



The Association of Food, Beverage  
and Consumer Products Companies

July 5, 2016

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Grocery Manufacturers Association

# Industry Handbook for Safe Processing of Nuts



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and Consumer Products Companies

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## EXECUTIVE SUMMARY

Foodborne illness due to *Salmonella* contamination of low-moisture foods including nuts continues to be a significant concern for the food industry. Two U.S. outbreaks of *Salmonella enterica* serotypes Tennessee and Typhimurium infections traced to peanut butter in 2006-2007 and 2008-2009, respectively, highlighted the problem of *Salmonella* contamination. Both were extensive countrywide outbreaks, and each caused illnesses in more than 600 persons across more than 40 states. In April 2009, millions of pounds of pistachios were recalled because of concerns of *Salmonella* contamination. Pistachios were not historically linked to disease outbreaks and thus not associated with pathogen contamination. However in March 2016, 11 cases of illness were associated with [Salmonella contamination of pistachios \(FDA 2016\)](#).

On a global level, a number of outbreaks associated with low-moisture products including nuts have been documented in the last several decades. Foods implicated in these outbreaks 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) 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 is applicable to various 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 Preventive Controls for Human Foods 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. The comprehensive manual, *Industry Handbook for Safe Processing of Nuts*, includes nine chapters. It also includes 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*.

Each chapter in the Handbook is divided into a number of sections, providing detailed guidance in topics covering management responsibility, food safety plans, process validation, segregated hygiene area assessment and environmental monitoring, allergen control, other controls including prerequisite programs, and principles of equipment design. A chapter on food defense is forthcoming.

### Management Responsibility

Each firm 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. The firm should have documented procedures

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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 firms should notify their affected customer base in a timely manner.

### **Food Safety Plan**

The finalization of the Preventive Controls rules necessitates a shift from the commonly used Hazard Analysis and Critical Control Point (HACCP) system to a food safety plan that contains the elements required by FDA. The food safety plan encompasses the seven HACCP principles should be applied as appropriate to address potential biological, chemical, and physical hazards associated with peanuts and tree nuts. The seven principles include: conduct a hazard analysis; determine the critical control points (CCPs); establish critical limits; establish monitoring procedures; establish corrective actions; establish verification procedures; and establish record-keeping and documentation procedures. The food safety plan 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 food safety plan elevates the status of programs that may formally have been considered prerequisite programs if those programs are necessary to control hazards identified in the food safety plan. 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. The plan must be developed, or the development must be overseen, by the Preventive Controls Qualified Individual, 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/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 and ethylene oxide (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 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 *Salmonella*, as demonstrated by a process and product-specific validation study. Experiments should be conducted to validate the log kill in each piece of equipment for each nut type. There are two types of validation studies: 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. A new addition to the update is the inclusion of a critical factors worksheet in which to capture information related to validation.

Shellers/hullers providing raw nuts as a non-ready-to-eat ingredient may not have a CCP to eliminate *Salmonella* in their process. However, if they are FDA registered facilities they will still need to develop a food safety plan, 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**

The facility 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 that there are no allergens in a specific finished product other than those declared on the label. Additionally, processors should have controls to ensure that 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, FDA introduced the concept of a supply chain program serving as a preventive control. If a facility receives an ingredient from a supplier who 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, etc.) then the food safety plan 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 that 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**

A number of prerequisite programs should be in place 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 food safety plan. 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 all 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. While 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 our scientific understanding of *Salmonella* in dry environments has improved, and as our 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 foods that have some exposure to the environment after processing. This includes many nuts and nut products.

A facility segregated area 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 *Salmonella* Control Area (PSCA) 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 PSCA 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 *Salmonella* control programs. Routine environmental monitoring for *Salmonella* is conducted on non-product contact surfaces, with samples taken primarily in the PSCA 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 *Salmonella* findings in the plant environment.

### **Principles of Equipment Design and Installation**

In order to ensure adequate cleaning and sanitizing, equipment used for nut processing

should meet basic sanitary design principles. This section provides guidance on ten 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/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 place holder for a chapter on food defense. In May 2016 FDA finalized a rule aimed at preventing the intentional adulteration of foods. Companies with more than \$10M annual sales will need to comply with this rule and will need to have developed and implemented a food defense plan beginning in May 2019.

This Handbook has been designed as a tool chest of guidance material for all of the nut industry to utilize in developing stronger food safety measures and programs relevant to their 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/input from shellers, hullers, processors, manufacturers and other interested stakeholders who use it.

## INTRODUCTION

Today's nut industry relies on a web of inter-company relationships. Successful implementation of preventive food safety plans 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.

To aid the nut industry in the development of a preventive food safety scheme, in 2009 the Grocery Manufacturers Association (GMA), the American Peanut Council, the Peanut & Tree Nut Processors Association, the American Council for Food Safety & Quality, 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 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, GMA and PTNPA, supported by other industry associations, updated the *Industry Handbook for Safe Processing of Nuts*, and 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.

This Handbook should be considered guidance for nut processors to develop their food safety plan, 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 either 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/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 Handbook, the term nuts refer to both 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, the term “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 food safety plan to its unique operations. It should also be recognized that 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. It should be the responsibility of the food safety team in each company to apply relevant aspects of the handbook.

## 1.1 Scope

The *Industry Handbook for Safe Processing of Nuts* 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 GMP guidelines for peanut buying points and GAP 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). The growing of 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 readers should be familiar with the exemption for produce considered to be rarely consumed raw (§112.2(a)(1)). This list includes cashews, hazelnuts, peanuts, and pecans.

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

## 1.2 Management Responsibility

### 1.2.1 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 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.

### 1.2.2 Documentation Requirements

Records should be established and maintained to provide evidence of conformity to requirements and 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.

### 1.2.3 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 their 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 their affected customers of any voluntary or involuntary retrieval of their product.

### 1.2.4 Communications with Customers

Communication in the supply chain is critical when events occur that could impact food safety. Processors should notify their affected customer base immediately, but in no event more 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 8, 2009, FDA opened the Reportable Food Registry electronic portal and requires 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 FDA (more information available at [Reportable Food Registry](#) (FDA 2016)).

## FOOD SAFETY PLAN

### 2.1 Introduction to Food Safety Plans

Facilities that manufacture, process, pack, or hold human food are required to register with FDA and are covered under many of the new rules related to the Food Safety Modernization Act (FSMA). FSMA impacts both 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 US Food and Drug Administration (FDA) on 17 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. Very similar requirements apply to the [producers of animal food](#) (FDA 2015).

Like other registered facilities, nut facilities subject to the Preventive Controls rule must have a written food safety plan. While there are some exemptions and modifications, 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 Hazard Analysis and Critical Control Point (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 food safety plan, but must update and expand upon these plans to meet the provisions set forth in the new regulation.

Within the Preventive Controls rules, updated cGMPs include protection against allergen cross-contact and requirements for handling 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 a food safety plan. This chapter will outline the key requirements of the regulation, and will discuss how to adapt a HACCP plan to build a 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 a food safety plan, which is prepared by a preventive controls qualified individual (discussed later in this chapter). The company’s food safety plan must consist of:

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 a food safety plan may also be part of HACCP plans and will be described in more detail later in this section. Like in HACCP, companies required to develop a food safety plan must conduct a hazard analysis to identify and evaluate known or reasonably foreseeable biological, chemical (including radiological) and physical hazards to determine whether there are any hazards requiring 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 (SMOPed).

These preventive controls include, as appropriate based on the hazard analysis:

1. Process controls (essentially HACCP critical control points, as discussed later in this section)
2. Food allergen controls
3. Sanitation controls
4. Supply-chain program
5. Recall plan (not truly preventive, but a requirement in a FSP)
6. Other controls as determined to be appropriate by the preventive controls qualified individual

When a hazard is controlled by another entity later in the distribution chain (e.g., commercial customer), the facility must disclose that 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 of 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 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):

- 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.

Corrective action procedures, which outline the steps to be taken in the event preventive controls are not properly implemented, are required. 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.

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

Reanalysis of the food safety plan 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. Reanalysis 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 Hazard Analysis and Critical Control Point (HACCP) system. Philosophically, HACCP also involves a proactive, preventive approach to control food safety hazards. HACCP provides a mechanism to prevent, eliminate, or reduce to an acceptable level, food safety risks. When utilizing 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 HACCP and the FSP plan is that HACCP focuses on CCPs whereas a 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 US by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1998) and internationally by the [Codex Alimentarius Commission](#) (CAC, 2003). According to NACMCF (1998), HACCP includes the following seven principles:

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

Principle 1 involves identifying potential food safety hazards associated with all process steps within an operation and determining what significant food safety hazards exist, i.e., hazards that are reasonably likely to cause significant illness or injury without their control. After the hazard analysis, principle 2 involves identifying critical control points 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) (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 particular CCP is not under control. Principle 6 establishes verification procedures (including supplementary tests, where appropriate) to ensure that 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 Preventive Controls Qualified Individual (PCQI) and assembling the food safety team.

Processors may choose to build upon their HACCP plan to develop the food safety plan that meets the FSMA 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 preventive controls qualified individual (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 FDA or is otherwise qualified through job experience to develop and apply a food safety system. Responsibilities of a preventive controls qualified individual include:

- Preparation of the food safety plan
- Validation of preventive controls
- Review of records
- Reanalysis

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 food safety plan should be included as part of the hazard analysis team. It is helpful for each facility to have a preventive controls and/or HACCP team leader who can take responsibility for the maintenance and upkeep of the plan documents.

In HACCP it is recommend the team 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. It is critical that the hazard analysis be scientifically based and well documented. It is the foundation upon which the food safety system is built. 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), or physical agent that has 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 food safety plans.

Although not required by FDA, it is recommended that the food safety team 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 information about:

- Raw materials and ingredients, processing aids, rework, water, compressed gasses, 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

There are several key differences in a HACCP hazard analysis and a FSP hazard analysis. Under a FSP, a facility producing ready-to-eat 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*. 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. It is helpful to review plant layout to assess each area or room in the processing facility to determine the potential for microbiological cross-contamination, as well as the potential for allergen cross-contact between areas. Examples of potential hazards that a nut facility may consider in a hazard analysis include:

Biological:

*Salmonella*, *L. monocytogenes* and enteric pathogens from incoming raw nuts/ingredients (e.g., peanuts, almonds, spices, dairy)

*Salmonella* and *L. monocytogenes* due to environmental re-contamination

Enteric pathogens from handling

*Staphylococcus aureus* growth from time/temperature abuse

*Salmonella* contamination from dust

*Salmonella* and *L. monocytogenes* re-contamination from condensate

Pathogen growth during storage (if applicable)

Chemical:

Aflatoxin

Undeclared allergen(s) due to incorrect label application (e.g., walnut label on peanut product)

Undeclared allergen(s) due to rework addition (e.g., peanut fines added to almond product)

Physical:

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 or debris from harvesting operations

### *Salmonella*

Although there is increasing recognition of the possible presence of *L. monocytogenes* 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 1 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), or non-thermal treatment (e.g., chemical processing using propylene oxide (not approved for peanuts) or ethylene oxide (for black walnuts only)). The other major control measure is to implement a program to prevent post-lethality recontamination prior to packaging (GMA, 2009).

