prerequisite programs (PPs) provide more reliable means of assuring product safety.
Therefore, the processor (customer) should implement a program composed of several components to address food safety. For example, the processor receiving (raw) nuts should have a supplier approval program in place to evaluate the adequacy of the control measures used by a supplier to control *Salmonella* in the supplier's facility. This approach is important if the nuts received by a customer received a lethal process at the supplier's facility and will not be exposed to a further lethality treatment. This situation would trigger the regulatory need for a supply-chain program as part of the FSP, which is discussed in Chapter Five. Additional information on supplier approval programs is available in the GMA
guidance on "Control of *Salmonella* in Low-Moisture Food Guidance Document", (GMA, 2009, pp. 45–49). Whenever possible, source an entire lot for delivery and strongly discourage shipment of a split lot distributed to multiple customers or multiple manufacturing plants. Use of such a purchasing logistics program will limit the scope of a potential pathogen problem. Accepting split lots can potentially cause one company's verification test results to implicate another company's or several companies' products.

Sampling Plans and Sampling Frequencies

Sampling plans commonly used by the nut industry for testing foods for the presence of *Salmonella* include those described in the the Food and Drug Administration's Bacteriological Analytical Manual (FDA BAM) (Andrews and Hammack, 2003 and 2007) and those developed by the International Commission on Microbiological Specifications for

Foods (ICMSF, 2002a). FDA BAM Categories I to III, or ICMSF sampling plans cases 10 to 15, may be used (see Tables 1 and 2, respectively, below) depending on the intended use of the ingredient and the robustness of the supplier's food safety program. The frequency of sampling may vary, e.g., once every lot (for instance, for a new ingredient from a new and unknown supplier), once every six lots, or less frequently, depending on the supplier's historical test results.

Table 1. The FDA BAM Sampling Plans [a]

Category I	Category II	Category III

Number of samples: 60 Amount tested per sample: 25 g	Number of samples: 30 Amount tested per sample: 25 g	Number of samples: 15 Amount tested per sample: 25 g
Products that would not normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption and are intended for highly susceptible population (e.g., the elderly, the young and immunocompromised individuals)	Products that would not normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption and are intended for the general population.	Products that would normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption and are intended for the general population.

[a] In all of the sampling plans, the acceptance criterion is that *Salmonella* is undetected in any of the samples (also referred to as analytical units).

Table 2. ICMSF Sampling Plan [a]

Conditions of use reduce concern	Conditions of use cause no change in concern	Conditions of use increase concern
Case 10 **n=5, c=0**	**Case 11** **n=10, c=0**	**Case 12** **n=20, c=0**
Products that would normally be subjected to a process lethal to *Salmonella* before consumption.	Products that would not normally be subjected to a process lethal to *Salmonella* before consumption.	Products to be used as an ingredient in another ready-to-eat (RTE) product that will support *Salmonella* growth, or there are questions about the robustness of the supplier's food safety program.
Case 13 **n=15, c=0**	**Case 14** **n=30, c=0**	**Case 15** **n=60, c=0**
As for case 10, but where products are produced for a highly susceptible population, e.g., hospital or nursing home.	As for case 11, but where products are produced for a highly susceptible population, e.g., hospital or nursing home.	As for case 12, but where products are produced for a highly susceptible population, e.g., hospital or nursing home.

In all of the sampling plans, "n" is the number of samples. A 25-g analytical unit is taken from each sample for testing, and c=0 means that *Salmonella* is not detected in any of the analytical units.

Each nut processor should determine whether or not finished product testing should be conducted based on an evaluation of risk and whether finished product testing will be conducted as a verification step. If product testing is used as a verification step, consider which analyte will serves as the best verification that the hazard was appropriately controlled. For example, if testing is used as a verification of a roasting step, consider if *Salmonella* is the best indicator that roasting was correctly implemented. Once the target organism has been identified, select a sampling plan appropriate for the product and process under consideration. The more robust a process is, the less the need for finished product testing. For example, if a nut processor uses a validated oil roasting step to inactivate *Salmonella*, has separation of raw from ready-to-eat (RTE) areas, and has effective post-lethality controls that are verified by robust environmental monitoring, periodic finished product testing using ICMSF case 10 or 11 may be appropriate as part of an overall verification program to control *Salmonella*. For a nut process that does not have a kill step (e.g., a process that combines ingredients into a finished product), periodic finished product testing using FDA Category I or Category II sampling scheme (see Table 1) may be appropriate; this would be equivalent to ICMSF case 13–14 in Table 2. Under special circumstances, finished product testing using a more stringent sampling plan would be recommended. Examples of such circumstances may include initiation of corrective actions in response to a positive S*almonella* finding on RTE product contact surfaces or reconditioning of a product lot that tested positive for *Salmonella*. In addition, finished product testing using FDA Category II (or ICMSF case 14, for product intended for the general public) or Category I (or ICMSF case 15, for product intended for highly susceptible population) may be appropriate under such circumstances.

Sampling Techniques

Initiate the process by first determining the number of samples to test; that number should be representative of the entire production lot. One approach to use to ensure representative sampling is to obtain samples based on production time. For example, pull a sample from the line every half hour throughout an eight-hour production run of a lot (or select another predetermined time interval, depending on how a lot is defined and how many samples may eventually be taken). Limited industry data and industry experience over the years suggest that *Salmonella* contamination of raw nuts is likely to be at low levels and not uniformly distributed; therefore, a time-based sampling strategy is more effective at finding the target pathogen, if it is present. According to the FDA (Andrews and Hammack, 2003), representative sampling can also be achieved by proper statistical sampling procedures.

Testing Methods

From each sample, a 25-g analytical unit is taken for testing. Each sample should be mixed thoroughly before the 25-g analytical unit is withdrawn. The analytical units can be composited with up to 15 (fifteen) 25-g units into a 375-g composite (Andrews and Hammack, 2003).

An official or validated method should be used to test finished product samples. The FDA BAM method (Andrews and Hammack, 2007) and the ISO 6579

method (ISO, 2002) apply to various products described in the methods, including nuts. The FDA BAM method and the ISO 6579 method are considered the official method in the United States and the European Union, respectively. A method that has been validated to be equivalent in specificity and sensitivity to one of these official methods may also be used. According to the FDA (Andrews et al., 2014), a validated rapid method is generally used for screening, with negative results accepted as such, but positive results require cultural confirmation by the appropriate official method. Subtyping the isolate with a method, e.g., serotyping or genetic fingerprinting may be used for tracking and troubleshooting purposes.

Results Interpretation

As indicated above, whenever finished product testing is performed on a RTE product, the lot under test should be isolated, placed on hold and only released into commerce if the product tests negative for *Salmonella*. The testing program should clearly state that if a product sample tests positive for *Salmonella*, the tested lot will be considered adulterated and it will not be released into commerce. Conduct an evaluation of the risk for *Salmonella* contamination to determine disposition of adjacent lots.

If a product sample tests positive for *Salmonella*, retesting **must not** be conducted for the purpose of negating the initial test results. Resampling almost always increases the chance of accepting a contaminated lot (Rainosek, 1997). The lower the prevalence level of *Salmonella* in the product, the more difficult it will be to confirm, and confirming low prevalence by resampling is nearly impossible (ICMSF, 2002b). Retesting for investigational purposes only (i.e., to determine level and source of contamination of the sample) may be appropriate.

The lot associated with a positive sample may be reworked using a validated inactivation step. In addition to appropriate product disposition, other corrective actions may be taken as appropriate. For recommendations on corrective actions, see GMA 2009, p. 63.

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Appendix C. Examples for Guidelines for Time/Temperature Parameters to Meet a 5-log Reduction in *Salmonella* for Specific Products

Type of Processing	Critical Reference Parameters [c]				
	Min. Temp.	**Min. Time for 5-log reduction (minutes)**	**Temperature.**	**D-value (min.)**	**z-value**
Dry Roasting (Continuous Process) [a]	129°C (264°F)	47.1	146°C (295°F)	2.8	42.9°C (77.5°F)
	138°C	25.1			
	146°C	14.1			
Hot Water Blanching [b]	82.2°C(180°F)	3.09	82.2°C (180°F)	0.62	30.0°C (53.0°F)
	85°C (185.0°F)	2.49			
	87.8°C (190.0°F)	2.0			
Hot Oil Roasting [b]	121°C (250°F)	2.4			
	127°C (260°F)	1.3			

[a] American Peanut Council sponsored study on thermal characteristics of *Salmonella* spp. on peanuts

[b] Almond Board of California sponsored study on thermal characteristics of *Salmonella* spp. on almonds. Du, Wen-Xian et al. 2010. Reduction of *Salmonella* on Inoculated Almonds Exposed to Hot Oil.*J Food Protect.* 73(7): 1238–1246.

[c] These parameters apply to the specific products indicated (i.e., dry roasting of peanuts and hot water blanching of almonds).

Appendix D. Examples of Forms Applicable to Food Safety Plans (FSPs)

Product/Product Category Description Process Flow Diagram
Ingredient/Packaging Assessment Processing Step Evaluation Ingredient Allergen Assessment
Allergen Cross-contact Production Assessment
Preventive Control (PC) / Critical Control Point (CCP) Documentation

HACCP/Food Safety Plan Number: **Plant Name:** Company X **Address:** Anytown, US	Issue Date	DD - MM - YY	PRODUCT:
	Supersedes	DD - MM - YY	Page Number

PRODUCT/PRODUCT CATEGORY DESCRIPTION – EXAMPLE 1

Purpose: To describe the product characteristics and storage and distribution factors as related to food safety

Product/Product Category (e.g., name, type, size)	
Raw Materials and Other Ingredients	
Process (e.g., oil roast, dry roast, steam, hot water, PPO- treated, ETO-treated)	
Condition, Function and Design of the Facility and Equipment	
Sanitation, Including Employee Hygiene	
Food Safety Characteristics (e.g., pH, a_w, % salt, pasteurization, cooking, preservatives, refrigeration)	
Intended Market (e.g., general public, age, adult, child, retail, food service, countries, regions, national)	
Consumer/Customer Use (e.g., Ready-to-eat, heat-and-consume, mix-and- consume)	
Labeling/Label Instructions **List Only Those Ingredients Containing Allergens, Sulfites** (e.g., preparation, storage needs, use by, best when used by)	

Packaging (e.g., foil, plastic, glass, cup, can, hermetically sealed, gas permeable, tamper evident, modified atmosphere packaging)	
Shelf Life (e.g., days and temperature conditions)	
Transportation Practices	
Storage and Distribution (e.g., ambient, refrigerated, frozen, relative humidity, high altitude)	

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PRODUCT/PRODUCT CATEGORY DESCRIPTION –EXAMPLE 1 (completed)

Purpose: To describe the product characteristics and storage and distribution factors as related to food safety

Product/Product Category (e.g., name, type, size)	Dry roasted peanut or almond snacks
Raw Materials and Other Ingredients	Raw peanuts, raw almonds
Process (e.g., oil roast, dry roast, steam, hot water, PPO- treated, ETO-treated)	Dry roasting
Condition, Function and Design of the Facility and Equipment	Facility built and equipment purchased with sanitary design in mind; well-maintained
Sanitation, Including Employee Hygiene	Sanitation conducted according to SOP 123; employee hygiene followed as per SOP 456; employees receive annual training and retraining as determined by verification
Food Safety Characteristics (e.g., pH, a_w, % salt, pasteurization, cooking, preservatives, refrigeration)	Low water activity
Intended Market (e.g., general public, age, adult, child, retail, food service, countries, regions, national)	General public
Consumer/Customer Use (e.g., ready-to-eat, heat-and-consume, mix-and- consume)	Ready-to-eat (RTE)

Labeling/Label Instructions **List Only Those Ingredients Containing Allergens, Sulfites** (e.g., preparation, storage needs, use by, best when used by)	Contains: peanuts (on peanut products) or almonds (on almond products) Best when used by: MM/DD/YY
Packaging (e.g., foil, plastic, glass, cup, can, hermetically sealed, gas permeable, tamper evident, modified atmosphere packaging)	Glass jar with plastic cap
Shelf Life (e.g., days and temperature conditions)	270 days at ambient temperature
Transportation	Shipped on contracted trucks inspected before loading (SOP 789)
Storage and Distribution (e.g., ambient, refrigerated, frozen, relative humidity, high altitude)	Ambient

PRODUCT/PRODUCT CATEGORY DESCRIPTION – EXAMPLE 2 (Developed by the Food Safety Preventive Controls Alliance)

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE
Product Description Distribution, Consumers and Intended Use		
Product Name(s)		
Product Description, including Important Food Safety Characteristics		
Ingredients		
Packaging Used		
Intended Use		
Intended Consumers		
Shelf Life		

Labeling Instructions related to Safety	
Storage and Distribution	
Approved: Signature: Print name:	Date:

HACCP/Food Safety Plan Number: **Plant Name:** Company X **Address:** Anytown, US	Issue Date	DD - MM - YY	PRODUCT:
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PROCESS FLOW DIAGRAM – EXAMPLE

Purpose: A graphical representation of **all** processing steps from raw material receiving to finished product storage directly under the control of the manufacturing facility

The following check list may be used as a guide in the development of a flow diagram.

☐ Raw material receiving and storage

☐ Addition of ingredients, pre-mix, intermediate product

☐ Use of air or other gases

☐ Filters, screens, magnets and metal detectors

☐ Process equipment (e.g., heat exchangers)

☐ Tanks and continuous systems (e.g., mix, balance, surge, buffer, cook, fill, cool)

☐ Filling and packaging equipment

☐ Recirculation, overflow (e.g., immediately returned to process)

☐ Rework, holdover, reclaim (e.g., material not immediately returned to process – stored material)

☐ Storage

☐ Waste

☐ By-products

☐ Numbered PC/CCPs shown at identified process steps

HACCP/Food Safety Plan Number: Plant **Name:** Company X **Address:** Anytown, US	Issue Date	DD - MM - YY	PRODUCT:
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INGREDIENT/PACKAGING ASSESSMENT – EXAMPLE 1

Purpose: To identify biological, physical, and chemical hazards that may be introduced by ingredients, ingredient packaging materials, rework, or finished product contact packaging materials and to determine the control mechanisms for the identified hazards.

INGREDIENT NAME	POTENTIAL HAZARDS INTRODUCED (B) Biological (C) Chemical (P) Physical	Does this potential hazard need to be addressed in the HACCP/Food Safety Plan? (Yes or No)	WHY? Justification for decision made in previous column. Base the justification on the severity and likely occurrence of the hazard	CONTROL MECHANISMS (What measures can be applied to significantly minimize or prevent the hazard to an acceptable level in the Food Safety Plan?)	Is the control measure a Critical Control Point (CCP), a Preventive Control (PC) or a prerequisite program (PP)?
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C)	(C)	
	(P)	(P)	(P)	(P)	
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C)	(C)	
	(P)	(P)	(P)	(P)	
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C)	(C)	
	(P)	(P)	(P)	(P)	
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C)	(C)	
	(P)	(P)	(P)	(P)	
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C	(C)	
	(P)	(P)	(P)	(P)	

HACCP/Food Safety Plan Number: **Plant Name:** Company X **Address:** Anytown, US	Issue Date	DD - MM - YY	PRODUCT:
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PROCESSING STEP EVALUATION – EXAMPLE 1

Purpose: To identify biological, physical and chemical hazards that may be introduced from the process and/or processing environment and to determine the control mechanisms for the identified hazards

PROCESS STEP	POTENTIAL HAZARDS INTRODUCED OR ENHANCED AT THIS STEP (B) Biological (C) Chemical (P) Physical	Does this potential hazard need to be addressed in the food safety plan? (Yes or No)	WHY? Justification for decision made in previous column. Base the justification on the severity and likely occurrence of the hazard	CONTROL MECHANISMS What measures can be applied to significantly minimize or prevent the hazard to an acceptable level in the food safety plan?	Is the control measure a Critical Control Point (CCP), or Preventive Control (PC)?
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C)	(C)	
	(P)	(P)	(P)	(P)	
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C)	(C)	
	(P)	(P)	(P)	(P)	
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C)	(C)	
	(P)	(P)	(P)	(P)	
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C)	(C)	
	(P)	(P)	(P)	(P)	
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C)	(C)	
	(P)	(P)	(P)	(P)	
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C)	(C)	
	(P)	(P)	(P)	(P)	

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Plant Name: Company X			
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PROCESSING STEP EVALUATION – Completed Example

PROCESS STEP	POTENTIAL HAZARDS INTRODUCED OR ENHANCED AT THIS STEP (B) Biological (C) Chemical (P) Physical	Does this potential hazard need to be addressed in the Food Safety Plan? (Yes or No)	WHY? Justification for decision made in previous column. Base the justification on the severity and likely occurrence of the hazard.	CONTROL MECHANISMS What measures can be applied to significantly minimize or prevent the hazard to an acceptable level in the plan?	Is the control measure a critical control point (CCP), or Preventive Control (PC)
Raw Peanut Receiving	(B) *Salmonella* spp.	(B) Yes	(B) Raw peanuts may contain Salmonella	(B) Roasting	PC/CCP
	(C) Undeclared Allergens	(C) Yes	(C) Peanuts are considered an allergen	(C) Labeling	PC
	(P) Foreign Material (Rocks)	(P) No	(P) Raw peanuts may contain foreign material rocks from the field	(P) Screens and Sifters	PP
Raw Peanut Storage	(B) None	(B) No	(B) The act of storing peanuts does not introduce any biological hazards		
	(C) None	(C) No	(C) The act of storing peanuts does not introduce any chemical hazards		
	(P) None	(P) No	(P) The act of storing peanuts does not introduce any physical hazards		
Peanut Roasting	(B) *Salmonella* spp.	(B) Yes	(B) Roasting is used to inactivate Salmonella	(B) Roasting	PC/CCP
	(C) None	(C) No	(C) The act of roasting peanuts does not introduce any chemical hazards		
	(P) None	(P) No	(P) The act of roasting peanuts does not introduce any physical hazards		
Seasoning Coating	(B) Vegetative Pathogens – Human Handling	(B) No	(B) Strict adherence to cGMPs s by employees reduces the risk of contamination	(B) cGMPs	PP
	(C) None	(C) No	(C) The act of seasoning peanuts does not introduce any chemical hazards		
	(P) Extraneous Metal from Seasoning Container	(P) No	(P) Strict adherence to cGMPs s by employees reduces the risk of contamination	(P) cGMPs	PP

Rework addition	(B) Vegetative Pathogens – Human Handling	(B) No	(B) Strict adherence to cGMPs s by employees reduces the risk of contamination		
	(C) Tree Nut Protein	(C) Yes	(C) Addition of incorrect rework could result in addition of undeclared tree nut allergen	(C) Rework Handling (SOP 825)	PC
	(P) None	(P) No	(P) The act of rework addition does not introduce any physical hazards		
Fill into packaging and seal	(B) *Salmonella, Listeria monocytogenes*	(B) Yes	(B) Post process contamination during packaging peanuts may introduce *Salmonella* and/or *Listeria monocytogenes*	(B) Sanitation, verified by environmental monitoring	PC
	(C) None	(C) No	(C) The act of packaging peanuts does not introduce any chemical hazards		
	(P) None	(P) No	(P) The act of packaging peanuts does not introduce any physical hazards		
Metal detection	(B) None	(B) No	(B) Packages are sealed so no significant risk of biological hazards		
	(C) None	(C) No	(C) Packages are sealed so no significant risk of chemical hazards		
	(P) Foreign Material (Metal)	(P) Yes	(P) Potential metal contamination from previous processing steps or from raw peanut shelling	(P) Metal Detection	PC/CCP

INGREDIENT/PACKAGING/PROCESSING ASSESSMENT – EXAMPLE 2 (Developed by the Food Safety Preventive Controls Alliance)

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Hazard identification (column 2) considers those that may be present in the food because the hazard occurs naturally, the hazard may be unintentionally introduced, or the hazard may be intentionally introduced for economic gain.

B = Biological hazards including bacteria, viruses, parasites, and environmental pathogens

C = Chemical (including radiological) hazards, food allergens, pesticides and drug residues, natural toxins, decomposition and unapproved food or color additives P = Physical hazards include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects

Hazard Analysis

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential 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? *Process including PC/CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	**No**			**Yes**	**No**
	(B)							
	(C)							
	(P)							
	(B)							
	(C)							
	(P)							

HACCP/Food Safety Plan : **Number: Plant Name:** Company X **Address:** Anytown, US	Issue Date	DD - MM - YY	PRODUCT:
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INGREDIENT ALLERGEN ASSESSMENT – EXAMPLE 1

Note: Full Allergen Assessment consists of Forms 1 and 2.

Purpose: To identify whether the product(s) being assessed can introduce undeclared allergens into other products currently run on the manufacturing line **OR** whether products currently run on the manufacturing line can introduce undeclared allergens into the product(s) being assessed **AND** to identify or describe the control mechanism to manage the allergen. Determine whether the control mechanism(s) should be a Preventive Control (PC) or prerequisite program (PP).

PER MANUFACTURING LINE: (There should be as many Forms 1 and 2 as manufacturing lines present in the plant.)

A	B	C
List all ingredients containing allergens per Food Allergen List. List any processing aids that may come in contact with product contact surfaces or	List identified allergens of ingredients	List identified carryover allergens

HACCP/Food Safety Plan Number: **Peanut 1** **Plant Name:** Company X **Address:** Anytown, US	Issue Date	21 - Jul - 09	PRODUCT: DRY ROASTED NUT SNACKS
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INGREDIENT ALLERGEN ASSESSMENT – EXAMPLE 1 (completed)

Note: Full Allergen Assessment consists of Forms 1 and 2

Purpose: To identify whether the product(s) being assessed can introduce undeclared allergens into other products currently run on the manufacturing line **OR** whether products currently run on the manufacturing line can introduce undeclared allergens into the product(s) being assessed **AND** to identify or describe the control mechanism to manage the allergen. Determine whether the control mechanism(s) should be a preventive control (PC) or prerequisite program (PP).

PER MANUFACTURING LINE: (There should be as many Forms 1 and 2 as manufacturing lines present in the plant.)

A	B	C
List all ingredients containing allergens per Food Allergen List. List any processing aids that may come in contact with product contact surfaces or with product.	List identified allergens of ingredients	List identified carry-over allergens
Raw peanuts	Peanut	
Roasted almonds	Almond	
Rework nuts	Peanut, almond	

HACCP/Food Safety Plan Number: **Plant Name:** Company X **Address:** Anytown, US	Issue Date	DD - MM - YY	PRODUCT:
	Supersedes	DD - MM - YY	Page Number

ALLERGEN CROSS-CONTACT PRODUCTION ASSESSMENT EXAMPLE 1

Note: Full Allergen Assessment consists of allergen Forms 1 and 2.

PER MANUFACTURING LINE: (There should be as many forms 1 and 2 as manufacturing lines present in the plant)

List all finished products produced on the manufacturing line including use of common equipment, e.g., rework tanks, fillers.	Are all identified allergens listed in Form 1 labeled on the package of the finished product? This should be done for each finished product listed in the first column of this form. **YES** (list allergens)	**NO** (list allergens)	If "No" identify control mechanism(s) (_ - PC) (_ - PP)

ALLERGEN CROSS-CONTACT PRODUCTION ASSESSMENT – Completed Example 1

Note: Full Allergen Assessment consists of Forms 1 and 2.

PER MANUFACTURING LINE: (There should be as many Forms 1 and 2 as manufacturing lines present in the plant.)

List all finished products produced on the manufacturing line including use of common equipment, e.g., rework tanks, fillers	Are all identified allergens listed in Form 1 labeled on the package of the finished product? This should be done for each finished product listed in the first column of this form. **YES** (list allergens)	**NO** (list allergens)	If "No" identify control mechanism(s) (_ - PC) (- PP)
Roasted peanuts snack pack		Almonds	Barcode Labeling – PC, Label Check at Changeover – PC, Rework Handling – PC
Roasted almonds with cranberries		Peanuts	Barcode Labeling – PC, Label Check at Changeover – PC, Rework Handling – PC
Roasted peanuts seasoned with herbs		Almonds	Barcode Labeling – PC, Label Check at Changeover – PC, Rework Handling – PC
Roasted peanuts with mixed fruit		Almonds	Barcode Labeling –PC, Label Check at Changeover – PC, Rework Handling – PC

HACCP/Food Safety Plan Number: **Plant Name:** Address:	Issue Date	DD - MM - YY	PRODUCT:
	Supersedes	DD - MM - YY	Page Number

PREVENTIVE CONTOROL (PC) / CRITICAL CONTROL POINT (CCP)

DOCUMENTATION EXAMPLE Purpose: Purpose: To define food safety limits and monitoring and corrective action requirements

CCP ID/Process Step	
Hazard(s) to be addressed	
Critical Limit(s)	
Monitoring 1. Activity (What?) 2. How? 3. Frequency (How often?) 4. Responsibility (Who?)	
Corrective Action Activity 1. Activity (What?) 2. Responsibility (Who?)	
Minimum CCP Verification Activities 1. Activity (What?) 2. Frequency (How often?) 3. Responsibility (Who?)	
List the scientific basis for the critical limits	
Records (includes location of each record)	

CRITICAL CONTROL POINT (CCP) DOCUMENTATION
Completed Example (a Company-Specific Program)

Note: A company-specific program or policy will be more prescriptive and may use wording, e.g., “shall” and “must.”

CCP ID/PROCESS STEP: Oil roasting time and temperature for almonds **HAZARD:** Biological (vegetative pathogens – Salmonella spp.) **CRITICAL LIMIT:**

Time/temperature conditions to achieve a four-log or five-log kill for Salmonella spp. are listed below. If the processor wishes to achieve a five-log kill, then the Almond Board of California will allow the claim of "pasteurized."

Minimum Temperature*	Minimum Time 4-log kill	Minimum Time 5-log kill
127◦C (260◦F)	1.6 min	2.0 min

*Temperature to be achieved in the oil between the nuts.

MONITORING ACTIVITY/FREQUENCY/RESPONSIBILITY:

Time/temperature (Batch): Time/temperature is recorded on a continuous chart recorder.

Time/temperature (Continuous):

Temperature: Temperature of the product at the coldest spot or demonstration of sufficient time at temperature shall be recorded on a continuous chart recorder. Note: Determination of the coldest spot must be documented with supporting data and filed with the HACCP/Food Safety Plan.

Time: The flow rate shall be recorded continuously, or belt speed setting will be recorded once per shift and after speed changes by a designated, trained employee. Note: The correlation flow rate/holding time for the fastest particle must be documented and filed with the HACCP/Food Safety Plan.

Oil Level: Oil levels must be monitored and recorded at a frequency to demonstrate control by a designated, trained employee. Note: The oil level must be maintained at a level to ensure submersion of all nuts. The appropriate level must be determined and documented and filed with the HACCP/Food Safety Plan.

Bed Depth - Belt roaster: The product bed depth as validated and documented in the validated safety critical process profile shall be verified via measurement and/or recording the setting for bed depth adjustment systems at the beginning of processing by a designated, trained employee. The bed depth shall not exceed the maximum limit as defined by the validation study. This activity shall be conducted once every shift during production by a designated, trained employee.

CORRECTIVE ACTION ACTIVITY/RESPONSIBILITY:

Product shall be considered as under-processed if oil temperatures fall below established limits, if throughput is above established limits, if oil levels fall below required validated level, or if belt speeds/residence time are above established limits. Under-processed product shall be re-treated or post-processed product shall be identified and put on Quarantine Hold by designated trained employee. Notify the designated responsible personnel to determine disposition.

In cases where time/temperature deviations are detected after finished product is produced, designated trained employee places all affected product on Quarantine Hold and notifies the designated responsible personnel to determine disposition.

Hold/ Release documentation is required. Corrective action must be documented.

VERIFICATION ACTIVITIES/RESPONSIBILITY:

Designated responsible employee, other than the operator creating the records, (usually the supervisor) reviews and signs processing records at least daily.

Designated employee reviews all disrupted process records.

A designated trained employee(s) will calibrate all measuring devices used to monitor critical control parameters shall be calibrated at a frequency sufficient to demonstrate control (minimum every six months).

SCIENTIFIC BASIS:
Harris, Linda and Du, Wen-Xian. 2005. Survival of Salmonella Enteritidis PT 30 on inoculated almonds after treatment in hot oil. Report to FDA-CFSAN on behalf of the Almond Board of California (ABC). University of California, Davis.