Processors of a ready-to-eat nut products may or may not have a PC/CCP to eliminate *Salmonella* in their process. If the processor uses a nut ingredient without a kill step in their product (i.e., the nut ingredient is considered a "sensitive ingredient"), their 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.

Shellers/hullers 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 customer in writing and on the product label that the nuts have not been processed to control *Salmonella* and obtain annual written assurance from the customer that the hazard will be controlled, including identification of the procedures used.

COAs can be used as part of a facilities supplier verification program, as well as to understand the microbial load that is entering a facility in order 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 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 food safety plan 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 prerequisite program with zoning and other controls. *Salmonella* contamination may occur at very low levels, 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, 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 very complex subject, and the information included here should not be considered as comprehensive. During the development of a food safety plan, 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).

### *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 are capable of causing 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 Flow Chart (Diagram 1) to help determine whether or not 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

### 2.2.3 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 cGMP/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 would 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 Good Agricultural Practices (GAPs), and shellers/hullers, using cGMPs and prerequisite programs, prior to providing the product for manufacturing or handling a ready-to-eat product. Certificates of analysis (COAs) may be requested for pesticide residue and aflatoxin results on incoming lots.

Severity should be determined taking into consideration 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:

- Effectiveness of prerequisite programs (PP)
  - For a 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 a 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

In the determination of whether a hazard is reasonably foreseeable, the team may consider likelihood of 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 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:

- 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

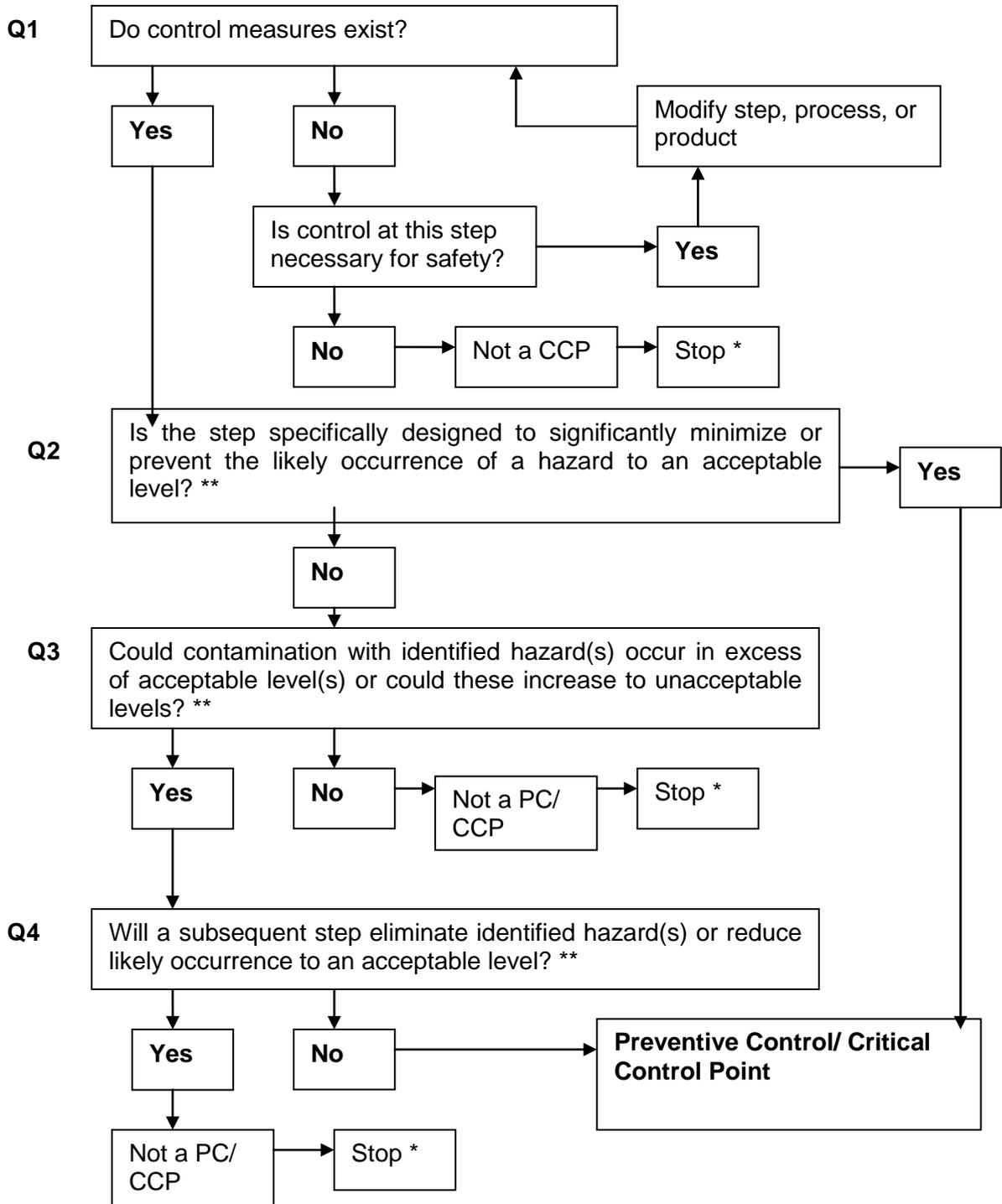
Further elaboration of using the two-stage (i.e., hazard identification and hazard evaluation) approach to conduct a hazard analysis can be found in published technical papers (Bernard et al., 2006; Bernard and Scott, 2007; Scott and Chen, 2009).

## **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). FDA is likely developing a guidance document on this topic to support implementation of the preventive controls rule. The team may use a decision tree, such as the adapted Codex Decision tree 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 CCPs (CODEX DECISION TREE, ADAPTED)

(Answer questions in sequence)



\* 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.

## 2.2.4 CRITICAL LIMITS, PARAMETERS AND VALIDATION

All facilities supplying processed tree nuts, peanuts, and/or associated products (e.g., 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 critical control point (CCP) or other preventive control.

As described in Chapter 3, the effectiveness of specific CCPs (process preventive controls) 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, such as a metal detector is “on and functioning”, or a screen is “present and intact”, rather than a numerical value.

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, FDA included this term “parameter” in the regulation.

## 2.5 Monitoring

Once the critical limits or parameters are set, it is important to show, through monitoring, that they are actually 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 CCPs. Monitoring can also be accomplished through observation that activities are occurring (such as sanitation). All monitoring activities must be documented and reviewed (see verification).

## 2.5 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 7 working days, although many facilities conduct a review of records on a daily basis. 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

## 2.6 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 there is no food safety risk, for example, when a pre-op inspection shows that a production line is not clean. 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.

In the event that a deviation is noted during processing, post-processing, or after packaging, all 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 of these activities must be documented. Hold/Release documentation should be available.

## 2.7 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, traceability records. While industry voluntarily practiced HACCP for many years, the Preventive Controls Rules substantially increase the number of required practices, and with them, record requirements. FDA will have access to these records upon verbal request as part of a routine inspection. It is critical that plant personnel understand that these records will be scrutinized by inspectors. They must be legible, accurate, and accessible.

## 2.8 HACCP and Food Safety Plan Administration

A completed food safety plan should be inclusive of a facilities 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
- Critical Control Point (CCP) Documentation
- Identification of other Preventive Controls (allergen, supplier, sanitation)
- Monitoring, Corrective and Verification Plans
- Validation for Process Controls/CCPs
- Recall Plan
- Food Safety Plan Approval

There is no regulatory requirement for 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. FDA has stated that records related to the food safety plan be maintained for 2 years.

## 2.9 Food Safety Plan Reanalysis Procedures

Verification of the food safety plan ensures that 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 whether 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.

### 2.9.1 When to Reanalyze the Plan

- Whenever there is a significant change in the process.
- Whenever there is a systematic or recurring product safety issue, or industry recall of similar product
- 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 CCP deviation records
- Review test results from sample monitoring (e.g., analytical and/or microbiological, if applicable)
- Review industry recalls/withdrawals/import alerts for the product category
- Determine if there are any new or emerging hazards
- 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 CCP and other preventive controls to determine:

- Are all hazards that need to be addressed in the food safety plan addressed?
- If addressed by CCP, is the CCP the right one?
  - The modified Codex Decision Tree may be used (refer to Section 2.2)

- If there is no CCP, 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 check list (see an example below from the National Conference on Interstate Milk Shipments (NCIMS) to identify new food safety information. Note that this organization uses the term “validation” rather than reanalysis, and references HACCP rather than a food safety plan.
- New information, if identified, should be evaluated by the team and documented.
- If needed, the plant HACCP coordinator/ preventive controls qualified individual should update the food safety plan, as determined by the food safety team.

Whenever there are changes to product, package or process, 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**

SUBJECT <b>HACCP Validation Checklist</b> PLANT NAME ADDRESS	ISSUE DATE	PRODUCT
	SUPERSEDES	PAGE <b>x of xx</b>

**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:

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

<b>3. Evaluate adequacy of CCPs, critical limits, monitoring, corrective action, CCP verification, and record keeping procedures. Review current CCP documentation.</b>					
Do the CCPs control the hazards?	<input type="checkbox"/>	<input type="checkbox"/>			
Are the CCP critical limits adequate?	<input type="checkbox"/>	<input type="checkbox"/>			
Do monitoring methods and frequency demonstrate control?	<input type="checkbox"/>	<input type="checkbox"/>			
Do corrective actions properly address affected product and correct deviations?	<input type="checkbox"/>	<input type="checkbox"/>			
Does validation include review of consumer complaints?	<input type="checkbox"/>	<input type="checkbox"/>			
Other, e.g., Prerequisite Programs or procedures may affect the hazard analysis	<input type="checkbox"/>	<input type="checkbox"/>			

## 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 GMPs, zoning requirements, and adherence to validated nut processing requirements. 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. Thermal and chemical processing (e.g., roasting, blanching, and PPO) can be effective control mechanisms. Processors should defer to legal requirements for the appropriate log reduction for *Salmonella* (e.g. 7 CFR Part 981.442 – Almonds Grown in California). The appropriate log-reduction for *Salmonella* in a nut commodity should be determined by studies such as a risk assessment. For example, the Almond Board of California has established a minimum 4-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).