RECORDS/LOCATION:
Temperature Charts, Thermometer Calibration Logs, Residence Time Records, Oil Level Records, Hold and Release Records, Corrective Action Records, Verification Records – located in Quality Assurance Office

Traceability Records located in Accounting Office

Example Critical Control Point – Metal

Critical Control Point (CCP)	Hazard(s)	Critical Limits for Each Control Measure	Monitoring				Corrective Actions	Verification Procedures	Record-keeping Procedures
			What	How	Frequency	Who			
Metal detector	Hard, sharp metal 7-25 mm in finished product	Products pass through functioning metal detector with proper sensitivities.	Products conveyed through metal detector. Metal detector is operable and reject mechanism is capable of rejecting: mm (") ferrous, mm (") nonferrous and mm (") stainless steel spheres from product stream*.	Visual observation to ensure the detector is on and the product is conveyed through detector. Challenge detector with product samples seeded with the appropriate size metal in accordance with SOP #MD101	Approximately once every two hrs. at the start and end of production Approximately once every two hrs. at the start and end of production	Wrapper or Relief Operator Wrapper or Relief Operator	When an inoperable metal detector or reject mechanism is found, wrapper is shut down and product made since the last positive calibration check is placed on hold pending evaluation and disposition. This may include 100% inspection by an operable metal detector or other analytical technique. Wrapper will not be started until the detector/reject mechanism is repaired and verified to be working. QA or Manufacturing will file Incident Reports when critical limits are exceeded.	QA personnel checks the sensitivity of the detector and reject mechanism by running ferrous, nonferrous and 316 nonmagnetic stainless steel test pieces through the geometric center of the aperture, once per shift QA and Production management review and sign records daily Plant QA performs HACCP system audit annually, reviewing procedures/paperwork for compliance and effectiveness. Annual metal detector calibration per manufacturer's recommendation. (Manufacturer should be contacted for maintenance procedures specific to make/model in use.)	Wrapper production form (which contains records of monitoring and verification activities: visual observations, challenge and sensitivity tests by operator or QA, and record review) Incident reports describing the deviation, corrective action, and results of evaluation and product disposition. Metal detector calibration logs

* Note: Sensitivity to be specified based on product and equipment capability and specific line set-up. Sensitivity of new products needs to be determined

Process Preventive Controls – Landscape Layout

Process Controls	Hazard(s)	Parameters, values or critical limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			

ADDRESS	PLANT NAME
SUPERSEDES	ISSUE DATE
PRODUCT CODE	PAGE

.

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Form Name: Food Allergen Preventive Controls

Allergen Control	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Form Name: Food Allergen Ingredient Analysis

		Food Allergens in Ingredient Formulation								Allergens in Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	

NOTE:

The above format is an alternative for an allergen specific hazard analysis. If you choose to use a form like this, there will be no need to duplicate allergen considerations in your hazard analysis chart. Duplication of information in multiple forms can create extra work and may lead to inconsistencies.

Some organizations may even choose to do an ingredient hazard analysis that considers allergens and other hazards. This may be a useful option for you.

How to Use the Chart

List all ingredients received in the facility. Identify allergens contained in each ingredient by reviewing ingredient labels or contacting the manufacturer. Any allergens listed in "May contain" labeling or other precautionary labeling on ingredients should be listed in the last column and reviewed to determine if allergen labeling is needed on the finished product.

PLANT NAME	**ISSUE DATE**	**PAGE**
ADDRESS	**SUPERSEDES**	**PRODUCT CODE**

Form Name: Food Allergen Label Verification Listing

Product	**Allergen Statement**

PLANT NAME	**ISSUE DATE**	**PAGE**
ADDRESS	**SUPERSEDES**	**PRODUCT CODE**

Form Name: Production Line Food Allergen Assessment

Product Name	Production Line	Intentional Allergens							
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)

Scheduling Implications:

Allergen Cleaning Implications: (Required)

How to Use This Form

Complete for each production line. Identify each allergen contained in each product produced on the line. Identify any allergens unique to a specific product. Then indicate scheduling information (i.e., run unique allergens last) and allergen cleaning information.

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Form Name: Sanitation Preventive Controls

Location		
Purpose		
Frequency		
Who		
Procedure		
Monitoring		
Corrective Actions		
Records		
Verification		**Date**

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Corrective Action Form

Date of Record:	Code or Lot Number:
Date and Time of Deviation:	
Description of Deviation:	
Actions Taken to Restore Order to the Process:	
Person (name and signature) of Person Taking Action:	
Amount of Product Involved in Deviation:	
Evaluation of Product Involved with Deviation:	
Final Disposition of Product:	
Reviewed by (Name and Signature):	Date of Review:

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Food Safety Plan Reanalysis Checklist

Reason for reanalysis:

Task	Date Reviewed and Initials	Is Update Needed? (yes/no)	Date Task Completed	Signature or Initials of Person Completing the Task
List of Food Safety Team with individual responsibilities				
Product flow diagrams				
Hazard analysis				
Process Preventive Controls				
Food Allergen Preventive Controls				
Sanitation Preventive Controls				
Supply-chain Program				
Recall Plan				
Updated Food Safety Plan implemented				
Updated Food Safety Plan signed by owner or agent in charge				
Reviewer Signature:			Date Review:	
Date issued: DD - MM -YY		Supersedes: DD - MM -YY		

Food Safety Plan/Preventive Controls Reanalysis Report	Code:	
	Issue Date:	
	Version No.:	
	Page No.:	
PRODUCT(S):		
PROCESS LINE:		
Plant Name:		
Address:		

Reanalysis Type (Check One):

☐ Initial Reanalysis (within 12 months of implementation)

☐ Reanalysis (Reassessment) due to changes made in raw materials or source of raw materials; product formulation; processing method or systems, their software; packaging; finished product distribution systems; or the intended use or intended consumers of finished product and rate or type of consumer complaints.

☐ Annual Reanalysis (Reassessment) of the Food Safety Plan including Hazard Analysis

Date Conducted: _____ **Conducted By:** _____

Topic	Yes	No	Food Safety Implication?	Are modifications to the Food Safety Plan required?
1. Evaluate product & process				
Product description changed, e.g., intended use, consumer?				
Formula changed?				
Ingredients/Packaging changed?				
Any new product consumption or storage methods?				
Any new suppliers?				
Process flow changed?				
Equipment / computer software changed?				
Finished Product Distribution changed?				
Other, e.g., production volume increased				

Topic	Yes	No	Food Safety Implication?	Are modifications to the Food Safety Plan required?
2. Evaluate product / process history				
Repeat Preventive Control/CCP deviations?				
Any recent industry recalls of similar product since the last annual validation?				
New or emerging hazards, e.g., recent CDC Morbidity and Mortality problems identified with product?				
Regulatory Agency recommendations, e.g., guidance documents, regulations?				
"Any confirmed food safety consumer complaints?" Other:				

Topic	Yes	No	Food Safety Implication?	Are modifications to the Food Safety Plan required?
3. Evaluate adequacy of Preventive Controls (PC) / CCPs, critical parameters / limits, monitoring, corrective action, PC/CCP verification, and record keeping procedures. Review current PC/CCP documentation.				
Do the PCs/ CCPs control the hazards?				
Are the PC/CCP critical parameters/ limits adequate?				
Do monitoring methods and frequency demonstrate control?				
Do corrective actions properly address affected product and correct deviations?				
Does reanalysis include review of consumer complaints?				

Other, e.g., Prerequisite Programs or procedures may affect the hazard analysis:				

Topic	Date Reviewed	Is Update Needed? (YES/NO)	Date Task Completed	Signature or Initials of Person Completing the Task
4. Food Safety Plan Reanalysis				
List of Food Safety Team with individual responsibilities				
Product flow diagrams				
Hazard analysis				
Process Preventive Controls				
Food Allergen Preventive Controls				
Sanitation Preventive Controls				
Supply-chain Program				
Other Preventive Controls				
Recall Plan				
Updated Food Safety Plan implemented				

Appendix E. Illustrative Examples Illustrative Example: *Salmonella* Control Objective

As described above, thermal processing, gas treatment and other control measures can be effective mechanisms to control *Salmonella*. To be effective, the process should consistently deliver a minimum degree of lethality to eliminate *Salmonella*. The only defined log reduction standard at the time of this writing is for almonds bound for delivery within North America: Processing conditions must be sufficient to deliver a minimum four-log reduction of *Salmonella* per USDA Agricultural Marketing Service regulation (AMS, 2007) and the Almond Board of California (ABC, 2007).

The adequate reduction can be determined by the industry or by the FDA based upon prevalence/enumeration studies and other studies such as a quantitative risk assessment (under development) as appropriate. Some prevalence studies that have been published for nuts include:

- Calhoun, R.S., L. Post, B. Warren, S. Thompson, and A.R. Bontempo. 2018. Prevalence and concentration of *Salmonella* on raw, shelled peanuts in the United States. *J. Food Protect*. 81:1755-1760.
- Kaitylyne E. Caulli, S. Calhoun, and D.W. Schaffner. 2019. Modeling the risk of Salmonellosis from consumption of peanuts in the United States. *J. Food Protect*. 82(4) 579–588.
- Lambertini, E., J. Barouei, D.W. Schaffner, M.D. Danyluk, and L.J. Harris. 2017. Modeling the risk of salmonellosis from consumption of pistachios produced and consumed in the United States. *Food Micro*. 67:85-96.
- Sanders, T.H., R.S. Calhoun. 2014. Effect of oil and dry roasting of peanuts at various temperatures and times on survival of *Salmonella* and *Enterococcus faecium*. *Peanut Science*. 41:65-71.
- Santillana Farokos, S.M., R. Pouillot, R. Johnson, J. Spungen, I. Son, N. Anderson, and
  J.M. Van Doren. 2017. A quantitative assessment of the risk of human Salmonellosis arising from the consumption of almonds in the United States: The impact of preventive treatment levels. *J. Food Protect*. 80(5):863-878.
- Santillana Farokos, S.M., R. Pouillot, R. Johnson, J. Spungen, I. Son, N. Anderson, G.R. Davidson, and J.M. Van Doren. 2017. A quantitative assessment of the eisk of human Salmonellosis arising from the consumption of pecans in the United States. *J. Food Protect*. 80(9):1574 – 1591.
- Santillana Farokos, S.M., R. Pouillot, R. Johnson, J. Spungen, I. Son, N. Anderson, and
  J.M. Van Doren. 2019. A quantitative assessment of the risk of human Salmonellosis arising from the consumption of walnuts in the United States. *J. Food Protect*. 82(1):45- 57.

In the absence of such studies, the FDA has suggested a five-log reduction for peanuts (FDA, 2009a) and pistachios (FDA, 2009b). Survey studies and thermal and non-thermal resistance studies are being undertaken to determine the appropriate log reduction and validate processing conditions for *Salmonella* elimination in peanuts and certain tree nuts. As industry standards are developed and as additional tree nut risk assessments are completed, results will be included in updates to this document.

Management Responsibility

All facilities supplying processed tree nuts and/or peanuts should ensure instructions are developed, documented, communicated and followed and should ensure responsible employees are designated and adequately trained to meet the minimum processing standards outlined in the plan.

Critical Limits for Nut Process Preventive Control (PC)/ Critical Control Points (CCPs)

Critical limits should be based on data found in the literature or through in-house studies. Parameters are specific to the nut/process in which validation studies have been conducted and may not apply to other nut types and processes. Critical limit temperatures are to be achieved in the space between the nuts. If the temperature cannot be measured between the nuts, a process validation should be performed to correlate air or steam temperature with nut/nut bed temperature, which must ultimately be shown to result in the prescribed *Salmonella* reduction.
The temperature of product entering the thermal process should be greater than the minimum initial temperature (lowest temperature) established during validation.

The FDA requires that the scientific basis be cited for the critical limit in the Food Safety Plan (FSP), e.g., regulatory guidelines, experimental studies, scientific publications.
The following are examples of writing style conventions for scientific citation:

Scientific Publication

Smith, A.B. 1996. Thermal Processes for Foods. J. Food Sci. 47:650-657.

Regulatory Guideline

Food and Drug Administration. 2009. Guidance for industry: Measures to address the risk for contamination by *Salmonella* species in food containing a peanut-derived product as an ingredient. https://www.fda.gov/regulatory-information/search-fda-guidance- documents/guidance-industry-measures-address-risk-contamination-salmonella- species-food-containing-peanut.

Experimental Studies

Company X, Inc. Microbiology Dept, (City). Product - Challenge Study. Microbiologist, Last name, First Initial, year. Notebook # or other identification.

If the process, e.g., a heat treatment, is milder (e.g., lower time or temperature) than the experimental process parameters or the regulatory safe harbor, then the process must be validated experimentally at that lower temperature to demonstrate adequate reduction of *Salmonella.* For example, to establish the critical limits for roasting to eliminate *Salmonella*, time and temperature limits, bed depth and/or belt speed and nut volume would be established using process capability studies and kill step verification for each individual roaster.
Considerations for process validation are described in Chapter 3.

Critical Limit Example: Oil Roasting

In the United States, for almonds, the time/temperature conditions for oil roasting to achieve a four-log or five-log kill are in Table 1 below. Through a letter of determination issued to

the Almond Board of California (ABC), the FDA has not objected to use of the term "pasteurization," if the

almond processor can achieve a five-log kill by meeting the minimum parameters specified below. Further studies are necessary to determine whether these data can be applied to nuts other than almonds. Critical limits specific to other nuts will be provided when data are available.

Table 1. Time/Temperature Conditions for Oil Roasting Almonds (Du and Harris, 2003)

Minimum Temperature	Minimum Time	Minimum Time
	4-log kill	5-log kill
127°C (260°F)	1.6 min	2.0 min

Temperature is to be achieved in the oil among the almonds and based on an oil temperature greater than 127°C (260°F) at the coldest point in the oil roaster (ABC, 2007)

Monitoring Activity/Frequency

Examples of monitoring procedures for dry roasting, oil roasting, and steam pasteurization are provided below. In all cases, the following procedures should be used:

- An audible or visible alarm should be in place to notify operators of deviations in the controls that lead to achievement of appropriate time/temperature settings (e.g., belt speed). The alarm should be verified as the equipment starts up and/or as the equipment shuts down.
- For batch and continuous systems, the temperature of the product or oil is continuously monitored and recorded at the coldest spot in the roaster and should reflect the temperature achieved between nuts. Under the Food Safety Modernization Act (FSMA), exception records in lieu of continuous records are allowed.
- Flow rate or belt speed setting should be recorded continuously and checked at the beginning of the process run once per shift after start-up and after adjustments to the belt speed/product changeover.
- Product bed depth is to be measured or controlled continuously.

For continuous dry roasting, the following procedures should be used:

> The bed depth and belt speed should be monitored and controlled to ensure the maximum validated thickness and maximum belt speed are not exceeded as per process validation data. Roaster temperature should be monitored and controlled to ensure minimum temperatures are maintained during production. Product variables, e.g., nut type, size/density, moisture, and incoming nut temperature may be critical; if they are, they will need to be monitored.

For oil roasting, the following procedures should be used:

> Oil levels should be monitored and maintained at a level to ensure submersion of all nuts. The appropriate level should be determined and documented within the Food Safety Plan. For continuous oil roasters, belt speed should be monitored to ensure the maximum speed is not exceeded as per process validation data. Oil temperature

must be monitored to ensure the temperature at the coldest spot exceeds the minimum required temperature.

For steam/moist heat pasteurization, the following procedures should be used:

Parameters should be monitored and recorded automatically for each batch or continuous production run. For a continuous steam treatment, the bed depth and belt speed should be monitored and controlled to ensure that the maximum validated thickness and maximum belt speed are not exceeded per process validation data. For batch and continuous systems, steam treatment temperature should be monitored and controlled to ensure minimum temperatures are maintained during production. Product variables, e.g., nut type, size/density, moisture, and incoming nut temperature may be critical; if they are, they will need to be monitored. The system should stop the process if the critical limits are not met.

Contingencies should be in place for diverting deviated under-processed product and properly sanitizing any potentially contaminated post-process conveyors, etc. See more discussion on corrective actions below.

Corrective Action Activity

Corrective actions for deviations to critical limits at the roaster may include resetting temperature, belt speed, or bed depth and may include rechecking readings to ensure compliance with the critical limits. In addition, a product run since the last acceptable checks on critical limits must be placed on hold and evaluated for appropriate disposition. Disposition may include reprocessing with a validated kill step, evaluation by a qualified person/process authority (*Salmonella* testing may be used as part of the evaluation as appropriate) and clearance, or controlled disposal.

In some cases, a processor of tree nuts might conduct generic *E. coli* testing as part of process verification. If the organism is found in processed tree nuts, additional reconditioning procedures relative to generic *E. coli* are described in the FDA Compliance Policy Guide (CPG) 570.550 and CPG 570.450 (FDA 1988, FDA 2005).

Verification Activities

Examples of verification activities specific to this example include the following:

- Verification of bed depth setting systems
- Verification of belt speed/residence time readout devices
- Verification of the diversion system
- Calibration of measuring devices used to monitor critical control parameters
- Independent checks such as a second person conducting the monitoring
- Periodic finished product sampling and testing where appropriate

Record Location

Examples of records include temperature charts, thermometer calibration logs, Hold and Release records, corrective action records, verification records and traceability records.

Illustrative Example: PC/CCPs to Eliminate Metal Objective

Harvested peanuts or tree nuts may contain dirt, sticks, stones, nut grass, field glass, field metal, other nuts and bone fragments. The majority of these potential hazards are not food safety concerns and would not be included in the hazard analysis and would be managed at the sheller locations through prerequisite programs (PPs). This section focuses on preventive controls designed to eliminate metal fragments in an operation where the food safety team concludes in the hazard analysis that metal fragments, unless controlled, are likely to cause a significant injury.

Management Responsibility

All processors should ensure instructions are developed, documented, communicated and followed and ensure responsible employees are designated and trained to meet the minimum metal detection and control standards outlined by this section.

Critical Limits for Nut Process PC/CCPs

Critical limits for metal detection and final magnets, described below, are based on data in the literature or through in-house studies. The manufacturer of the metal detector may be a useful resource. These parameters are examples only and must be validated for specific types of metal and magnet/metal detection equipment.

The detecting limit for an endpoint metal detector will depend on the type of product and the detection equipment. Detection equipment settings should be determined and applied to achieve the most sensitive level possible to provide maximum protection from metal contamination. At no time should they be larger than 7mm for all metals. (FDA. CPG Sec. 555.425 Foods, Adulteration Involving hard or Sharp Foreign Objects)

The reject mechanism should direct product rejects from the process flow automatically into an identified area, bin, or container. An action level, based on the number of rejects and the size of the metal fragments found, should be defined on the basis of historical trend analysis:

- All rejects should be evaluated to determine cause for rejection.
- Action limits should be available to the responsible operator, and corrective actions should be described.
- Action limits should include unusual findings and excessive rejects which would trigger an immediate corrective action.
- On a routine basis, several test products should be run through the detector successively to determine that the rejection mechanism will reject multiple defects.
- All the findings should be documented, including time, test results and operator's name.
- The responsibility and methodology for evaluating rejected product should be specified and documented.

Monitoring Activity and Frequency

Each facility must determine the appropriate monitoring activities and frequency of those activities. The Food Safety Plan (FSP) must document, in writing, the monitoring activities and

corresponding frequencies the facility selects. Monitoring is generally performed by an equipment/line operator. Examples of monitoring procedures for metal detection are provided below.

- Visual observation, to ensure the detector is on and product is passing through the detector, should be performed and documented at the start-up and end of each shift and approximately once every two hours during the shift.
- The reject mechanism should be tested at start-up and end of each shift and approximately once every two hours during the shift to confirm that it will reject metal pieces larger than critical limits.

Corrective Action Activity

Corrective action for deviations to critical limits at the metal detector may include repair or recalibration of the metal detector or replacement of the reject mechanism. In addition, product run since the last acceptable checks on critical limits must be placed on hold and evaluated for appropriate disposition. Corrective action may include 100% inspection by an operable metal detector or other approved analytical technique to ensure compliance with the critical limits.
Disposition may include release of re-inspected and cleared nuts/finished product and further cleaning (e.g., further cleaning of the nuts through magnets and/or cleaning equipment as opposed to just rerunning through the metal detector) or controlled disposal of rejected nuts/finished product.

See FDA's Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Foods Chapter 5 https://www.fda.gov/media/99576/download for additional information regarding Preventive Control Management Components.

PC/CCP Verification Activities

Functionality verification for electronic detection and rejection devices, e.g., x-rays and metal detectors, should take place during production with the normal product flow. As an example, frequencies for rejection system verification should occur at the following times:

- After a production changeover, which includes changes in primary packaging and/or formulation whether between shifts or within a shift
- Following any repairs, maintenance, or adjustments
- Regularly as determined by the site (length of time based on acceptable risk/value of held product and process capability experience or studies)

The functionality verification method should assure 100% detection and rejection of the test piece(s). At the start of production each day and at each package or product change, two passes of each test piece (ferrous, non-ferrous and 316 nonmagnetic stainless steel) should be detected and rejected. Consideration should be given to using a combination of leading edge and trailing edge passes where possible. This means the test piece should be placed at the front end of the package (leading edge) as well as at the back end of the package (trailing edge). Placing test pieces in the least sensitive area of the test chamber should be considered. The verification test pieces should be clearly identified and differentiated from product. If a metal detector is not working at its design limit (e.g., if it fails to detect a test piece), the material

produced since the last time the metal detector was verified to be operating at its design limit should be placed on hold.

The rejection device should be checked on a series of test containers, e.g., three consecutive ones, to ensure devices with pneumatic rejection mechanisms have enough air capacity to blow off a third consecutive sample.

Examples of verification activities include the following:

- QA personnel checks the sensitivity of the detector and reject mechanism by running ferrous, non-ferrous, and 316 nonmagnetic stainless steel test pieces through the geometric center of the aperture on a regular basis (less frequent than monitoring), e.g., once/shift.
- A Preventive Controls Qualified Individual (PCQI) or QI designee (e.g., trained qualified individual under the oversight of the PCQI) reviews and signs metal detector records within seven working days of generation (the timeframe required by FDA) and preferably daily or before product release.
- QA personnel performs system audit annually, reviewing procedures and paperwork for compliance and effectiveness.
- The PCQI reviews and signs calibration records according to metal detector calibration per manufacturer's recommendation (e.g., annually).

Record Location

Examples of records include metal detector calibration logs, metal detector verification records, Hold and Release records, corrective action records, and traceability records.

Appendix F. Pesticide Registration Information for Propylene Oxide and Ethylene Oxide

Please note: The registrations listed below are for the United States. Other countries may not allow the use of these chemicals or have different tolerances.

Propylene oxide (CAS Reg. No. 75-56-9; 40 CFR 180.491). Registered as a post-harvest fumigant for tree nuts in crop group 14, with a general residue tolerance of 300 parts per million (ppm). Crop group 14 includes almond, beech nut, Brazil nut, butternut, cashew, chestnut, chinquapin, hazelnut (Filbert), hickory nut, macadamia nut, pecan and walnut. The use of propylene oxide on pistachios and their inclusion in group 14 is registered through an IR-4 Food Use Request (PR # 07903 C).

Ethylene Oxide (CAS Reg. No. 75-21-8; 40 CFR 180.151). Registered as a post-harvest fumigant. General residue tolerance is 50 ppm in walnut.

Sources: Electronic Code of Federal Regulations e-CFR: https://ecfr.io/

Appendix G. Example of Calibrating or Verifying Accuracy of a Temperature Sensor Prior to Validation of a Process

A procedure for calibration check or verification of data loggers is described below:

1. Program the data loggers at short sampling interval (e.g., 0.5 minute). Shorter sampling intervals are usually recommended for adequate resolution in measurements. If a processor is using a "Fluke" device, skip this step and proceed to Step 2.
2. Blanching Process: Submerge the data loggers into a beaker containing boiling water. Use a reference thermometer (NIST thermometer recommended) to verify the temperature of water. Record the temperature at regular 30-second intervals.
3. Oil and Dry Roasting: Submerge the data loggers into oil bath set at a temperature close to the set roasting temperature. Record the temperature at regular 30-second intervals.
4. After 15 minutes, remove the data loggers from the boiling water/hot oil and download the data. If using a "Fluke" device, record the data every 30 seconds.

If the data loggers are functioning properly, the data should match with that of the NIST reference thermometer. Repeat the calibration check/verification process if any offset in the data are observed. If the offset in the data is consistently observed, record this offset value for the corresponding data logger and contact the service agent for appropriate data logger model. Adjust the temperature reading accordingly during field sampling.

Appendix H. Examples of Roaster Thermal Process Validation

Example A

VALIDATION OF PEANUT ROASTING PROFILES FOR 5-LOG OR GREATER *SALMONELLA* REDUCTIONS WITH AEROGLIDE ROASTER

INTRODUCTION

Because nuts are a raw agricultural commodity, *Salmonella* is likely to be present. It is known to be in peanuts and almonds. Roasting, a dry heating process, is considered as a Critical Preventive Control (PC) / Control Point (CCP) to inactivate *Salmonella* on raw nuts. Raw peanuts are likely to be contaminated with *Salmonella* at low levels (< 10 CFU/g) (Calhoun et al., 2013). Laboratories from three countries tested peanuts as an investigation associated with an outbreak in 2001 and reported *Salmonella* concentration, ranging from <0.03 to 2 CFU/g (Kirk et al., 2004). *Salmonella* is unlikely to grow on raw peanuts with 6-8% moisture (a_w <0.65) but may survive some period of time. The Almond Board of California (ABC) recommended a four-log *Salmonella* reduction as sufficient lethality treatment "*Salmonella* performance standard" for almonds, and the USDA Agricultural Marketing Service (AMS) published it in a final rule in the Federal Register (AMS, 2007), based on risk assessments (Danyluk et al., 2006). The appropriate log reduction for *Salmonella* in peanuts (e.g., whether a four-log reduction is adequate or if five-log is needed) is being determined by ongoing industry-led survey and further studies, e.g., a risk assessment. According to the FDA's guidance for industry, (Measure to address the risk for contamination by *Salmonella* species in food containing a peanut-derived product as an ingredient) published in 2018, recommends that manufacturing adding peanut- derived ingredient into finished product should have gone through a validated kill step of 5 log reduction. For more information on outbreaks refer to Harris, L. J., S. Yada, L. R. Beuchat, and
M. D. Danyluk. 2019. Outbreaks of foodborne illness associated with the consumption of tree nuts, peanuts, and sesame seeds (version 2) [Table and references].

Each roasting operation must be evaluated for its efficacy in *Salmonella* inactivation. The typical roaster time/temperature profile is either with a single roasting temperature

throughout roasting or with a roasting temperature that starts lower and increases as roasting progresses. In this study, an approach was used to deliver the maximum lethality against *Salmonella* consistent with the desired product characteristics. That is, roasting starts at the highest temperature of the profile and is lowered during roasting.

The roasting validation profiles consist of operational parameters, e.g., bed depth, air flow rate, air distribution, total roasting time (associated with belt speed) and roaster air temperature.
Validation profiles parameters varied per nut due to physical and chemical properties. For example, as peanuts lose moisture and the water activity (a_w) of the peanuts decreases, the lethality of the heat will be less effective against *Salmonella* (Shachar and Yaron, 2006). In addition, as the peanut temperature and air temperature between peanuts typically increase at the slowest rate in the middle layer of the peanut roaster bed. The higher the peanut bed depth, the greater the temperature variation expected. As a result, the variation in roasting color and quality is expected to be greater as the peanut bed depth increases. For additional guidance, refer to Almond Board of California's guidelines for validation of dry roasting processes.

In this study, the experiments were carried out with inoculated and uninoculated peanuts. Two types of peanuts and two test organisms were studied. Peanuts were roasted at various time/temperature profiles and various peanut bed depths.

Description of the process: This actual process is omitted here due to proprietary reasons. In an actual report, information would be provided on the process, e.g., type and brand of processing equipment (batch *vs.* continuous), processing conditions, belt thickness, bed length, description of zones, type of temperature sensors and location, shutdown features and other features as appropriate.

The objective of this study was to determine and validate the peanut roasting time/temperature profiles with specified roasting operational parameters to achieve >five-log *Salmonella* log reduction and produce high-quality roasted peanuts. The goal was to meet the safety requirement before meeting the roasting quality requirement.