To be effective, a treatment process must consistently deliver an appropriate lethality - typically 4 logs or greater of the target organism (e.g. *Salmonella*), as demonstrated by a process-specific and product-specific validation study. FDA currently suggests a minimum 5-log reduction for peanuts and pistachios, unless data are available to support that less than a 5-log reduction is adequate (FDA 2009a and 2009b). In 2013 FDA requested comments, scientific data and information that may help them in performing a quantitative assessment of the risk of human salmonellosis associated with the consumption of tree nuts. [Risk assessment](#) work associated with the consumption of tree nuts is currently underway by FDA (2013).

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 they types of documents described in this chapter.

### 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. 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, known resistance (thermal/chemical) compared to *Salmonella*, and 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 types of 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. 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
	Inoculation Challenge Study	Measurement of Physical Delivery of Process		
*1 Oil Roasting		X	Demonstrate that the nut is exposed to a minimum required oil temperature for a specific amount of time (e.g. 260F for 2 minutes for almond 5-log process)	Throughput (residence time, i.e., belt/chain speed; bed depth,); 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 2 minutes for almond 5-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 ventilation tempering, aeration cycles

\*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.

A 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 there to be a reliable correlation. Theoretically, surrogates of equal or greater resistance compared to the target pathogen can be used as long as 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 in order to: 1. Identify 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 device to validate that 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. Once cold spots are identified and addressed, specific locations or lanes for placement of micro samples can be determined. It is also beneficial to conduct time/temperature profiling simultaneously while running inoculated samples in order to determine specific temperature profiles during the run.

Processing units must be tested under “worst case” conditions, e.g., highest bed height, fastest belt speed, lowest zone temperatures, coldest location, coldest possible initial product temperature, maximum load per batch, lowest concentration 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 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. 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 in order 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, e.g., the temperature sensor has to run three times through the equipment. It is desirable to do the three test runs on different days using three different lots of product in order to account for the potential variations between production runs as well as beginning and ending processing conditions. Once a process is validated, periodic work such as time/temperature profiling may be conducted in order to verify that the scheduled process is being achieved. Anytime there are changes to the process/equipment (e.g. new air source, change in throughput, new heater, change in airflow, etc.), or new products or formulations, re-validation 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 for facilities that are 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<sup>3</sup>), 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**

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 equivalent device. Before the trials, the uniformity of the temperature sensors should be checked at room temperature and 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.

### 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. It is important to establish the correlation between the surrogate and *Salmonella* in the nut under validation, if such data are not already available. 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., roaster, settings are equilibrated, 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 a data-tracking unit. Record the temperature of the nuts and heating environment throughout the entire run, and the time through the system, e.g., roaster. Use multiple leads in order to track temperature variations within a run, attaching each lead to the outside surface of the nuts. In a belt dry roaster, vary the location of the unit for each run in order to monitor the right, left, and center of the roaster, attaching new nuts to the leads for each run. Ensure the leads are placed within the center (top to bottom) of the bed. A temperature tracking unit is usually sealed in an insulated box with the thermocouple leads exposed outside the insulation. It is recommended to place the insulated unit on the belt so that it can be easily retrieved at the end of the roaster. In a batch roaster, vary the location of the leads to account for circulation of air/oil. For a drum roaster, depending on the configuration of the drum and sturdiness of the data tracking unit, the thermocouples should reflect the temperature of the nuts, not the air.

For drum roasters and belt roasters with baffles, for example, the configuration of the drum or baffles may preclude the use of thermocouples and warrant a surrogate inoculation study. When using a surrogate, it is necessary to ensure that nuts inoculated with the surrogate are exposed to cold spots and other worst case conditions as described above. Rotary / drum roasters are particularly challenging to validate given that they primarily use product endpoint temperature as the primary process control and that there is variation from batch to batch in the time it takes to reach the endpoint. Validation objectives for rotary/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 (both 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 should 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, as with 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 and 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. 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. Almond Board of California 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.

Validation parameters that should be evaluated for all nut types are:

- the selection of an appropriate surrogate for a specific nut type and process,
- the optimal culture preparation and appropriate inoculation procedure for *Salmonella* and the surrogate on the tree nuts/peanuts, especially in shell nuts,
- the most effective method for recovering the surrogate from the processed nuts, and

- 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 (Example Table 3.2, not to be used for processing critical limits. Processors must determine heat resistance parameters for their own Critical Control Points).

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	100		47F	Max temp of process is 300F using aluminum almond or equivalent device Almond Board of California Dry roasting validation Guidelines (ABC, 2007)
	265	50			
	280	23			
	295	12			
	300	9			
OIL ROASTING Almonds	260	1.6	2.0	NA	ABC Guidelines; Harris and Du (2005)
BLANCHING Almonds	190	1.6	2.0		Almond Board of California (ABC, 2007b)
	185	1.99	2.49		
	180	2.47	3.09		

To calculate specific time/temperature parameters for a specific roaster when actual temperatures applied are different than 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 processor 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 and z values were established. Equivalent time at temperature should not be applied outside of this range. When it is necessary to make extrapolation 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 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. In addition, a summary sheet should be prepared, outlining the critical factors necessary for ensuring that the process is met. The critical factors summary sheet should be visibly by 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<sup>3</sup>, off gassing / tempering

Amount of product treated per chamber

Shutdown/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/ 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

### ***Establishment of Worst Case Conditions - Time (Continuous Process)***

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

### ***Establishment of Worst Case Conditions – Temperature***

Describe method and results to determine appropriate location of temperature probes including identifying temperature profile across the bed/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, as 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 moisture will vary from season to season, then the validation study must be conducted at the lowest moisture possible. If it is determined that moisture is 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 worst case for any other parameters identified as necessary for monitoring. For example:

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

### ***Design/Monitoring Validation***

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

### ***Corrective Action***

Describe corrective action design features (e.g., alarm, automated divert, or shutdown) and the parameters that trigger them.

### ***Operational Aspects of Validation Report for New Equipment or Nut Type***

Describe assessment of start-up process to demonstrate at least a 4-log reduction (at least 5-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 records monitoring start-up conditions are available.

### ***Monitoring Records***

Attach examples (completed) of monitoring records (log sheets) and calculated log reduction to demonstrate actual practices are in line with design assessment.

### ***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 results of the inoculation trials and cross-reference the full trial report. Include all recommendations generated from the validation study.

## ALLERGEN PREVENTIVE CONTROLS

### 4.1 Allergen Management

The US Food and Drug Administration (FDA) identifies eight major food allergens under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (FDA, 2006):

1. Milk
2. Eggs
3. Fish (e.g., bass, flounder, cod)
4. Crustacean shellfish (e.g. crab, lobster, shrimp)
5. Tree nuts
  - a. Almonds
  - b. Beech nut
  - c. Brazil nut
  - d. Butternut
  - e. Cashew
  - f. Chestnut (Chinese, American, European, Seguin)
  - g. Chinquapin
  - h. Coconut
  - i. Filbert/hazelnut
  - j. Gingko nut
  - k. Hickory nut
  - l. Lichee nut
  - m. Macadamia nut/Bush nut
  - n. Pecan
  - o. Pine nut/Pinon nut
  - p. Pili nut
  - q. Pistachio
  - r. Shea nut
  - s. Walnut (English, Persian, Black, Japanese, California), Heartnut, Butternut
6. Peanuts
7. Wheat
8. Soybeans

These are the food identified by FDA as food allergens; however, other countries may include additional foods. 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  $\geq 10$  ppm. It is the responsibility of the company to be familiar with the regulations for the countries in which business is being conducted, so that the appropriate allergens are included on the label.

FDA's Food Safety Modernization Act (FSMA) sets requirements for a written food safety plan to include preventive controls, which includes allergens. Facilities must 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.

These measures are required to ensure that hazards requiring a preventive control will be eliminated, minimized or prevented. The final rule provides flexibility in the steps needed to ensure that preventive controls are effective and to correct problems that may arise. The FSMA final rule requires preventive controls to include monitoring, corrective actions and verification as appropriate to the food, facility, nature of the preventive control, and the role of that control in the facility's food safety system. Monitoring is designed to provide assurance that preventive controls are consistently performed. Corrective actions are taken to timely identify and correct a minor, isolated problem that occurs during food production. Corrective actions must be documented with records. Verification activities are required to ensure that preventive controls are consistently and effectively implemented. They include reviewing records to verify that monitoring and corrective actions (if necessary) are being conducted. The rule does not require that allergen controls be validated; however some facilities choose to do this.

A robust, thorough, and comprehensive allergen management program has the following main components: avoiding allergens, having allergen preventive 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**

While some allergens are unavoidable because the allergen is a key component of the product (e.g., peanut allergen in a salted nut mix) other allergens can be avoided. Where possible, allergens should be "designed out" of the product. This may be achieved by avoiding allergens in initial formulations or reformulation to remove allergenic ingredients. It is recommended that allergenic ingredients should only be added to formulations where they contribute to the taste or functionality of the product, and not to avoid clean-up. As an example, do not add peanuts to a tree nut mix for the purpose of avoiding an allergen clean-up.

#### **4.1.2 Supplier Control Programs**

Good management of suppliers can also aid in managing the risk of unintended allergens entering the nut manufacturing facility and assure correct handling and storage of ingredients containing allergens. As part of an approved supplier program, the nut processor should review their supplier's allergen control programs to assure that the potential for unlabeled allergens is minimized. This requires each supplier to have their own established policies and procedures, including an Allergen Control Plan, to control allergens at each of their manufacturing locations. Suppliers must disclose all allergens in their formulations (e.g., spice blends and mixes) and meet all regulatory requirements for 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 any changes.

#### **4.1.3 Allergen Controls**

Nut processors must have an allergen control program to ensure that there are no allergens in a specific finished product other than those declared on the label. For example, even though they may be handled in the same facility, packaged cashews must not have traces of walnuts in them. Additionally, processors must have controls to ensure that 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 brought together, make up an allergen control program. These strategies represent a variety of ways to help manage allergens and reduce risk to the product and consumers.

**4.1.3.1 Identification and Segregation of Allergens** One component to managing allergens is keeping allergenic ingredients and products separate from other ingredients and products as appropriate. The segregation of allergens begins when 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 following practices can be used to manage the segregation of allergens:

**4.1.3.1.1 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 clear manner that is visible to any employee handling the ingredient (e.g., a flavoring that contains 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. As well, 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.