MATERIALS AND METHODS

Inoculum Preparation and Peanut Inoculation

In this study, two test organisms (*Salmonella* Enteritidis BAA-1045 [originally isolated from raw almonds] and *Salmonella* Tennessee ATCC 10722) were studied. Experiments were carried out either with *S*. Enteritidis or *S*. Tennessee. The cultures were inoculated into the Trypticase Soy Broth (TSB) from the stock culture slants and incubated at 35°C for 22–24 hrs. The TSB culture was centrifuged at 10,000 rpm for 10 min. After decanting the supernatant, the cell pellet was resuspended in Butterfield's Phosphate Buffer (BPB) approximately 1/20 ratio of the TSB culture volume to obtain concentrated inoculum. The inoculum concentration was about 10^{10} CFU/mL (10^{10} colony forming units per milliliter).

Raw peanuts on the trays were put into the biohazard hood. The culture was then sprayed evenly onto the single layer of raw peanuts using a spray bottle. The inoculated peanuts were air-dried overnight in the hood before using them for the experiments.

Peanut Roasting Time/temperature Profile Determination

The lab-scale mini roaster was used for the experiments to simulate the production scale roaster. The roaster had a roasting tray (basket) with 8.25”x 8.25”x 9” dimensions. Either shelled, medium whole peanuts with skin or a peanut blend of medium whole + split peanuts (50/50) were roasted at various depths (3–4”) depending upon the objective of each experiment. The flow rate of the roaster incoming air to the heater was set to 2750 feet per minute (fpm) to obtain 190-200 fpm hot air flow rate to the peanuts according to the manufacturer’s recommendation. Roaster temperature was set according to the roasting profiles used in the experiments. Roaster incoming hot air temperature, exhaust air temperature and air flow rate were monitored during the experiments.

Two thermocouple thermometers (Fluke 54 II Dual input thermometer from Cole-Parmer) with Type K thermocouple peanut penetrating and air probes were used to measure the peanut temperature and air temperature between peanuts, respectively. One of the peanut-penetrating probes with a peanut attached was located at about the geometric center of the peanut bed (T1). The second peanut-penetrating probe (T3) was embedded into the middle of the peanut bed and two inches away from the T1. In addition, air probes were positioned about one inch away from the peanut-penetrating probes in the middle of the peanut bed (T2 and T4). For two

experiments, a pair of peanut and air probes were positioned 0.5” from the bottom and/or top of the peanut bed. Thermocouple thermometers were set to record temperature at 1-min intervals.

Although this experiment was done using four probes, a higher number (e.g., 10–15) of probes are recommended to assess temperature uniformity and differences and to verify cold spot(s) especially when conducting temperature measurements in processing equipment. Ensure peanuts are in the cold spot location(s) in the experiments.

***Salmonella* Log-reduction Determination**

Pre-roast Salmonella level determination on inoculated peanuts.

Ten 25-g pre-roast samples representing each batch of inoculated peanuts were collected and stomached in 225 mL BPB for two minutes to obtain 1/10 dilution. After making serial dilutions with BPB, the appropriate dilutions were plated on duplicate Xylose Lysine Decarboxylase (XLD) plates. The plates were incubated at 35°C for 48 hrs before counting the typical colonies. The plates that had the best countable colonies and were closest to the statistical range (25– 250 CFU) were counted and included in log (CFU/g) *Salmonella* calculation.

Post-roast *Salmonella* Level Determination on Inoculated Peanuts

After roasting peanuts inoculated with one of the test organisms, the roasted single-layer peanuts on sterile trays were cooled at refrigeration temperature for 15 min. During the cooling process, the roasted peanuts’ temperatures were down to <130°F within 5 min, <100°F within 10 min and about room temperature range (70–80°F) within 15 min.

After cooling the roasted peanuts, ten 25-g roasted peanut samples representing the cross-section of the peanut bed were tested to determine the survival level of the *Salmonella* test organism. The procedure was the same as the procedure used for pre-roast *Salmonella* level determination except that the appropriate dilutions of the samples were pour-plated

with Trypticase Soy Agar (TSA) and overlaid with XLD agar instead of surface-plating on XLD plates.

Calculation of Log-*Salmonella* Reduction

In this study, log-*Salmonella* reduction (LSR) was calculated based on the log average of 10 pre-roast samples and 10 post-roast samples. Averaging is only possible if there is uniformity of temperature profiles.

In the absence of data demonstrating a uniform treatment of nuts, one cannot assume all of the nuts in the experimental trials received the same treatment; therefore, each inoculated sample must be treated as an individual sample and the lowest LSR represents the effectiveness of the process. In this case, the minimum LSR will be based on individual values, not averages.

Testing Quality Attributes (Color, moisture and water activity):

Color, moisture, and/or water activity analyses of raw and roasted medium whole peanuts were tested as quality parameters. The color of the peanuts was tested using roasted peanut samples that are about 100% dry blanched (skin removed). The tests were performed by a Hunter colorimeter, calibrated with black/white tiles or with a special peanut tile. Moisture

analyses were performed by convection oven method. Water activity analyses were performed with Aqua Lab water activity meter from Decagon Devices, Inc.

RESULTS AND DISCUSSION

Tables and figures are excluded for this example; some data and discussion have been omitted from this example.

Roasting experiments were carried out with medium runners and the (50/50) blend medium runners and splits. Inoculated or uninoculated peanuts were roasted in various depths and time/temperature profiles depending upon the objective of the experiment.

In this study, the middle section of the peanut bed was assumed as to be the section in which the peanut temperature would increase at the slowest rate and be considered as the “coldest” spot. In addition, the variation in time/temperature profiles were expected to be greater across the peanut bed as the peanut depth increased. To verify these assumptions, medium runner peanuts were roasted at 3” and 4” peanut bed depths and time/temperature profiles were plotted. The results indicated that the peanut temperature in the middle of the peanut bed increased at the slowest rate as expected. The variation in peanut time/temperature profiles was also greater at 4” peanut bed at than the 3” peanut bed between the middle and bottom of the peanut bed.

The incoming hot roasting air temperature (roaster temperature) and roaster exhaust air temperature were plotted against roasting time. The difference between incoming and exiting air temperatures decreased with roasting time. The exhaust air temperature was about 10– 20°F lower than the incoming hot air temperature after about 10 minutes of roasting.

The differences in air temperature between peanuts and the peanut temperature were plotted. The peanut temperature and air temperature between peanuts had good correlation (R^2 = 0.9597).

Medium runner peanuts inoculated with *Salmonella* Enteritidis (6.85-log CFU/g) were roasted at a 3" peanut bed for total specified time. There were no detectable survivors. Therefore, the log reduction was >6-log CFU/g.

Medium runner peanuts inoculated with *Salmonella* Enteritidis or *Salmonella* Tennessee also were roasted at a 3" peanut bed for total specified times. Three trials were performed for each test organism. Profile 322 (which referred to a company-specific profile) with 3" bed depth was able to achieve >5.0-log reduction in *Salmonella* Enteritidis and *Salmonella* Tennessee.
Salmonella Enteritidis and Tennessee appeared to have comparable heat resistance in this study.

In addition to the medium runner peanuts, the 50/50 blended peanuts inoculated with *Salmonella* Enteritidis were roasted at 3" bed depth with 322 roasting profile. T1 and T2 temperatures were not recovered from the thermocouple thermometers. Therefore, T3 and T4 were the only temperatures plotted. The average log-reduction was >5.44-log (CFU/g). This result shows that the log-reduction was comparable in 50/50 blend peanuts and the medium runners.

A final set of experiments were performed with medium runners inoculated with *Salmonella* Enteritidis BAA-1045 by roasting peanuts at 3.5" bed depth. This time, the peanuts were roasted with roasting profile 220 (which referred to a company-specific profile). Three experimental trials were performed. The log reduction ranged from 5.12 to 5.72 log CFU/g.

SUMMARY AND CONCLUSION

The results of this study are as follows:

- The temperature of the peanuts in the middle of the peanut bed increases at the slowest rate. Thus, the peanut time/temperature profiles in the middle of the bed will be the minimum treatment profiles.

- The variation in time/temperature profiles of top, bottom and middle layers of the peanut bed increases as the peanut depth increases, which result in higher variation in log reduction and color.

- The roasting profile 322 with 3" peanut bed and the roasting profile 220 with 3.5" peanut bed achieved >5-log *Salmonella* reduction. The color (L-values) of the roasted peanuts was lighter than the target L-value (48 + 2) specifications of the roasted peanuts. However, the color is likely to be darker (smaller L-value) in actual production line due to less than 100% blanching efficiency (more skin left on the peanuts) during production.

- *Salmonella* Enteritidis BAA-1045 and *Salmonella* Tennessee ATCC 10722 appeared to have comparable heat resistance. In addition to the roaster air temperatures, the operational parameters, e.g., the flow rate of the incoming hot air to the peanuts, hot air flow distribution across the line, peanut bed depth and total roasting time (or belt-speed) can affect the LSR and roasting quality such as color.

- The air temperature between peanuts and the peanut temperature have a good correlation. Toward to the end of the roasting, the difference between these two temperatures was smaller (<5ºF). The LSR between the two peanut types were comparable.

In conclusion, > 5-log *Salmonella* reduction can be achieved by roasting peanuts at selected time/temperature profiles at 3 to 3.5" bed depth. The time/temperature profile variation will be less at smaller peanut depth, e.g., 3" bed depth than at 4" bed depth. Therefore, more uniform roasting and less roasted peanut color variation will be achieved at smaller bed depth.

To complete the peanut roasting validation process for the new roaster and to determine the roasting operational parameters for production, the actual roasting time/temperature profiles must be determined and validated for production, based on the information provided from this validation study.

RECOMMENDATIONS

- For safe and quality roasted peanut production, the operational parameters, e.g., roaster zone temperatures, hot air flow rate (fpm) for each zone, belt speed according to the roasting time (not including cooling time) and peanut bed depth should be set based on the type of data generated in this study.

- The following operational parameters produced high-quality roasted peanuts in addition to producing safely roasted peanuts, taking into account the equipment used in this study.

- Incoming hot air flow rate must be secured at >190 fpm during entire production time.

- Hot air flow direction (up or down) for each zone must be opposite to the air flow direction of the zone before.

- Even air flow distribution across the belt must be ensured at each zone.

- Three-inch peanut bed depth is an appropriate bed depth for food safety and quality.

- Roaster air temperature must be adjusted appropriately to achieve required *Salmonella* log reduction (>4.0-log) and to produce roasted peanuts at the required color specification (L-value: 48 + 2).

- Belt speed must be adjusted accurately to assure the roasting time required for safe and quality roasting (not including cooling time).

NEXT STEPS TO COMPLETE THE VALIDATION PROCESS

Peanut time/temperature profiles of the actual production (roasting) must be validated by following the procedure below:

- Multi-point thermocouples with 6–8 probes per thermocouple must be embedded into the middle of the peanut bed. One multi-point thermocouple must be positioned

at the center position of the belt, and the other two must be positioned at both sides of the belt at equal distances across the belt.

- Peanut-penetrating probes inserted into peanuts must be embedded in the middle of the peanut bed two inches away from each other. The air probes should be positioned between the peanut penetrating probes. The distance between peanut penetrating probes and air probes must be approximately one inch.

- The time/temperature profiles of the peanuts and the air between the peanuts must be determined for at least three roasting trials for the same operational parameters.

- The operational parameters relevant to the peanut roasting time/temperature profiles must be recorded during each roasting trial. The key for the success of the validation is capturing the peanut temperature variation across the belt for each roasting trial and capturing the peanut temperature variation between roasting trials due to the operational variation.

- Once the time/temperature roasting profiles are determined, the time/temperature profiles must be compared to those of the inoculation studies and evaluated to determine if >4- log *Salmonella* reduction can be achieved based on the results of this study.
- The following microbiological sampling and testing parameters should be considered minimal to evaluate the overall microbiological quality of the roasted peanuts and to finalize the validation process:
    - Take five samples (raw peanuts) before roaster and five samples after roaster per production shift.
    - Take samples at equal time intervals throughout the shift.
    - Take samples for 30 production shifts.
    - Test 25 g of each sample for Aerobic Plate Count (APC), coliforms, and *E. coli.*

Example B

VALIDATION OF ROASTER IN PEANUT BUTTER PROCESSING FACILITY

NOTE: Some data, figures (data plots) and discussion have been removed from this example.

An Aeroglide roaster is used to roast peanuts for manufacture of peanut butter and other products. It roasts by applying hot air to a maximum three-inch thick bed of peanuts on a 12- foot wide belt. During roasting, product moves on a belt through multiple roasting zones, and the hot air applied to the product alternates from the top and bottom to across the belt for even heating.

A study was done to validate effectiveness of the roaster for achieving food safety requirements. An Aeroglide lab-scale roaster was used for this study, and results show that a roasting process simulating that of the full-scale Aeroglide roaster achieves at least 5-log reduction of *Salmonella* (see Example A above). Air temperatures delivered to the peanuts were recorded during processing and represent the “minimum process” for validation purposes.

As described in the Hazards Analysis and Critical Control Point (HACCP) plan, settings for roaster temperatures are set at critical limits shown to achieve the validated minimum process. The actual time/temperature profile of air delivered to peanuts during roasting is in excess of the validated minimum process, thus assuring all peanuts are roasted using a process exceeding an equivalent of five-log *Salmonella* reduction. Roaster temperature settings are calibrated for accuracy, with the effectiveness of the roaster for achieving the validated minimum process verified at least annually.

Verification of roaster effectiveness is done by placing a temperature-recording probe into the vertical center of the peanut bed at the roaster entrance and retrieving the probe at the roaster exit. Temperature profiles of air delivered to peanuts are recorded in this manner multiple times at different vertical center positions across the peanut bed. This verifies uniformity of roasting time/temperature across the bed in addition to verifying the roaster delivers the minimum validated process for all peanuts.