**4.1.3.1.2 Process and Product Design**

- a. Run allergen-containing products on lines or equipment dedicated to that specific allergen profile, whenever possible, to reduce the risk of allergen cross-contact.
- b. Consider erecting a physical barrier, for lines in close proximity, to reduce the risk of allergen cross-contact (e.g., walls, curtains, partitions).
- c. If it is not possible to run allergenic product on dedicated equipment, then the equipment should be thoroughly cleaned and inspected prior to processing product that does not contain the same allergen profile. While it is not a regulatory requirement in Preventive Controls for Human Food rule, it is common practice to validate the effectiveness of a sanitation protocol. See the Sanitation section (Section 3.6 above) for further details.
- d. When adding an allergenic ingredient, add it as late in the process as possible to limit the amount of shared equipment that comes in contact with the allergen.

**4.1.3.1.3 Receiving**

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

#### **4.1.3.1.4 Storage**

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

#### **4.1.3.1.5 Traffic Patterns of People and Materials**

- Limit traffic patterns of people (all employees, including maintenance and management, contractors, visitors, etc.), 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.
- As much as 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 identified manner. Example: different colored outer clothing or different colored hair nets. If this is not practical, establish procedures for personnel to minimize the potential for allergen cross-contact in higher risk areas. Example: wash hands and change gloves between allergen and non-allergen lines; change of outer clothing.
- Manage employees' outer clothing to avoid allergen cross-contact in common areas within the plant (e.g., cafeterias, break rooms, locker rooms). Example: dedicated outer clothing (e.g., lab coat, smock) that remains in the processing room during production or the "brush down" of the employee 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 product to avoid the 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.
- If a process reuses materials (e.g., cleaning solutions, cooking or cooling water, oils, ) that contain allergens and/or containers that have been in contact with allergens, careful consideration must be made before reusing these materials and/or containers. If materials are reused, evaluate to determine that there is no cross-contact for non-allergen products.

#### **4.1.3.1.6 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 the dedicated tool, for use with a particular allergen, through color coding or another easily identifiable system.
- Store the dedicated tool separately from other non-allergen use tools and tools used for a different allergen.

- If the tool cannot be dedicated to a particular allergen or allergen profile, then thoroughly clean and inspect the tool prior to the tool's 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				
F R O M	Product (Allergens Present)	Product #1 (wheat)	Product #2 (wheat)	Product #3 (None)	Product #4 (wheat, soy, almond)	Product #5 (wheat, whey)
	Product #1 (wheat)		Non-allergen clean	Allergen clean (wheat)	Non-allergen clean	Non-allergen clean
	Product #2 (wheat)	Non-allergen clean		Allergen clean (wheat)	Non-allergen clean	Non-allergen clean
	Product #3 (None)	Non-allergen clean	Non-allergen clean		Non-allergen clean	Non-allergen clean
	Product #4 (wheat, soy, almond)	Allergen clean (soy, almond)	Allergen clean (soy, almond)	Allergen clean (wheat, soy, almond)		Allergen clean (soy, almond)
	Product #5 (wheat, whey)	Allergen clean (whey)	Allergen clean (whey)	Allergen clean (wheat, whey)	Allergen clean (whey)	

#### 4.1.3.1.7 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 also 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. Example: a scheduled production run includes 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.
- An Allergen Matrix may be created to aid employees and production scheduling. This matrix will identify which products are being run on a particular 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/or 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.

### **4.1.3.2 Control of Rework and Work In Process (WIP)**

#### **4.1.3.2.1 Practices**

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

- A common practice is for processors to only use rework for “like-into-like” applications, as soon as possible, preferably on the same day or shift.
- In the event that 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 not feasible, the containers and lids should be thoroughly washed using an effective cleaning method before being reused. If at all possible, containers that hold allergen-containing materials should be movable without the use of equipment (e.g., totes on wheels)
- In order 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 thereof. If labels are used, the following information should, at a minimum, include:
  - Name of the rework, or WIP material
  - Name of the allergen
  - Date/time of manufacture
  - Date/time put into storage
  - Date/time for using rework/WIP, where appropriate
- Whenever rework or WIP is generated, its storage and re-entry into the process stream should be tightly controlled in order 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 not feasible, 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, such as fork lifts, is unavoidable, care should be taken to prevent the spread of allergen-containing debris to other parts of the plant.
- If the origin of ingredients of rework cannot be determined, it 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.

#### **4.1.3.2.2 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 also include instructions on how to handle re-entry equipment before, during, and after add-back, including inspection and cleaning procedures.

#### **4.1.3.2.3 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. While specific systems often differ from plant to plant, certain basic records can help keep track of the movement of these materials. Here are some examples of helpful techniques:

- At the re-entry point, the pre-authorized production batch sheet should be reconciled with the information on the staged containers. A note of this reconciliation step should be entered onto the batch sheet, along with the initials of the operator and the time of the activity.
- During add-back, the following information may be entered on the batch sheet:
  - Identity of the allergen
  - Amount of rework/WIP material added
  - Time of addition
  - Batch number
  - Production line number
- Verification activities may be documented to assure 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.
- Records of added rework should be reconciled with other production records to make sure that all the materials are accounted for.

#### **4.1.3.3 Sanitary Design**

The value of well-designed equipment should not be underestimated. Equipment that has been built to sanitary design principles is easier and faster to clean, can be cleaned more effectively, requires fewer employees to clean, and better meets GMP/regulatory guidelines. In general, there should be no “dead spots” that allow accumulation of food or ingredients (no hollow rollers, no holes in welds, equipment that drains, etc.). Furthermore, processing lines and equipment should be positioned for easy access to clean and inspect. There are ten principles that could be used in sanitary design of equipment. These principles apply to allergen equipment as well as non-allergen equipment. See Chapter 4, Principles of Equipment Design, for more information.

#### **4.1.3.4 Product Changeovers**

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 order to prevent allergen cross-contact issues. Cleaning methods should take into consideration the form and amount of the 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. All 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 very similar to flushing changeovers. The

difference is that a flush uses a flushing agent (e.g., sugar or salt) while a push through is using the flowing product. A flush-through 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 not readily feasible in all operations. These methods should be used only after careful consideration and the changeover procedure may be considered a CCP in HACCP or a preventive control in a firm's food safety plan.

#### **4.1.3.5 Sanitation Expectations, Responsibilities, and Procedures**

Effective cleaning procedures are essential in order 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.

##### **4.1.3.5.1 Allergen 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.
- Clean all food contact surfaces and niches of any size for accumulation, debris, particulates, or pieces of product.
- Various 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 wash, and/or wipe down, as needed.
- All product zone surfaces should, at minimum, be visibly clean of any accumulation, debris, particulates, or individual pieces of product.
- 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 the 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. 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 build-up is a known concern.
- 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 otherwise be a dry system as it may create a microbiological hazard.

##### **4.1.3.5.2 Flushing Changeover Procedures**

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

- The line is flushed with non-allergen containing product to remove residual allergens. Flushing agents (e.g. sugar, salt, etc.) that can be used should be compatible with the products and not create an allergen cross-contact or labeling issue.
- The flushing process can be verified 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.
- Exactly how much product needs to be flushed through and/or how many flushes are required to achieve the level of cleanliness necessary can be determined by quantitative analyses of the flushing agent for the target allergen.
- The finding of allergenic material in the flushing agent or finished product would not be entirely unexpected. The appropriate corrective action could be to increase the number of flushes or quantity of the flushes to reduce allergenic residues below detectable limits.

#### **4.1.3.5.2 Flow-through/Push-through Changeover Procedures**

- Empty the processing system, remove hand-weighed ingredients, recover and account for materials (e.g. ingredients, WIP, rework, etc.) and any previous labels or pre-printed packaging materials.
- Labeling programs should be in place to avoid misbranding.
- Exactly how much product needs to be pushed through to achieve the level of cleanliness necessary can be determined by quantitative analyses of the new product as it is pushed through for the target allergen.
- The finding of allergenic material in the product would not be entirely unexpected. The appropriate corrective action could be to increase the amount of product pushed through to reduce allergenic residues below detectable limits.
- Quality specifications could be used to determine that 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.

#### **4.1.3.6 Validation of Allergen Cleaning**

Validation is the process used to assure that defined sanitation procedures, when properly followed, are adequate to remove allergens to a visibly clean or analytically tested standard. Once a cleaning procedure has been validated for a process or packaging system, ongoing verification may be needed to ensure that cleaning programs and procedures have been executed according to the validated protocol. An Allergen Validation Checklist that will soon be available as a resource at [Grocery Manufacturers Associations website](#) has additional information regarding validation. Note that the Preventive Controls rule does not require validation of allergen cleaning.

##### **4.1.3.6.1 Validation Procedure**

- Draft an initial 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 the method(s) used to determine the results were successful; such as allergen testing or inspection to ensure a visually clean system. See the [GMA SSOP Checklist](#).
- The SSOP could include a “critical equipment list” that defines hard-to-clean areas and those pieces of equipment requiring disassembly.
- Perform a production run involving the allergen.
- Conduct the cleaning process exactly 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-op checklist is helpful.

- Ensure the “visibly clean” standard is achieved. If the visible clean standard has been achieved, consider performing any applicable allergen analytical testing as appropriate. See 3.7.3.6.1.1 Analytical Allergen Testing for Validation for more information.
- If visibly clean or acceptable allergen analytical results are not attained:
  - Revise plant SSOPs.
  - Re-clean the line.
  - Re-inspect the line.
- Continue this cycle until acceptable results have been obtained.
- If allergens cannot be effectively removed after repeated attempts, alternate strategies, such as product/ingredient reformulation, redesign of equipment, or dedicated equipment/lines options could be considered.
- Records should document the approved and validated SSOP cleaning procedure. Validation documents/records (e.g. procedures, checklists) should be retained at the facility.
- Following SSOP validation, responsibility reverts to the existing line inspector(s) for the ongoing allergen cleaning and verification process.
- Consider re-validation when there are changes in: formula, allergen or allergen form, equipment, line configuration, product, process, significant personnel changes or sanitation procedures.

#### **4.1.3.7 Analytical Allergen Testing for Validation**

While many foods are classified as allergens, reliable analytical tests for both finished products and equipment are available for certain allergens. It is important that the analytical procedures/method be validated for the product type/matrix prior to use for allergen validation.

When no tests are available, the validation process can assure cleaning adequacy through careful visual examination of the processing equipment. Product or rinsate sampling is not required. There is no need to hold the next finished product since validation is made on the basis of visibly clean only and failed inspections are followed by another sanitation cycle(s) until a visibly clean system is attained.

When reliable allergen test kits are available, the allergen validation testing may include the following:

- After completion of the SSOP and attainment of the visual clean standard, some of the following samples could be analyzed using allergen test kits. Obtaining acceptable results from this testing serves to further validate the effectiveness of the SSOP. Samples may include:
  - Equipment swabs, including clean out of place equipment, tools, and utensils
  - First product after start-up
  - Intermediate or in-process product
  - Rinsate, if applicable
- When conducting product-based sampling, it can be difficult to collect a statistically significant sample, so equipment swabbing may provide another acceptable testing option.
- Equipment swabs should represent all equipment used in the process. If multiple lines are used, sample all lines.
- Product testing should be indicative of all the equipment used in the process.
- Sample 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 products being analytically tested should be placed on hold until 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, a determination of action steps must be made by management.

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 nonallergenic, 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.

#### **4.1.3.8 Monitoring and Verification of Allergen Cleaning**

Monitoring is the process used to assure that the sanitation procedures are accurately being followed on an ongoing basis. Monitoring should be completed by whatever method has been designed into the validated program, either visually clean or using allergen analytical test methods. This should occur at every allergen changeover.

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

The monitoring activities for allergens should use the checklist developed during validation to assure that all the 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 firms perform the monitoring by using a person that is not associated with the SSOP procedure. Monitoring records must be reviewed (or overseen by) by a preventive controls qualified individual as a part of verification that the line was cleaned appropriately and cleaned according to the sanitation procedure. This record should be retained according to the facility's record retention program and to be compliant with preventive controls requirements if an allergen control is determined to be necessary to control the hazard.

#### **4.1.4 Allergen Advisory Statements**

Allergen advisory statements on the label are a voluntary warning to consumers (e.g. may contain milk). Its goal is to indicate a product not intended to contain a specific allergen(s), but may sporadically contain low levels of the allergen due to unintentional and unavoidable cross-contact in the manufacturing process, even after implementing the appropriate allergen controls in the food safety plan. FDA advises that advisory statements should not be used in lieu of GMPs because adhering to GMPs 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 is being considered, the manufacturer should conduct a risk assessment to assess its operational practices and evaluate the hazard that a food allergen may come in contact with a food where its presence is not intended. It is recommended that manufacturers 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.

#### **4.1.5 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 in place to assure that labels are correctly and consistently applied to materials. Controls should assure that labels meet all regulatory requirements, materials' formula and customer specifications. Two important aspects of label management include controls for design and controls for inventory and label application.

#### **4.1.5.1 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 use of written orders, not verbal, for art work and labeling copy.
- A revision control program to assure that each revision is separately identified for easy management and separation. This can assist in the removal of old label versions from inventory.
- Prior to printing labels, labels are reviewed for regulatory compliance, including declaration of allergens.
- The use of commonly understood terms in consumer friendly language for all allergenic ingredient declarations (e.g., milk, not whey or casein) – a regulatory requirement under Food Allergen Labeling and Consumer Protection Act (FALCPA).
- Methods to confirm accurate listing of product ingredients in the appropriate order.
- Design and copy proofreading.
- Written approval of label and package proofs.
- Identity coding (e.g. color and/or numerical) of printed labels and packages.
- Risk-based decision tree for allergen advisory statements (e.g. May contain..., 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, net quantity, storage conditions, and preparation instructions (if applicable).

#### **4.1.5.2 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/packaging at the end of a run to assure that the next run of materials is not inadvertently mislabeled. These procedures could include:

- Any packaging that includes ingredient statements (e.g., labels, cups, film, external cartons) should be checked upon receipt against approved standards to ensure the labeling statements are correct and any other additional allergen labeling requirements are present.
- Unused packaging and labels are removed after the production run. The unused packaging materials should not be mixed with other packaging materials during storage.
- Labels and pre-labeled packaging should not be co-mingled inside shipping and storage containers.
- Proper control procedures should be in place and effective for label and packaging inventory.
- Packaging stored in boxes, such as plastic cups and lids, should have the boxes sealed closed.
- Labels or pre-printed packaging for the product currently being packaged is the only label/packaging in the packaging area.

- Ensure packaging samples are accurate before placed into packaging machinery.
- Monitor, document, and verify the correct label at all changeovers as they occur.
- During processing, product containers and labels are inspected to reconcile allergen-related label information on the containers with the ingredient specifications of the product.
- Changes to product specification or formulation should be immediately reflected on labels.
- Discard all out-of-date or obsolete labels or packaging in a timely manner.

Another technique to consider are accounting for quantities of labels used versus quantity of packages produced during a production run. Units produced should approximately equal labels used. If these two numbers are different, it could indicate that the wrong label was used or there are unlabeled packages in the production run.

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

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

#### **4.1.6 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. Their proper action is based on their understanding of what their responsibilities are and why they have those responsibilities. Understanding allergens and the facility's allergen control procedures is aided by a strong allergen training program.

Additionally, the preventive controls rule, specifically section 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”.

Employees at all levels of the company should receive general allergen awareness training. All facility employees should receive general allergen awareness training when new to the facility and refresher training should occur at a certain frequency thereafter (e.g. annually). The training material should also be refreshed at least annually.

Employees with specific allergen-related job activities should receive specific training on those responsibilities. This job-specific training should occur when the employee is new to those responsibilities and as often as necessary, but at least annually. Records documenting employee training should be kept on file. Examples of specific topics for training may include, but not limited to:

- HACCP/ Food Safety Plan 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 Act](#)  
[Food Allergy Research and Resource Program](#)

## SUPPLY CHAIN PROGRAM

Many companies have general supplier approval and supplier management programs that would be outside the scope of the FDA requirement in Subpart G of the 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 [GMA Food Supply Chain handbook](#) provides comprehensive information on managing food safety through supply chains and elements from the handbook were used to develop this chapter (GMA, 2008).

This chapter focuses on the specific circumstances that trigger that a supply chain program be implemented as a preventive control as part of the food safety plan. 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 their supplier to implement that control.

In some cases, a facility may need to approve suppliers and conduct ongoing verification. In other cases, a facility may be subject to such approval and verification by its customer. It is important to consider that from a regulatory standpoint, these requirements 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 would need to develop and implement a supply chain program, that would include activities to verify that the nut processor had adequately treated nuts to control for *Salmonella*.

### 5.1 Obtain Ingredients from an Approved Supplier

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, as well as experience with the supplier.

The following reflects potential processes facilities could use to approve suppliers.

- **Supplier Approval Program:** Develop a written program with flow charts to outline the approval process including which corporate and facility functions are involved and who signs off (e.g., R&D, Purchasing, QA).
  - FDA specifies that these specific elements need to be considered as part of the supplier approval process:
    - Hazard analysis
    - How far back in the supply chain the control is applied, and who is applying it
    - Supplier performance:
      - Food safety procedures and practices
      - Regulatory compliance (e.g., import alerts, warning letters etc.)
      - Food safety history
      - Test results
      - Audit results
      - Responsiveness to problems
- **Supplier Information Form:** Develop a detailed form asking appropriate questions to include technical data about the ingredient, significant hazards, chemical make-up, contact name, etc. An example of those questions is included at the end of this element in Figure 5.1.
- **Samples Received and Reviewed**
  - Ensure Quality Dept. is involved in the ingredient approval and decision process. Review the technical data sheets when received by Purchasing, R&D, and Quality. Have a mandatory sign-off by all departments on final formulas and ingredients.
  - Write into the supplier specification that if they use or switch to any other supplier or facility (such as to obtain cost savings or increase availability) you must be notified beforehand. At that point you will want to evaluate the risk of the new supplier or facility, and this facility will need to go through the approval process.
  - Review ingredient technical data sheets and supplier information annually to ensure nothing has changed.

## 5.2 Evaluate 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, existing audits by qualified third party auditors.

- Risk Assessment Matrix

### Raw versus Unpasteurized versus 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 (this is the case for almonds and oysters – FDA does not object as long as the physical and chemical characteristics 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.

In order to avoid confusion between businesses, other terminology might be preferable to communicate the way in which hazards, such as *Salmonella*, have been addressed. A more general term that can be used may be “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.

- Maintain a Vendor/Supplier Contact Information list with risk assessments determining the audit frequency of each supplier. Review annually to ensure contacts have not changed. Provide comments on each risk assessment as to why frequencies of audits are chosen.
  - *Salmonella* is considered a hazard that can cause a serious adverse health consequence or death (a SAHCODHA hazard) and as such, FDA expects that facilities (or their designees, such as 3<sup>rd</sup> party auditors) will conduct an annual on-site audit of the facility, unless another verification tool can be shown to provide the same level of assurance that the supplier is controlling the pathogen.
- Include whether a supplier is from a high-risk country and who is auditing that supplier.
- If you source an ingredient from a broker, you will need to identify the actual product manufacturer so that you can conduct supplier verification directly, unless the broker is conducting verification on your behalf and provides you with adequate documentation. Also, if you rely on the broker to verify the actual manufacturer, do not just accept the broker's assurance of ingredient safety. How is the broker verifying/validating the supplier's food safety program? Even if the broker performs verification activities, FDA requires that receiving facility still approve the supplier (which is the location/facility where the hazard is being controlled).
- On-site audit
  - If an on-site audit is warranted from your risk assessment of the ingredient or supplier, you can either conduct the audit yourself (using an employee who is appropriately qualified) or use a qualified third party.
  - If you elect to do the audit yourself, use an audit template with probing questions about their food safety (*Salmonella* mitigation, allergen management) and supplier programs. See Vendor Approval Program Highlights, Figure 5.1, below. Send this prior to the on-site audit and verify the responses when on site.
  - If an audit is conducted by a third-party, , and is acceptable to you in lieu of an on-site audit conducted by your company, ask for the complete audit report, not just the certificate. You may have to sign a confidentiality agreement that states you will not circulate the document without the owner's permission, but bear in mind that some of this information is available to FDA. Review the deficiencies and corrective actions closely. Follow up with the supplier for more detail if needed.
    - If the audit is identified in the supply chain program as a verification tool, you will need to create a record of your 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 Incoming Ingredient Testing

As an alternative to, or in addition to auditing, testing can also be used as part of supplier verification. 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, push to have them tested prior to arrival at your facility. Have the supplier send samples to an independent lab with results to both you and the supplier. (Who should pay for these tests should be predetermined.)
  - Sampling and testing, at a minimum, should be in accordance the [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 use of a third party sampling service.
  - If testing must take place after receipt of the ingredient, provide clear communication to the supplier of your intent. Discovery of a potential SAHCODHA hazard could result in a requirement for you to notify the FDA through the Reportable Food Registry (RFR).
  - If testing must take place after your receipt of the ingredient, ensure that the entire lot remains “on hold” pending receipt of the testing results.
- Tolerances and Frequencies
  - Establish and follow set frequencies of tests based on risk
    - **Never retest a lot if it tests positive for *Salmonella* for the purpose of releasing the product.**

### 5.4 Corrective Actions for Non-Conformance if *Salmonella* Found

- Develop a written corrective action program with step-by-step instructions of what to do if *Salmonella* is detected through product testing. Hold the affected ingredient or product, segregate the lot, and notify the supplier for immediate disposition.
- 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.