Results of Verification for the roaster on ___[Date]_____ :

Table 1. Comparison of Time/Temperature Profile Data for Validated and Verified Processes

	Time/Temperature Profile		
Validation	First roaster zones	Second roaster zones	Third roaster zones
Minimum Equivalent Process Validated (Air Temp Delivered to Peanuts)	X min Y ^{o}F	X min Y ^{o}F	X min Y ^{o}F
Verification			
Critical Limits for Aeroglide Roaster (Air Temperature Settings)	X min Y ^{o}F	X min Y ^{o}F	X min Y ^{o}F
Roasting Process: Verified 12-04-08 (Air Temperature Settings)	X min Y ^{o}F	X min Y ^{o}F	X min >Y ^{o}F
Roasting Process: Verified 12-04-08 (Air Temp Delivered to Peanuts)	X min Y ^{o}F	X min Y ^{o}F	X min Y ^{o}F

Conclusions: Results for verification done on _[date] indicate that the _____ roaster delivered a process (air temperature delivered to peanuts) with microbial lethality in excess of the validated minimum process.

Appendix I Example of Thermal Process Calculation

The following thermal process equation is used to calculate equivalent time/temperature parameters (critical limits) when actual temperatures applied are different than those stated in the PC/CCP Models:

$F = F_R \times 10^{[TR - T]/z}$

T = temperature (ºF)
F = the equivalent time required at actual applied temperature T

F_R = the time required at given T_R (i.e., the reference time/temp stated in Model PC/CCP)
z = the z-value is the increase/decrease in temperature required to decrease/increase time by a factor of 10.

Calculation Example:
Reference Model PC/CCP: Nut Dry Roasting Treatment
Hazard: *Salmonella*
Critical Limit: 284°F for 19.3 min

What is the equivalent time (F) at 270°F?

T = 270°F
F = ?
F_R = 19.3 min (reference Model PC/CCP, above)
T_R = 284°F (reference Model PC/CCP, above)
z = 78°F (reference Model PC/CCP, above)

$F = 19.3 \times 10^{[284-270]/78}$
$F = 19.3 \times 10^{0.179}$
F = 19.3 x 1.51
F = 29.2 min at 270°F

Appendix J. Critical Factors Summary Sheet

CRITICAL FACTORS SUMMARY SHEET

Food Manufacturer	XYZ Nut Company

Equipment Information

Description	Equipment Manufacturer	Model #	Serial #	Validation #	ID#
Blancher	Blanching Specialists Inc.	S15	7887	ABC-XYZ-5L	Blancher 1

Scheduled Process

Process	Process Lethality	Minimum Scalder temperature (°F)	Minimum Residence Time (Minutes)
Blanching	5-Log	198.0°F	2

Operating Critical Factors
(To ensure the scheduled process is reached)

Process Parameters	Critical Factors	Monitor Frequency	Monitor Method
1. Almond Product Input Temp	60.0°F (minimum)	At start up and every hour during run	Manual Temperature Probe
2. Scalder Temperature	198.0°F (minimum)	Continuously	Built-in Temp Probe Chart Recorder/PLC
3. Scalder Speed Setting	23.0 Hz (maximum)	Continuously	Chart Recorder/PLC
4. Product Loading (Conveyor	25.0 Hz (maximum)	Continuously	Chart Recorder/PLC

Setting)			

General Description/ Deviation Instructions
Product Identification: Blanched Almonds
Product Segregation: Incoming raw almonds are stored upon arrival in a separate warehouse; Blanched product is segregated in a finished product storage warehouse.
Product Packing: 50 lbs cartons, bulk bins,
Deviation Instructions:
• All involved product segregated immediately upon identification of a deviation • Production ceased immediately if deviation occurs and is noted during a run • All involved product to be further treated, re-blanched, and/or reviewed by Process Authority for disposition determination. • Production to resume once deviation is corrected and equipment has been properly cleaned and sanitized

Process Validation	
Validation Date(s)	1/1/16
Process Authority	P.A. Nutz
Audit Frequency	Annually
Process Re-Validation frequency	If equipment is altered or moved

Appendix K. Guidelines for Water/Air Including Treatment Options and Limits

Air

- All plant exterior air intake ports should be visually examined for physical integrity at a frequency determined by risk evaluation, but minimum annually. Examination should be included in preventive maintenance plans.

  The air filtration requirements vary according to the classification of the different products and production areas.

Additional requirements for specific use:

- Air blown on the surface of microbiologically sensitive materials should normally be sourced from within the processing area, complying with the filtration requirements. Air sourced from outside should be filtered to the level required for the given product.
- Where air is used to transport fine, particulate products and there is high incorporation of air into the product, it should be filtered appropriately, e.g., using an F5/MERV8-10 filter if it is used to transport non-microbiologically sensitive ingredients or sensitive ingredients with a further kill step. For transport of sensitive ingredients with no further kill step, an appropriate filter size, e.g., F7/MERV 13-14 should be used. The appropriateness of the filter should be based on a risk evaluation of the product and process.

Compressed air

- When used as an ingredient, in contact with microbiologically sensitive products or their packaging, or in contact with material or product contact surfaces (e.g., during cleaning) after the kill step, compressed air should be filtered appropriately (e.g., using a 0.3µ filter) at the point of use. Alternatively, a risk evaluation should be carried out to determine product susceptibility and potential contamination sources and implement suitable safeguards.

- Distribution piping should be of approved material (e.g., ABS plastic, zinc-plated steel, stainless steel, aluminum).
- When used in direct contact with non-sensitive ingredients or prior to the kill step, an appropriate filter (e.g., 1µ filter) should be used.
- Preventive maintenance of air filters to manufacturer specifications is of prime importance and should be documented.

Water

- Filtration systems (e.g., charcoal, reverse osmosis) should be regularly inspected and maintained. Water systems should not have cross-connections between treated and untreated supplies. Incoming water lines should be fitted with one-way valves or a header tank.
- Disinfection (e.g., chlorination, ozonation, UV light) of surface and well (ground) water should be utilized for all direct product uses (e.g., ingredient, sanitation, rinse, drinking) and indirect product uses (e.g., recirculated cooling water, hand wash). Residual chlorine and ozone should be periodically tested (e.g., daily).
- Water used as a processing aid, for brine solutions and as sanitation final rinse should be tested for APC and coliforms. Additionally, water should be evaluated for chemical

  contaminants (e.g., lead) as well as radionuclides. The water should meet potable water standards set by the Environmental Protection Agency (https://www.epa.gov/dwreginfo/drinking-water-regulations).
- Chemical contaminant testing results may be available through the local municipality's annual water quality testing report if the potable water is sourced through the city or testing may be needed periodically (e.g., annual) if using a well water source.
- APC and coliform tests should be performed periodically (i.e., weekly or monthly, based on product/process sensitivity). Tests also should be performed after maintenance or repair.
- If results above the established limits are found, corrective actions should be implemented and documented, e.g., repeat sampling and testing, identify and eliminate source of contamination, clean piping, initiate chlorination (if possible).
- For surface or well water sources, a turbidity visual assessment should be carried out daily. Testing should also be carried out following any event that may adversely affect turbidity, such as abnormally heavy rain or flooding.

Steam

- Process steam is steam used indirectly during processing (i.e., steam for jacketed equipment) or used for direct product contact surfaces with a subsequent rinse. It should be produced using water treatment and/or boiler additive chemicals that are approved under relevant local/national regulations and have levels of additives that are not in excess of that required for the intended functional purpose.
- Culinary steam is steam used to for direct injection into product (e.g., steam treated nuts) or used to clean/sterilize product contact surfaces. This type of steam is produced using water treatment and/or boiler additive chemicals that are approved under relevant local/national regulations (e.g., FDA 21 CFR 173.310; 3-A Accepted Practices for a Method of Producing Steam of Culinary Quality, number 609) for human consumption and have levels of additives that are not in excess of that

required for the intended functional purpose. It is also usually filtered before direct contact with food to remove contaminants (e.g., rust, scale, particulate matter).

Microbiological tests that should be performed include total aerobic plate count and coliforms (if water is used for wet cleaning). The following table lists examples of test methods and acceptable criteria from a company-specific program.

Test Type	Sample Size	Examples of Test Methods [Options – list is not exhaustive]	Acceptance Criteria
Free chlorine	Sample 25 ml Note: Test immediately for free chlorine, concentration should be read within one minute of adding DPD* free chlorine reagent.	HACH AccuVac™ HACH Free chlorine test [Model CN-70 or CN-66] LaMotte Colorimeter [Model 1200 CL] HF Scientific DPD chlorine photometer Hellige DPD	Minimum 0.1 ppm or mg/L. Maximum 5.0 ppm De-chlorinated water – reverse osmosis systems – maximum 0.1 ppm
Aerobic Plate Count (APC)	Direct and indirect product contact water - Sample size 120 ml total. Test amount APC per 1 ml.	Petrifilm (Replace Sodium Thiosulfate collection with 1:10 dilution in Letheen broth for chlorine neutralization) Standard Plate Count Agar [Standard plating techniques] BAM Chapter 3.	Less than 500 per ml
Coliforms	Direct & indirect product contact water. Sample size 120 ml total. Test amount coliform per 100 ml	Presence/Absence Coliform test [Colilert® – IDEXX or Readycult® EMD] Colitag Neogen Membrane filtration [mf endo agar] MPN [10 tubes/10 ml each] double strength LST+MUG	Absence in coliform test kit Less than 1 per 100 ml MPN less than 1.1 per 100 ml.

* DPD: N,N Diethyl-1,4 Phenylenediamine Sulfate, a chemical widely used in testing methods for free and total chlorine.

Appendix L. Hygiene Zoning Example

To establish the applicable and necessary zoning barrier, the different processing environments and the potential sources of pathogen and non-pathogen cross-contamination (e.g., product handling areas, storage areas, processing areas, raw materials) should be identified through a risk evaluation of each production area. The following points should be evaluated during the zoning assessment:

Physical measures/barriers are as follows:

- Is a plant layout map in place, designating each manufacturing area accordingly and showing traffic flow patterns between areas to prevent the transfer of microorganisms from the contaminated to the non-contaminated areas?
- Is a structural separation in place between different areas (e.g., compartmentalization, closed pipes, and tanks of product)?
- Does physical separation exist between raw product handling and other manufacturing areas?
- Are common coolers for storing raw ingredients and finished products or packaging/supplies prevented and adequately controlled?
- Are common docks for receiving of micro-sensitive ingredients and shipping of finished product prevented and adequately controlled?
- Are waste areas physically separated from production areas?
- Are common clean in place (CIP) systems between raw liquids and processed product prevented and adequately controlled?
- Is contamination via packaging material prevented?

Traffic control is as follows:

- Are traffic patterns of people, trucks, materials and equipment defined, differentiated and controlled by, e.g., physical barriers, labeling, or color coding to prevent cross contamination?
- Are common elevators, hallways, etc., between different classified areas prevented and adequately controlled?
- Are separate vestibule facilities used as entrances and exits with coat/shoe-changing measures and hand sanitation in place where applicable?

Infrastructure:

- Are floors constructed and maintained to resist deterioration?
- Are cracks in wall/floor interfaces and along floor expansion joints, and is missing floor grout repaired?
- Are floors kept dry wherever possible to prevent microbial harborage? Are floors constructed to prevent standing water and cleanable? Is there any evidence of water flow between the current floor and the sub-flooring? Is any water seepage noted between rooms and doors?
- Are floor drains (including overhead drains from the floor or roof above) adequately designed?
- Is there separation of effluent and wastewater drains coming from product areas with potentially higher contamination risk (i.e., no connection between drains or back-flow prevention installed)?
- Are any water lines coming from different sources (e.g., well and municipal water) and used in the manufacturing process properly separated and identified?
- Are ceilings and walls dry, cleanable and constructed to resist deterioration? Are false ceilings designed with rigid insulating and proper sealing?
- Are temporary containment barriers in place and traffic controls maintained during plant construction activities?

Air and water control is as follows:

- Are negative air pressures in place for raw areas when adjacent to process areas (e.g., raw peanut area to roasted peanut area)?

- Are positive air pressures in place compared to outside production areas for finished product areas where the products support growth (e.g., peanut butter processing and packaging)?
- Is air appropriately filtered in all areas where necessary (e.g., nut cleaning and roasting rooms, micro lab)?
- Are relative humidity levels and level of air turns/hour maintained in production and storage areas? Are refrigeration units and air ductwork cleaned and maintained on a periodic basis?
- Are all compressed air lines used on product contact surfaces adequately filtered at point of use?
- Are programs in place to control water microbiological quality?
- Is condensate adequately controlled in processing areas to prevent product contamination? Are condensate and water piped to a sanitary drain or are drip pans in place and maintained?

cGMPs measures are as follows:

- Is dedicated clothing (lab coats, aprons, jackets, and shoes) used in production areas?
- Are dedicated employee uniforms and/or footwear worn only in the plant?
- Are clothing restrictions and cGMPs rules enforced for visitors and outside contractors?
- Are hand wash and sanitizer stations installed, functioning and indicated by signs at entrances of manufacturing areas? Are hand sanitizing units available to all employees working with sensitive product contact?
- Are sticky mats, footbaths, foot washing stations and door foamers in place and maintained where applicable?
- Are sanitizer concentrations in foot baths and door foamers verified and changed on a routine basis?
- Are air, water, and electrical hoses properly maintained and stored away from exposed product areas?
- Are maintenance tools and operator utensils and tools cleaned and sanitized after usage or dedicated to one area? Are they color coded?
- Are common pipe connections for receiving or unloading of different liquid ingredients prevented or adequately controlled?

Sanitation controls are as follows:

- Are cleaning and sanitation procedures in place after equipment downtime and after maintenance activities (including activities of external contractors/suppliers) have been completed? Are sanitation controls and environmental sampling procedures in place before start-up after maintenance/repairs?
- Are “deep cleaning” equipment procedures in place after construction or after major repairs are completed?
- Are sanitation procedures and environmental swabbing procedures in place after new equipment installation?

Appendix M. Personal Hygiene Practices

Personal practices

The following actions should not be allowed in production areas:

- Eating or drinking permitted in authorized areas of the facility only
- Chewing gum, candies, throat candies, throat lozenges and tobacco
- Holding toothpicks, matchsticks or other objects in the mouth
- Placing pens or cigarettes behind the ears
- Wearing false eyelashes or fingernails. Nails are not to be decorated in any way (including decals, nail polish, etc.)
- Carrying objects above the belt or waistline, e.g., pens, flashlights, thermometers
- Expectorating (spitting) in production areas
- Rings, watches, earrings, necklaces, other jewelry (including ornaments in exposed pierced body areas such as tongue and nose) not worn in production areas

Additionally, the following rules should be observed:

- If smoking is permitted in facility, it should only be permitted in designated areas and never in production areas.
- Use of badges and clip-on identification cards should be worn below the waist. Visitor identification badges are permitted but should not be a source of contamination at the plant.
- Lunches should be stored in designated areas. Lunches should be completely enclosed in cleanable, reusable containers or in single-use packaging (e.g., lunch paper bag or plastic bag/wrap).
- Personal lockers should be maintained free of trash and soiled clothing. Food and direct product contact tools should not be stored in employee lockers.