### 5.5 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 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 hold stock.
- FIFO (First In, First Out)
  - Use the first in, first out protocol to keep from pulling ingredients out of rotation and to aid lot bracketing.
  - If another company receiving these same ingredients from the supplier tests the lot and finds positive results, your lots may become involved. Insist 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 Food Safety Plan.

## Figure 5.1. VENDOR APPROVAL PROGRAM HIGHLIGHTS

- Review the results of supplier visits /audits (both when conducted by your company or a 3<sup>rd</sup> 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?

## 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 such as 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 in order 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* <sup>1</sup>
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 <sup>1</sup>	Training
Pest Control	

\* Additional information available in appendices.

<sup>1</sup> 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.
- 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):

- Ingredients
- Cleaning
- Reclaimed water
- CIP make-up water
- Process aid/post-process pack cooling
- Incoming water from wells or municipalities
- Drinking (fountains and coolers)
- Ice (drinking or product contact)
- Re-circulated cooling water
- Sanitation final rinse
- 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 with regard to the tests, frequency, and acceptable limits.

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

- Sample location and size
- Test frequency

- Required tests
- Test methodology
- Acceptance criteria
- 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

- The structure should be free of cracks, holes, openings, and pest entry or nesting areas.
- 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).
- During construction, adequate control should be in place to prevent contamination.

#### Doors and Entrances

- Doors should be self-closing and form an adequate seal when closed.
- Loading docks should be protected to prevent pest entry.
- The entrance should control foot traffic into the RTE area and provide the utilities necessary to wash and dry employees' hands.
- 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.
- Entry of air should be limited by vestibules, air curtains or pressure differential, as appropriate.

#### Roof

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

#### Windows and non-HVAC Ventilation

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

#### Unauthorized People Control

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

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

- The plant layout should be designed to physically separate raw and processed product areas.
- 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

- All should be cleanable and constructed to resist deterioration from product or cleaning chemicals.
- Floors should be sealed, in good repair, and sloped adequately to avoid standing water.
- Wall and floor junctures should be concave.
- 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

- The location and number of hand washing, drying and sanitizing facilities provided should allow for optimum usage by employees.
- 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.
- Separate sinks and cleaning stations should be provided for hand washing, food contact equipment cleaning, and waste disposal.
- The location and number of toilet facilities provided should be adequate, and include hand washing and drying facilities.
- Toilets and shower facilities should not have direct entrance to food production areas.
- Toilet areas should have negative air pressure (draw in) versus their surroundings.
- 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 in order 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 and maintenance records. Priority should be given to maintenance 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 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 (equipment and area to be cleaned and sanitized, as applicable, prior to release for food production).

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 4. 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.

### **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 *Salmonella* Control Area (PSCA). In a nut handling facility, the PSCA is the area where handling of ingredients and product requires the highest level of hygiene control. The PSCA 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 PSCA are referred to as basic GMP 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 PSCA, a basic GMP, and a possible transition area that allows for a hygiene juncture between the PSCA and the basic GMP area may be included. For example, an operation that does not employ an inactivation step may designate the entire processing area as the PSCA, 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 PSCA and the rest of the processing area as the basic GMP area, e.g., a peanut roasting or peanut butter operation (Figure 1).

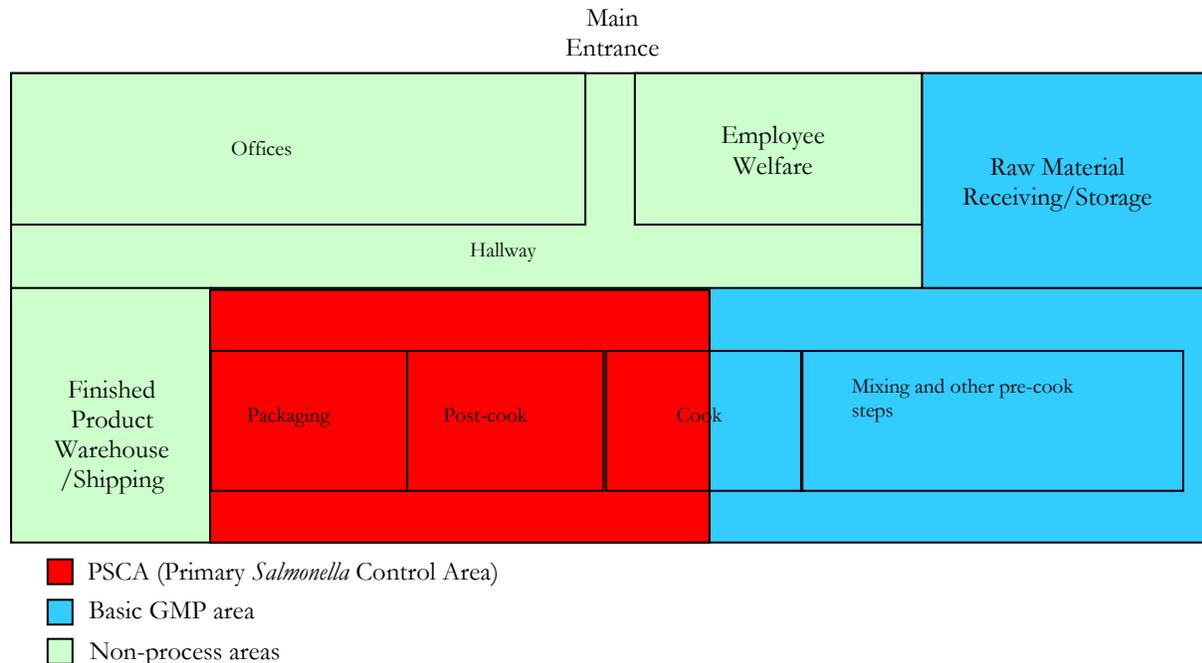


Figure 6.1. Example of a conceptual plant layout showing two process areas with different hygiene control: a Primary *Salmonella* Control Area (PSCA) in red and a basic GMP area in blue. The need for GMPs in non-process areas should be assessed on a case-by-case basis.

### 6.3.1 The 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 PSCA and designate basic GMP 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.

### 6.3.2 Preventing PSCA 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 *Salmonella* into the PSCA 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 4.
- Structural separation of the PSCA
- Optimized traffic patterns of people, materials, and equipment to protect the PSCA
- Use of a vestibule or hygiene juncture to enter and exit the PSCA
- Hand washing/sanitizing and foot barrier controls (captive boots, booties) established when moving between the PSCA and basic GMP 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 waste water 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 (section 3.6) below.

### **6.3.3 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:

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

## **6.4 Personnel**

### **6.4.1 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, 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, 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.
- 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 PSCA; see Section 3.3, above) 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.

#### **6.4.2 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/mislabeled. 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

<b>Often Transmitted</b>	<b>Occasionally Transmitted</b>
Hepatitis A virus	<i>Campylobacter jejuni</i>
Noroviruses	<i>Entamoeba histolytica</i>
<i>Salmonella</i> Typhi	Enterohemorrhagic <i>Escherichia coli</i>

<i>Shigella</i> species	Enterotoxigenic <i>Escherichia coli</i>
<i>Staphylococcus aureus</i>	<i>Giardia lamblia</i>
<i>Streptococcus pyogenes</i>	Nontyphoidal <i>Salmonella</i>
	<i>Sapoviruses</i>
	<i>Taenia solium</i>
	<i>Vibrio cholerae</i>
	<i>Yersinia enterocolitica</i>
	<i>Cryptosporidium parvum</i>

## 6.5 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.

### 6.5.1 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.

### 6.5.2 Sanitation Procedures

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

- Method to ensure the most current procedure is in use
- Frequency of cleaning
- Chemicals to be used along with chemical 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

### 6.5.3 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 & brush” methods, dry steam technology, CO<sub>2</sub> technology, and taking wet cleaned parts out of the processing room for cleaning in cabinet-style washers or wash rooms. 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 “7-Steps of Dry Sanitation”) and Appendix O (the “7-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<sub>2</sub> 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<sub>2</sub> blasting is used in conjunction with vacuums or other cleaning tools.

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.

#### 6.5.4 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 hr 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 6.3 Cleaned Equipment - Guidelines only**

		Post-heat treatment - taken before sanitizing		Post-heat treatment - pre-op taken after sanitizing	
		cfu/100 cm <sup>2</sup>	cfu/40 in <sup>2</sup>	cfu/100 cm <sup>2</sup>	cfu/40 in <sup>2</sup>
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 (3) 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 so as to help establish a baseline for reference. The individual performing swabbing must receive proper training.

ATP measurement (adenosine triphosphate measurements are based on the detection of ATP by bioluminescence) 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., 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 2 years).

## **6.6 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:

- 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 (see further detail at 3.6.4 above).
- Examples of swabs that could be used include Culturette Transwab™, Cotton, Rediswab™, Quickswab™.
- 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 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 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 3 consecutive results are acceptable. If re-sampling results remain out of compliance, possible corrective actions could include:
  - a. Break down equipment further and inspect for microbial harborage areas.
  - b. Re-sample the equipment to identify potential niches.
  - c. Re-clean the line while it's disassembled.
  - d. 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.

## **6.7 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 ¼" (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.

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.

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

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 Material Safety Data Sheets (MSDS), 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.

## **6.8 Control of Raw Materials and Products**

### **6.8.1 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 in order 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.

GMA has 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 or around 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 a customer-approved 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. Suppliers to customer U.S. locations are required to provide a Continuing Pure Food Guarantee signed by an officer of the supplier.

### **6.8.2 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. In order 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:

- 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.

### **6.8.3 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.

#### **6.8.4 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 unlabelled

allergens should be placed on Category II hold. If the material is determined to contain unlabelled 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 done before the release of the ingredients for production or the release of the lot/code of product to the customer. Effective pathogen testing hold/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.

### **6.8.5 Control and Disposition of 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.

### **6.8.6 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 above 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.

### **6.9 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 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., GMPs, 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 (e.g., salt, sugar, starches, etc.), 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, 2 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 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 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 in order 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 4 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 in the event that 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.

### **6.10 Corrective and Preventive Action (C&PA)**

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 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 C&PA 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
- C&PA 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 C&PA by the management team

## 6.11 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 air tight to prevent entry of microorganisms. Exhaust air ducting should be air tight 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 has also published a 2016 [Guidance on Laboratory Selection and Evaluation](#)

## **6.12 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 GMPs 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 food safety plan.