<u>Clothing and personal equipment</u>

- All clothing should be kept in good condition. Employee clothing should not be a source of contamination.
- Employees who work in production areas should wear only company-approved clothing. Clothing should provide adequate coverage that ensures hair, perspiration, or other foreign materials do not contaminate the product, e.g., no shorts, tank tops, sleeveless shirts. Non-production employees, contractors, and visitors who enter production areas should wear a lab coat (or other approved covering) and wear appropriate footwear consistent with plant policy.
- Pockets above the waist should be removed or sewn shut. Only zippers, grippers, or snaps should be used as the fasteners on shirts, coats, laboratory jackets, or smocks.
- Workwear dedicated to specific product areas should be restricted to those areas. Such areas should be defined in local procedures (typically high-care areas where clothing change is required on entry and exit). They should not be permitted in other plant or non-plant areas where they may be subject to allergen or microbiological contamination (e.g., cafeteria, external rest areas, any area not subject to cGMPs controls).
- If a captive clothing and footwear policy exists, employees who work in microbiologically sensitive areas should not wear the company clothing and footwear outside of the plant.

  When not in use, such clothing should be stored in a sanitary manner, e.g., on hangers or hooks.
- To help avoid product contamination (and for personal safety), shoes worn in production areas should be designed and constructed as follows: fully enclosed (no

open toes, open weave, or sandals); made with leather or vinyl outer materials (no canvas or nylon mesh); low-heeled; sole groove depth should not be a source of contamination. Shoes in wet microbiologically sensitive areas should not trap or absorb water when walking through footbaths at room entrances or deposit water on the floor as employees walk through a room.

- Safety helmets should be maintained in a sanitary condition. Labels or stickers, if used, should be permanently affixed and cleanable. Helmets used in microbiologically sensitive areas should be cleaned and sanitized on a frequency determined by the plant Quality Department. Helmets should not be used for storing or carrying objects, e.g., cigarettes, notepads, food, pens.
- Ear protection devices should be secured to prevent product contamination. These include ear plugs attached by string worn around the neck, earplugs with rigid attachment worn around the neck and earmuffs attached by a headband. If available, metal- detectable earplugs should be used, especially in facilities where production lines are equipped with metal detectors.

Hands

- Personnel working in production areas should wash hands at the following times: when entering a production area; after each visit to the toilet facility, rest room, and/or lunch and break room facilities; prior to touching product or product contact surfaces; or any time when hands have become soiled or contaminated.
- Personnel working in a microbiologically sensitive area should sanitize their hands after proper washing. If soil is observed on hands, hands should be washed prior to re- sanitizing.
- When working in production areas, the use of hands for unsanitary practices should be avoided. Specifically, hands should not be used to scratch head or body, touch face or wipe forehead, or place fingers on or in mouth, nose, or ears.
- Hand lotions should not be used if hands are in direct contact with product or product- contact surfaces. However, approved gloves may be worn over hands having non- perfumed lotion if it is compatible with work conditions and regulatory rules.
- Fingernails should be kept clean, properly trimmed, and undecorated, e.g., decals or fingernail polish. False fingernails should be prohibited for employees working in production areas.
- Personnel with minor cuts or injuries on hands should be able to protect the wound and keep it clean and free from infection. They may be allowed to work on production lines as long as the cuts are bandaged and covered with an impermeable sanitary material. Adhesive bandages should be metal-detectable in facilities where metal detectors are used.

Hair

In production areas, hair should be maintained as follows:

- Hair should be kept clean.
- Hair curlers, hair combs and bobby pins should not be allowed.
- Barrettes (at least five centimeters or two inches long), clasps, scarves, or bandannas may be worn neatly under the hair net but should not contain gemstones or decorative attachments.

Plant-supplied hair restraints should be worn in production areas in the following way:

- Hairnets and restraints should be of a design that prevents hair contamination (e.g., close mesh type and non-elastic mesh 1/8 x 1/8 in or 0.3 x 0.3 cm).
- Hairnets/restraints should completely contain the hair and cover the ears.
- If safety or bump helmets are used, they should be worn over appropriate hair restraints.

In production areas, facial hair should be maintained as follows:

- Employees should be clean-shaven or cover the exposed hair as completely as possible with a plant-supplied beard and mustache restraints.
- Sideburns should be trimmed and be no longer than the bottom of the ear.

Appendix N. The Seven Steps of Dry Sanitation

Many techniques and principles exist for cleaning food equipment, including the "7-Steps of Dry Sanitation." The seven steps represent general principles of cleaning equipment that lay the foundation of sanitation sequencing to reduce the risk of cross-contamination from sanitation activities. If these principles are used, cleaning procedures should be constructed based on the 7 Steps, which are as follows:

Step 1: Sanitation Preparation

- Purge all systems and empty all product reservoirs
- Remove all ingredients, packaging and garbage
- Gather and stage safety gear, cleaning tools and supplies, sanitation chemicals, etc.

Step 2: Secure and Disassemble Equipment

- Lock-out-tag-out (LOTO) and secure equipment and de-energize
- Remove guards and release belt tension from all conveyors
- Remove loose parts, e.g., belts, rollers, catch pans and take them for off-line cleaning
- Disassemble all other components, e.g., socks, dividers, molds
    - NEVER place food contact equipment directly on floor Step 3: Dry Clean

- Protect adjacent process if running
- Brush down and vacuum
    - Refrain from blowing equipment with air
    - DO NOT USE AIR ON ALLERGENS
- Use systematic approach, e.g., top down/one side to the other
- Sweep or vacuum up soils and remove
- Remove, empty and clean trash receptacles Step 4: Detail Cleaning

- Hand scrape surfaces (use compatible scraper and do not damage equipment)
- Detail brush down equipment and use correct brush
- Vacuum all remaining product fragments and hard to reach areas
- May use dry ice (CO_2) cleaner
- Wipe down equipment as necessary
- Clean framework and equipment legs

- Clean guards and parts off-line as necessary
- Wipe excess grease from fittings

Step 5: Post Cleaning Self-Inspection and Re-clean

- Run equipment for at least one cycle to dislodge any remaining soils
- LOTO and self-inspect equipment and area with flashlight
- Ensure all food contact surfaces are free of all residues
- Clean again as needed

Step 6: Pre-operational Inspection Reassembly

- LOTO and complete pre-operational inspection with flashlight, correct any noted deficiencies and document (should be completed by someone other than the employee(s) performing the cleaning)
- Ensure all loose parts are dry, return them to their area
- Remove sanitation outerwear and put on appropriate current Good Manufacturing Practice (cGMPs) clothing
- LOTO and reassemble equipment
- Remove lockout lock and tag Step 7: Sanitize and Final Release

- Sanitize using low-moisture EPA-registered sanitizer approved for food contact and allow for dry time, if necessary, to ensure complete drying
- Document pre-operation inspection process, sanitizing and all corrective actions
- Release to production or maintenance

Appendix O. The Seven Steps of Wet Sanitation

Many techniques and principles exist for cleaning food equipment, including the "7-Steps of Wet Sanitation". The seven steps represent general principles of cleaning equipment that lay the foundation of sanitation sequencing to reduce the risk of cross-contamination from sanitation activities. If these principles are used, cleaning procedures should be constructed based on the 7 Steps, which are as follows:

Step 1: Dry Clean and Secure

- Secure the room
    - Remove remaining ingredients and production supplies from the area
    - Ensure all water-sensitive areas (e.g., control panels) are cleaned and covered
    - Collect and remove remaining trash
    - Bring sanitation supplies to the area
    - Empty drain baskets and return as necessary
    - Lock-out-tag-out (LOTO) and lock out all equipment requiring disassembly
- Disassemble equipment
    - Set up to handle equipment (e.g., racks, stands) only twice
    - NEVER place food contact equipment directly on floor
- Dry clean
    - Remove gross soils from all equipment and floors
    - Take care with removal of allergens and Do Not Use Air
    - Work top down, side-to-side and use best tools for job

Step 2: Pre-rinse

- Remove and rinse visible gross soils (130°F) and personal protective equipment (PPE) is required
    - Gross soils should be removed to enable the chemical application in Step 3 to break down remaining films and clean the surface
- Work top down and one side to the other
- Use squeegees to clean up piles of debris
- Clean debris from drains, bring trash receptacles to drain and do not carry drain materials across production areas to the trash receptacles.

Step 3: Soap and Scour

- Foam or soap the floors, walls, and equipment – PPE required
    - Work from bottom to top
        - Foam the floors
        - Foam the walls
            - Minimum of five feet from the floor
            - Working from bottom to top
        - Foam the equipment – working from bottom to top.
    - After foam or soap is applied, allow 5–10 minutes set time (or as directed by soap supplier)
    - While soap is setting, scrub surfaces to remove fats, protein films and/or biofilms; use designated brushes (food contact, non-food contact, drains)
    - DO NOT ALLOW FOAM OR SOAP TO DRY because dry foam supports the development of biofilms
    - Clean drains prior to Step 4

Step 4: Rinse and Inspect

- Remove chemical with a flood rinse – no high pressure – PPE required
- Rinse in the order the chemical was applied (floors, walls, equipment)
    - Do not spray floors once the post-rinse begins on the equipment to reduce the risk of contamination from aerosols and splashing
- Verify by sight and feel that equipment is 100% free of soils, water beads, hazes, films, and mineral residue
    - Use a powerful flashlight Step 5: Prepare for Pre-operation

- Remove water from ceiling and overheads if applicable
- Run equipment briefly to remove any pooling water
- Verify chemical is removed - visual and pH paper
- Follow LOTO procedures when coming in contact with equipment
- Re-lubricate where appropriate
- Sanitize parts and components that are inaccessible once assembled and use PPE
- Remove sanitation outerwear and put on appropriate current Good Manufacturing Practice (cGMPs) clothing
- Assemble applicable parts Step 6: Pre-Operation Inspection

- Complete the pre-operation inspection per plant procedure and LOTO
    - Use a powerful flashlight

- Someone other than the employee(s) performing the cleaning should complete this
- Correct all deficiencies and document corrective action
- Conduct micro monitoring per the plant Clean Equipment Swab program. This is NOT the pathogen monitoring swabs. ATP swabs may also be taken at this time.
- Provide constructive feedback to employees conducting the cleaning.

Step 7: Sanitization

- Ensure no standing or pooling water before beginning
- Flood-sanitize the equipment at no rinse concentrations and use PPE
  - Follow manufacturer's label directions
  - Use like sanitizers or consult chemical manufacturer to understand the effect if two sanitizers come in contact with one another
  - Equipment may need to be run while sanitizing to ensure coverage
- Re-assemble all equipment
- Foam-sanitize the walls (five feet down minimum), then the floors.
- Foam-sanitize the floor using an appropriate sanitizer (e.g., 800 to 1000 ppm Quat sanitizer).
  - Target contact time according to product label (e.g., 10 minutes for Quaternary Ammonium (Quat)).
  - Do not rinse with water. Allow to drain and air dry.
  - Work your way out of the room
- Squeegee pooling sanitizer to drain
- Document pre-operation inspection process, sanitization and all corrective actions
- Release line to production or maintenance

Appendix P. Examples of Sanitation and Good Housekeeping Practices

Water Handling	Water should not be splashed from the floor or from unclean equipment onto cleaned equipment or processes during operation. The use of permanent or temporary partitions is advised. Water from cleaning operations in one area should be prevented from flowing into areas where product is being produced. Water used for cleaning and personal hygienic use should be potable and analyzed on a regular predetermined schedule.
Sanitary Handling of Sanitation Tools and Equipment	To prevent product contamination, certain tools and equipment should be used only for the intended purpose, dedicated to these specific uses, and handled and/or stored separately. For example, tools and equipment *used, dedicated, handled and/or stored* should be treated in the following way: • Separately for use in raw and ready-to-eat areas • According to allergen control programs • According to color code programs • Stored in clean condition and off the floor

Gaskets Handling	Gaskets should be handled and stored in a sanitary manner: • Product-contact gaskets should be cleaned or replaced at a defined frequency. • Used, damaged, or worn gaskets should be discarded to prevent inadvertent later use. • New gaskets should be washed before use. • Clean gaskets should be stored in a designated sanitary container.
Cleaning and Handling of Product Equipment	Cleaned equipment should be handled in a manner that maintains its sanitary condition and that prevents damage, including the following: • Cleaned equipment, parts, cleaning aids/tools, etc., should not be placed directly on walking surfaces. Examples of sanitary storage include placement on sanitary rubber mats designated by color for their intended use or on designated sanitary carts or racks. • Cleaned equipment should not be dragged across the floor or walking surfaces. • Clean parts should not be stored in unclean containers. • Clean parts should not be stored with dirty parts.
Using Sanitary Mats	Designated sanitary mats should be handled to maintain sanitary conditions, including: • The mats should not be stepped on. One side of the mat should be marked to distinguish between the floor contact side and the container or part contact side. An “X” or color-coding can be used for this purpose. • When not in use, mats should be stored off the floor in a manner that allows them to dry, e.g., on a hanger designed to hold mats. Rubber mats used for employee comfort at workstations should be distinguishable from sanitary mats, e.g., by color.

Good Housekeeping	General Do's and Don'ts • Avoid spillage and damage to product by careful handling. • Maintain bagged product in a neat and orderly manner. • Avoid product overhang on pallets. • Immediately seal damaged bags or drums to prevent product spillage and contamination. • Do not use contaminated ingredients should not be used. • Prohibit littering or practices that cause poor housekeeping or other unsanitary conditions. • Place all waste and refuse in trash containers, which should be labeled as "trash" or otherwise identified by specific plant programs and training. • Empty trash containers on an appropriate schedule and maintained in a sanitary condition by using liners and/or routine cleaning of the containers.
Bringing Accessories into Production Area	Radios, cameras, televisions, cell phones, laptops, backpacks, books, and magazines should not be allowed in production areas unless permitted by local policies. Other areas where these items are allowed should be defined by site-specific rules. Live plants, flowers, or animals should not be brought into the following areas: • Production • Production offices • Corridors opening directly into production

Preventing Aerosols on Finished Product and Product Contact Surfaces	Water hoses or compressed air hoses should not be used near sanitized equipment and in areas of exposed finished product to clean the floor or equipment due to the formation of aerosols. Use of high-pressure water greater than 100 psi/7 bar should be restricted to use two hours prior to sanitizing and should not be used during operation.