Training for production employees must include a general awareness of the principles of food safety and quality including hygiene and GMPs, 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.

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.

## 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 Good Hygienic Practices (GHP's) and Food Safety Plans, such as a Hazard Analysis Critical Control Points (HACCP), or the Food Safety Plan now required for many FDA-regulated facilities 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.

For low moisture foods, such as nuts, *Salmonella* contamination has emerged as a concern over the past two decades. 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 (ABC, no date). 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 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 the predominant pathogenic hazard in nuts. As such, an effective Pathogen Environmental Monitoring Program (PEMP) should be developed with the purpose of aggressively seeking out, destroying and preventing the establishment of *Salmonella* niches before they lead to product contamination. However, each facility should design their PEMP to address environmental pathogens of specific concern for their product(s) and operation. It cannot 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.

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. Verification procedures such as a Pathogen Environmental Monitoring Program (PEMP) are also required.

An environmental pathogen, as defined by FDA in the PC 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. In addition, as established in the rule, environmental monitoring is to be used as a verification activity as appropriate to the facility, the food and the nature of the preventive control and its role in the facility's food safety system. 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).

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)) clearly state the requirements for environmental monitoring as a verification activity. Environmental monitoring is required if indicated by a facility's food safety plan. 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. The environmental pathogen relevant to most nut processes is *Salmonella* spp., although other organisms may be of concern depending on the product, its use and the intended consumer etc. A PEMP could target the environmental pathogen identified in the hazard analysis, or an appropriate indicator organism. However, FDA has stated in the preamble to the rule that they do not recognize an indicator for *Salmonella*.

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 GHP's 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 in order to verify efficacy of Environmental Control and GHP programs. The document will discuss key components of a PEMP including:

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

The guidance 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 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 (before and after a pathogen reduction step), 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 established concept in pathogen control is the designation of a Primary *Salmonella* Control Area (PSCA). In a nut handling facility, the PSCA is the area where handling of ingredients and product requires the highest level of hygiene control. The PSCA is sometimes referred to as the high hygiene area or the high risk area. The PSCA is also referred to as the ready-to-eat area, the critical side, the instant product side, or the dry side of the operation.

Production areas outside of the PSCA are referred to as basic GMP 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, non-processing areas are also delineated such as bathrooms, the plant entrance, locker rooms, administrative offices, storage areas for non-exposed (packaged) products, 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 PSCA, a basic GMP, and a possible transition area that allows for a hygiene juncture between the PSCA and the basic GMP area may be included. For example, an operation that does not employ an inactivation step may designate the entire processing area as the PSCA, 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 PSCA and the rest of the processing area as the basic GMP area, e.g., a peanut roasting or peanut butter operation (Figure 7.1).

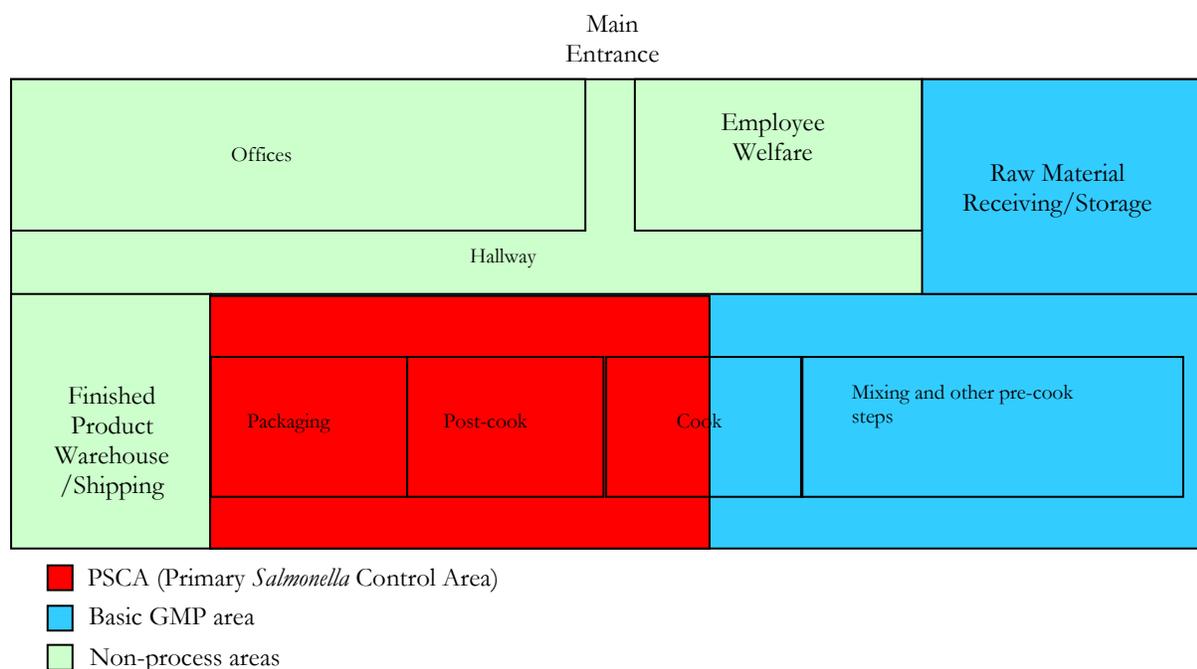


Figure 7.1. Example of a conceptual plant layout showing two process areas with different hygiene control: a Primary *Salmonella* Control Area (PSCA) in red and a basic GMP area in blue. The need for GMPs in non-process areas should be assessed on a case-by-case basis.

### 7.2.1 The Production Area Risk Evaluation

A risk assessment is conducted to define processing areas and establish the level of risk of product and product-contact surface contamination posed by or to different areas of the manufacturing facility. A practical approach is to assess the product and product-contact-surface exposure risk from the environment and determine how conducive the environment is for microbial contamination, growth and transfer of contamination. Drafting a process diagram of the facility to identify designated control areas with color coding can reflect the risk of each area. This process is called hygienic zoning, and may be considered to be a preventive control under the FDA PC Rule.

- 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 PSCA and designate basic GMP 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 not be used or used in a controlled manner.
- Consider how people, ingredients, products, packaging materials, refuse, equipment, water, air, pests or other carriers could transfer pathogens from dirty zones to clean zones

--Identify and implement any special employee practices or sanitary design requirements for each of the designated areas

### **7.2.2 Preventing PSCA 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 potential spread of *Salmonella* into the PSCA where preventing product contamination is most critical. The following are some commonly used control measures:

- Closed systems (e.g., closed 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 PSCA from less hygienic process areas
- Optimized traffic patterns for people, materials, and equipment to protect the PSCA
- Use of a vestibule or hygiene juncture to enter and exit the PSCA
- Hand washing/sanitizing and foot barrier controls (captive boots, overshoes, disposable booties, alcohol-based sanitizer sprayed on shoes) established when moving between the PSCA and basic GMP 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 PSCA 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 PSCA to other areas outside the PSCA
- 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.

### **7.2.3 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 7.2.4)
- 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 Food Safety Plan. 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.

#### **7.2.4 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.

### **7.3 Pathogen Environmental Monitoring for *Salmonella***

A comprehensive Pathogen Environmental Monitoring Program (PEMP) is designed to assess the effectiveness of *Salmonella* control programs and to 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:

- A baseline microbiological assessment of a plant’s environment
- Potential sources of *Salmonella* 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)

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 *Salmonella* control in the plant environment. This information is used to 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 *Salmonella* 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 *Salmonella* is typically conducted on non-product contact surfaces (non-PCSs) within the PSCA (Zones 2 and 3, see Table 7.1). Product contact surfaces (PCS),

and product scrapings, etc., that could implicate finished product (Zone 1, see Table 7.1) are generally only sampled and tested for pathogens under certain circumstances such as in response to possible high-risk pathogen contamination issues (e.g., an abnormal moisture event in the PSCA), investigation of a *Salmonella*-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* 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 PSCA. While these general indicator assays do not typically correlate directly with the presence or absence of *Salmonella*, they can be very useful in verifying the general hygienic state of PCS (lack of product build-up, lack of moisture). 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 PSCA should be the main focus of routine monitoring for *Salmonella*. 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 *Salmonella* 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 *Salmonella* to be present and potentially spread into the PSCA. This also provides 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 1. Sampling sites within segregated areas (Figure 1) should be selected considering the likelihood of finding *Salmonella* 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. 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 *Salmonella* samples that can serve as a composite sample of the PSCA, 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 PSCA 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	<b>Direct or indirect product contact surfaces<sup>1</sup></b> , e.g., product conveyors and product discharge chutes; pipeline interior and storage hoppers to product fill; filler hoppers, nozzles, product scrapers/utensils, product scrapings	Indicator organisms (e.g., Aerobic Plate Count; <i>Enterobacteriaceae</i> ); <i>Salmonella</i> only when special circumstances dictate <sup>3</sup> .	Post-sanitation or as needed for investigational, validation or verification purposes
2	<b>Environmental surfaces immediately adjacent to product-contact surfaces in production area</b> , 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 <sup>2</sup> , HVAC vents, vacuum cleaners if used near PCSs, air filters, etc.	<i>Salmonella</i>	Weekly, twice monthly, or monthly
3	<b>Environmental surfaces further removed from product contact surfaces but still within the PSCA</b> , 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.	<i>Salmonella</i>	Weekly or monthly
4	<b>Outside of the PSCA</b> , e.g., warehouses, bathrooms, cafeteria, plant entrance, locker room, mechanical room, hallways, offices, and refuse/recycle areas, raw product area	<i>Salmonella</i>	Monthly or quarterly

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> Special circumstances include but are not limited to: response to possible pathogen contamination issues (e.g., roof leaks), investigation of a positive finished product, verification of cleaning and sanitation following an incident, or commissioning of new equipment upon installation. If equipment is wet cleaned, sanitized and dried as part of routine SSOPs and finished product is held until results are obtained, Zone 1 pathogen swabs may be used to verify preventive controls.

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 to 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 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 *Salmonella* are not typically part of a routine PEMP. 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. 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*, 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 *Salmonella* finding in Zone 1 will lead to an examination of product disposition for products that were produced on that equipment prior to swabbing.