Appendix Q. Proper Storage

General Storage Practices	Storage of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological) and physical contamination of food, as well as against deterioration of the food and container. Finished goods, raw materials, other ingredients and rework must be held at such temperature and relative humidity, stored in a location and in a manner that protects and prevent from allergen cross- contact, contamination and/or adulteration. Product or ingredient containers should not be stored immediately adjacent to containers for waste or non-product items, e.g., cleaning compounds, laboratory solvents. Non-food product items should be stored in separate, designated areas. All items should be stored to avoid direct contact with the floor or walking surfaces, e.g., on pallets or racks. Sitting or standing on product shipping cases should not be allowed. Over-stacking product should be avoided. Product should be stacked to appropriate heights.
Ingredient Storage Practices	Ingredients should be adequately protected and stored in in the original, labeled container or in another authorized sanitary container clearly marked for the use of the specific ingredient, e.g., sanitary pails or tote bins. Ingredient identification and lot number and traceability should be maintained. Containers should be properly closed, sealed, and/or covered. When returning ingredient containers to storage, ingredients should be stored in the proper temperature environment. Bulk pre-weighted ingredients should be stored in appropriate approved containers. Follow stock rotation procedures (e.g., First-Expired, First-Out; First-In, First-Out) Ensure procedures exist to ensure all ingredients, materials, Work In Progress, rework, and finished product are utilized within their designated shelf-life.
Packaging Storage Practices	Racks provided for the storage of packaging shall be constructed of impervious material and designed from becoming a harborage for pests or vermin.

	Packaging materials, in full or partial quantities, should be adequately protected and stored in a sanitary manner: • Material should be covered to prevent contamination, for example, closures and films. • Packaging materials should not be stored directly on walking surfaces. • Maintain the identification and traceability of packaging materials.
Rework Handling and Storage	Material scheduled for rework must be identified as such. Rework product should be adequately covered and protected during breaks, lunch periods, downtime, etc., with clean plastic or other suitable material. Traceability of rework should be maintained.

Reference Material:
21 CFR 117.80(b) raw material and other ingredients 21 CFR 117.93 warehousing and distribution

SQF Code, Edition 8.1
11.6.1 Storage and Handling of Goods

Appendix R. Foreign Material Prevention Procedures: Metal Detection

(Example of a Company-Specific Program)

Note: A company-specific program or policy will be more prescriptive and may use wording such as “shall” and “must.”

POLICY:

Measures shall be taken to detect, prevent and mitigate physical foreign material contamination. This policy applies to all finished food products manufactured by or for _____. The degree of detection, prevention and mitigation shall be optimized based on the best available technology for the specific application.

An assessment of the possible foreign material contaminants shall be conducted for every existing production line and for any new line installation or modification. Once an assessment is completed and documented, the defined control measures shall be implemented to prevent or mitigate the contamination of product. Procedures shall be in place to address root cause, corrective action and disposition of any potentially contaminated raw material, ingredient, or finished product.

RESPONSIBILITY:

Corporate and Plant Operations personnel shall be responsible for adherence to this procedure. They also develop, document, implement and validate site-specific practices involved in the utilization of metal detection equipment.

Plant Maintenance personnel implements maintenance procedures to assure accurate functionality of the equipment. Specific responsibilities shall be assigned by plant

management to a designated trained production or maintenance employee(s) and shall further ensure that the responsibilities are clearly defined, documented, understood and implemented.

Plant Quality Lead personnel shall be responsible for understanding the site-specific practices and ensuring that all documents, plant procedures, work instructions, playbooks and one-point lessons are in place to assure operation and reliability of the metal detection system. The lead or designate shall be required to investigate and audit any report of deficient performance of a metal detection system in the food handling and production environment.

Employees shall be required to notify their supervisor in the event any metal detection equipment is not performing to required parameters in the food handling and production environment.

Supervisors shall be required to notify plant quality manager or designee of any deficient operation of a metal detection system and suspend line operation or implement approved alternative methods in the food handling and production environment.

Corporate Quality personnel provide assistance and support, as needed, and periodically assesses state-of-the-art capabilities of metal detection.

Corporate Engineering personnel provide technically-based recommendations regarding metal detection systems with the capabilities to reduce or eliminate metal contaminants.

DEFINITIONS:

Metal Detection System: Personnel, procedures, and equipment designed to work together to reduce or eliminate metal contaminants in finished products.
Foreign Material: An extraneous or indigenous object not intended to be part of the product formulation and is non-edible, e.g., metal, bone, plastic, rubber, glass, wood, steel, or lead shot.

Positive Reject Mechanism: A stop or reject device triggered automatically by the detection of metal. This device causes the line to stop or the product to be removed from the line when a positive is detected.

PROCEDURE:

This procedure defines the requirements for all production lines and material handling systems, which use metal detectors to control metallic foreign material contamination in the product.
This procedure defines the requirements for new or modified food handling and production and processing lines, which will use metal detectors to control metallic foreign material. It also should be used for existing systems and shall be used for new metal detection system installations.

1. Test samples shall be detected according to the supplied table in Section 7 below. Deviations from these minimum detection sizes shall be documented in writing by the facility and evaluated by Corporate Quality personnel:

a. The upper end of each metallic contaminant diameter range is considered the minimum required Metal Detection capability.
b. The “Foreign Material Matrix”, a key deliverable from the System Assessment department shall be used to develop a “realistic” up-front verification and in- production functionality testing program (e.g., the risk of detecting bones in peanut butter would be low; therefore, testing for bones would not be required).
   If the Foreign Material Matrix is unavailable, the responsible implementation team will generate the list. At a minimum, the team shall include the plant quality lead and the responsible corporate engineer.
c. Reliability of metal detection equipment should approach 100% (99.9%) for detection of each metallic contaminant greater than or equal to the specified size in Section VII “Sensitivity Requirements”.
d. An acceptable “False Reject Rate (FRR)” shall be defined by the responsible implementation team and included in the purchasing contract as a performance guarantee. Factors, e.g., line speed, package type, and product will be included in the development of the acceptable FRR. An FRR of 1/2000 to 1/20,000 is typically manageable at the plant level.

2. Metal detection equipment requirements:

   a. Each metal detector shall receive power from an isolation transformer.
   b. Metal detectors that operate near or alongside other metal detectors in the facility shall be calibrated to operate at different frequencies to reduce the effect of transmission interferences and false rejects.
   c. Rejection mechanism shall include alarm functionality. Alarms may be audio or visual.
   d. Metal detector apertures shall be twice the height of or three inches greater than the product being scanned, whichever is less.
   e. Convey speed of the product through the metal detection device should be greater than or equal to eight feet per minute or as listed in metal detector manual. The manufacturer must follow the metal detector manual to make a proper adjustment of the conveyor speed.

3. Metal detection system sanitary and safety requirements:

   a. Metal detection system must meet the sanitary design requirements (of Corporate Engineering) specifically for applications intended for wet wash-down environments and/or where product can make direct contact with system equipment.
   b. Metal detection system shall be manufactured to most current safety requirements.
   c. Designated plant safety officer to ensure all local and state regulations for metal detection systems are in compliance, e.g., certification, registration, annual audits.

4. Metal Detector System selection and factory acceptance testing:

   a. Metal Detector Systems shall be sized correctly for the product application by the equipment manufacturer and approved by a designated company expert.
   b. Minimum sensitivities for new metal detectors shall be determined by the manufacturer at the manufacturer’s works with the complete range of products intended to be run on the line. Once the sensitivity is determined, it

should not be adjusted as this can lead to false readings. Change to the sensitivities can make the metal detector provide wrong readings or inaccurate rejections.

c. Specified detection capabilities shall be verified on the production line following installation and start-up following specifications provided by the metal detector manufacturer.

5. Facility documentation shall include the following:

   a. Metal detector performance documentation obtained from testing at the manufacturer.
   b. Metal detector setup and calibration settings based on product trials at the manufacturer.
   c. Production facility setup and calibration settings after installation and start-up with actual product.
   d. Metal detection system operation and maintenance manuals.

6. Required product parameters for each Metal Detector System:

   a. Consistent product flow through the center of the metal detector aperture.
   b. Consistent product speed (at or above 8 ft/min) through the center of the metal detector aperture.
   c. Consistent product effect (background sensitivity of each unique product)
   d. In-product detection sensitivity verification (minimum contaminant detection size verified by on-line testing)

7. Metal detection systems shall have the following plant-level procedures:

   a. Metal Detection System Standard Operating Procedure (SOP).
   b. Plant quality sensitivity and verification test log procedure.
   c. Plant quality procedure for management of rejected product.
   d. Preventive maintenance and calibration procedure with interval frequency.
   e. Preventive maintenance and calibration log. (signed and dated)
   f. Operator documented training and skills testing available on file.

8. Monitoring activity:

   a. All products (packages) must pass through the center of the metal detector aperture. Scientific evidence must be provided for any exceptions.
   b. All product (packages) rejected by the metal detector shall be collected in a color-coded or labeled reject container.
   c. Before production start-up, at intervals throughout the production run and within the last hour of the day's production run a designated, trained employee verifies the metal detection system is operating properly for the product being run by doing the following:
      i. Use a test product/package to which a sanitized test sample contaminant is attached or inserted. The test product/package shall be passed through the detector three times and be successfully rejected.
      ii. Place the test sample on top of the package or insert it in the package as near to the center of the test package and metal detector aperture as possible.
      iii. Ensure the contaminated test sample package is consistently identical to the products being run on the line and at the sensitivity appropriate to the detection limits set for the line.

iv. Simplify the testing procedure (at Corporate Quality Assurance's discretion) to require testing with only a non-magnetic stainless-steel sample.

9. Corrective action:
    a. If a product (package) is rejected, the product shall be taken apart and the source of the rejection will be identified immediately, or the following will be done:
        i. Rotate the product/package 90 degrees and run the product/package through the metal detector again.
        ii. Repeat the rotation and re-inspection two additional times.
        iii. If the package passed through all three times without being rejected, the package can be considered acceptable; if it did not pass, then the package would be rejected, taken apart, and the source of the rejection identified.
    b. If a metal detection system is working improperly, the following will be done:
        i. Stop the line and repair or replace the metal detector.
        ii. Place all product produced since the last acceptable check on hold until all product can be run through a functioning metal detection system with the same or higher sensitivity.
    c. If more than 10 packages/pieces or 70 pounds of product (the number of packages/pieces diverted within the designated time to trigger corrective action may be different depending on product, process, statistical significance, etc.) are diverted during normal production within the designated time period for verification, and product is found to contain foreign material, do the following:
        i. Stop the process.
        ii. Place all affected product (packaged, unpackaged, rework) on hold back to the last acceptable lot or quality check.
        iii. Notify supervisor to determine the disposition.
        iv. Notify Director/Manager of Operations Quality (Ops Quality) or designee if metal is confirmed in product.
        v. Work with Ops Quality or designee to determine how held product will be handled. No product reclaimed from packages will be re-introduced to the product stream unless the contaminant has been identified and removed from the product material to be reclaimed.
    d. Any replaced metal detectors must be calibrated appropriately for the product being run on that line and must meet the detection sensitivity outlined in Attachment 1 and as determined above for the production line.
    e. Quality designee will document the detected and/or rejected contaminant, root cause analysis and corrective action.

10. Metal detection system verification activities:
    a. Verification of detection/rejection system effectiveness
        i. Test standards shall be used to verify detection and system effectiveness. The test standard shall be diverted by the unit.
        ii. Each facility shall have procedures for standard checks verifying units are detecting appropriately.
        iii. All verification tests shall be documented and recorded.
    b. Once per week, a plant quality designee reviews the foreign material control documents to ensure completeness and accuracy.

c. A certified outside company or trained internal maintenance person shall ensure accurate calibration according to manufacturer's specification on an annual basis.
d. Any changes or new products that may affect metal detection performance shall require the Metal Detection System to be qualified for that change or product by a metal detector operator.
e. Annually the metal detector must be calibrated by the State Department of Environmental Protection Bureau of Radiological Health.

11. Records and location:

a. Metal Detector System records and audits performed shall be filed in a designated facility location and be available upon request.
b. The Hold and Release records shall be located in a designated location and be available upon request.
c. The Corrective Action Records shall be located in a designated location and be available upon request.
d. Verification records shall be located in a designated location and be available upon request.
e. Calibration records and x-ray test standards shall be located in a designated location and be available upon request.

RELATED DOCUMENTATION:

The Food Defect Action Levels by FDA. Available at:http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/s anitationtransportation/ucm056174.htm

- FDA CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects. Available at: http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/u cm074554. htm

REVISION HISTORY:

Date	Revision	Reason	By

SENSITIVITY REQUIREMENTS:

Aperture Height	Product Classification	Sensitivity Standards
Up to 50 mm	Dry Product Wet Conductive Product Wet Non-Conductive Product	1.0 mm Diameter (Ferrous & Non) 1.5 mm Diameter (Ferrous & Non) 2.0 mm Diameter (Ferrous & Non)
50 to 125 mm	Dry Product Wet Conductive Product Wet Non-Conductive Product	1.5 mm Diameter (Ferrous & Non) 2.0 mm Diameter (Ferrous & Non) 2.5 mm Diameter (Ferrous & Non)

125 to 200 mm	Dry Product Wet Conductive Product Wet Non-Conductive Product	2.0 mm Diameter (Ferrous & Non) 2.5 mm Diameter (Ferrous & Non) 3.0 mm Diameter (Ferrous & Non)
		Add 0.5 mm to above Diameters for Stainless Steel (Optimum Conditions)

Metal detectors shall be tested to determine minimum sensitivity capabilities and detection limits with the actual product intended for use. Each metal detector found not in compliance with above noted sensitivities shall be brought to the attention of Corporate Quality for further review and action.