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 PSCA 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*. 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 PSCA. 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* 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 *Salmonella* 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. However, this should not be set up in a manner that excludes the sampling of an area of concern identified in a "non-scheduled" 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* 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: Plant Construction or New Equipment Installation**

Sampling and testing for *Salmonella* 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 *Salmonella* testing (Figure 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 buffer. The particular 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 are also available with removable handles that may be preferred for ease over sponge squares. Q-tip type swabs are available and are appropriate for sampling small areas (such as bolts) 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<sup>2</sup>, 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. 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.
9. A blank swab (negative control) should be included on a monthly basis or for each new lot number of *Salmonella* 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 g 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 food matrix 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 *Salmonella* contamination can be greatly enhanced through the use of some type of strain tracking. Determination of the serogroup or serotype can be useful. Molecular fingerprinting of the *Salmonella* isolate using such methods as Ribotyping, pulsed field gel electrophoresis (PFGE), repetitive sequence polymerase chain reaction (Rep-PCR), or Whole Genome Sequencing (WGS) can provide even greater strain differentiation. These subtyping methods 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 *Salmonella* control.

- Pooling (combining 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 "pooled" sample result is positive, the individual enrichments that made up the pooled 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 compositing or pooling should be carefully considered.
- More than one type of *Salmonella* could be isolated from an environmental sample. Multiple strains/serotypes of *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.

### **7.3.6 Corrective Actions**

Corrective actions must be taken when *Salmonella* is detected in an environmental monitoring sample. Many facilities begin corrective actions upon receiving a "presumptive" positive from a rapid detection method. This may be preferred to waiting for confirmatory *Salmonella* test results, since waiting for the final confirmation 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 food safety plan. 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 to determine the extent of the contamination and to ascertain potential causes of the problem. Vector swabbing entails taking additional environmental samples around the initial positive site. 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).

- 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 2, and be accompanied by re-sampling of the initial positive and adjacent areas.
- All corrective actions taken, including re-sampling results, must be documented.

Table 7.2. Examples of corrective action procedures following positive *Salmonella* findings in the plant environment

<b><u>Zone 2, 3, or 4: Response to a Single Positive</u></b>	<b><u>Special Circumstances: Multiple and/or Consecutive Positives (all Zones)</u></b>
<p>Corrective actions must be taken when a <i>Salmonella</i>-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.</p>	<p>When a sound control program for <i>Salmonella</i> 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.</p>
<p>Corrective actions common to Zones 2, 3, and 4 may include the following:</p>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Reinforce GMP training and hygienic practices and provide additional attention to sanitation procedures.</li> <li>• Visually inspect areas for potential harborage sites or growth niches. Intensify cleaning activities around these areas.</li> <li>• Visually inspect handling practices (production, sanitation, maintenance, material handling) and correct non-hygienic employee practices.</li> <li>• Review equipment cleaning and preventive maintenance protocols and revise, if necessary.</li> <li>• Examine processing equipment and consider equipment redesign, if necessary.</li> <li>• PCS or product testing may be necessary or need to be intensified for</li> </ul>
<ul style="list-style-type: none"> <li>• 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.</li> <li>• Take immediate actions to correct any GMP deficiencies based on findings. These may include: <ul style="list-style-type: none"> <li>- Quarantine the suspect area and limit access to the area.</li> <li>- Reinforce hygienic practices with appropriate employees (retrain if necessary).</li> <li>- Re-examine cleaning frequencies and revise, as appropriate.</li> <li>- Eliminate water and water collection points, if present.</li> <li>- Repair damaged floors/walls and other structural damage, as appropriate.</li> <li>- 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.</li> </ul> </li> <li>• 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.</li> <li>• Thoroughly clean/sanitize and dry the positive site and the surrounding area. Use dry, controlled wet, and/or wet cleaning, as appropriate, according to guidelines described in this document and appendices and the</li> </ul>	

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GMA *Salmonella* Guidance (GMA, 2009).

- 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.

Zone 2 consecutive positives. 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.

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.

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## 7.4 Management of a Pathogen Environmental Monitoring Program

Under FSMA, the designated Preventive Control Qualified Individual (PCQI), responsible for the development and management of the facility's Food Safety Plan, 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 PSCA should all be derived from the facility's hazard analysis.

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. The individual will require a thorough knowledge of facility processes and be able to identify sites that require further investigation.

One-on-one instruction and demonstrations will be required to learn how to take a swab properly. Training should include how to determine which sites to sample, as well as collecting, recording, and mapping data. They must also be trained to respond to a positive result. Periodic updates or follow-up training sessions may be needed. All employees should be retrained at a minimum, on a yearly basis. Training records must be kept and available for inspection.

## EQUIPMENT DESIGN AND INSTALLATION

In order 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.

### **Principle 1: Cleanable**

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

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.

### **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.

### **Principle 3: Accessible for Inspection, Maintenance, Cleaning and Sanitation**

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. 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.

### **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.

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.

### **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.

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.

### **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.

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.

### **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.

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.

## **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 of the maintenance enclosures and other connections to the equipment are appropriately designed and also can be cleaned and sanitized.

## **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.

## **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.

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.

## **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.

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

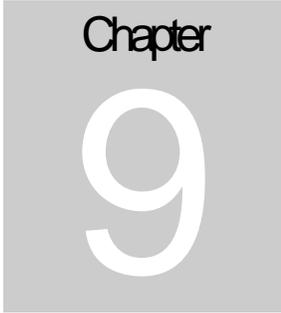
All plant personnel, contractors, and visitors to processing plants must be trained in and required to follow plant hygienic and sanitation requirements. Programs must be in place at equipment manufacturing locations to assure elimination of the potential for physical, chemical or microbiological contamination 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.

When suppliers and contractors visit or work to install new equipment they need to follow all of the company's GMP rules. 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.

**FOOD DEFENSE**

This chapter will be finalized at a future date.



## REFERENCES

# Chapter 10

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## APPENDICES

### Appendix A. Acknowledgements

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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 that 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, such as 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 SOP 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 SOP 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 that there are limitations and benefits. The levels of sampling that are 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, such as implementation of a food safety plan inclusive of HACCP, and GMP and other prerequisite programs 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 that is 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 especially 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 food safety plan, which is discussed in Chapter 5. Additional information on supplier approval programs is available in the GMA guidance on "Control of *Salmonella* in Low Moisture Food", (GMA, 2009, pp. 45–49). Whenever possible, source an entire lot for delivery and strongly discourage shipment of a split lot that has been 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 FDA BAM (Andrews and Hammack, 2003 and 2007) and those developed by the International Commission on Microbiological Specifications for Foods (ICMSF, 2002a). FDA BAM Category I to III, or ICMSF sampling plans Cases 10 to 15 may be used (see Tables 1 and 2 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 (such as for a new ingredient from a new and unknown supplier), once every 6 lots, or less frequently, depending on the supplier’s historical test results.

Table 1. FDA BAM Sampling Plans <sup>a</sup>

Category I	Category II	Category III
<b>Number of samples: 60</b> <b>Amount tested per sample: 25 g</b>	<b>Number of samples: 30</b> <b>Amount tested per sample: 25 g</b>	<b>Number of samples: 15</b> <b>Amount tested per sample: 25 g</b>
Products that would not normally be subjected to a process lethal to <i>Salmonella</i> between the time of sampling and consumption, and are intended for highly susceptible population (e.g., the elderly, the very young, and immunocompromised individuals)	Products that would not normally be subjected to a process lethal to <i>Salmonella</i> 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 <i>Salmonella</i> between the time of sampling and consumption, and are intended for the general population.

<sup>a</sup> In all of the sampling plans, the acceptance criterion is that *Salmonella* is not detected in any of the samples (also referred to as analytical units).

Table 2. ICMSF Sampling Plan <sup>a</sup>

Conditions of use reduce concern	Conditions of use cause no change in concern	Conditions of use increase concern
<b>Case 10</b> <b>n=5, c=0</b>	<b>Case 11</b> <b>n=10, c=0</b>	<b>Case 12</b> <b>n=20, c=0</b>
Products that would normally be subjected to a process lethal to <i>Salmonella</i> before consumption.	Products that would not normally be subjected to a process lethal to <i>Salmonella</i> before consumption.	Products that will be used as an ingredient in another ready-to-eat product that will support <i>Salmonella</i> growth, or there are questions about the robustness of the supplier’s food safety program.
<b>Case 13</b> <b>n=15, c=0</b>	<b>Case 14</b> <b>n=30, c=0</b>	<b>Case 15</b> <b>n=60, c=0</b>
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.

<sup>a</sup> 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 serve 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 that is 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 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, 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 *Salmonella* finding on ready-to-eat 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 8-hour production run of a lot (or select another pre-determined 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 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 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 US and EU, 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 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 such as 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 ready to eat 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 is 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 it is virtually impossible to confirm very low prevalence by resampling (ICMSF, 2002b). Retesting for investigational purposes only (i.e., to try 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 <sup>c</sup>				
	Min. Temp.	Min. Time for 5-log reduction	Temp.	D-value (min.)	z-value
Dry Roasting (Continuous Process) <sup>a</sup>	129°C (264°F)	47.1	146°C (295°F)	2.8	42.9°C (77.5°F)
	138°C (280°F)	25.1			
	146°C (295°F)	14.1			
Hot Water Blanching <sup>b</sup>	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			

<sup>a</sup> American Peanut Council sponsored study on thermal characteristics of *Salmonella* spp. on peanuts

<sup>b</sup> Almond Board of California sponsored study on thermal characteristics of *Salmonella* spp. on almonds

<sup>c</sup> These parameters apply to the specific products indicated (i.e., dry roasting of peanuts and hot water blanching of almonds) and may not be appropriate for other type of nuts

## **Appendix D. Examples of Forms Applicable to Food Safety Plans**

Product/Product Category Description  
Process Flow Diagram  
Ingredient/Packaging Assessment  
Processing Step Evaluation  
Ingredient Allergen Assessment  
Allergen Cross-contact Production Assessment  
Critical Control Point (CCP) Documentation

<b>HACCP/ Food Safety Plan Number:</b> <b>Plant Name:</b> <b>Address:</b>	Issue Date	DD -	PRODUCT :
		MMM - YY	
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**PRODUCT/PRODUCT CATEGORY DESCRIPTION – EXAMPLE 1**

**Purpose:** To describe the product characteristics and storage and distribution factors as related to food safety.

<b>Product/Product Category</b> (e.g., Name, type, size)	
<b>Raw Materials and Other Ingredients</b>	
<b>Process</b> (e.g., oil roast, dry roast, steam, hot water, PPO-treated, ETO-treated)	
<b>Condition, Function and Design of the Facility and Equipment</b>	
<b>Sanitation, Including Employee Hygiene</b>	
<b>Food Safety Characteristics</b> (e.g., pH, a <sub>w</sub> , % salt, pasteurization, cooking, preservatives, refrigeration)	
<b>Intended Market</b> (e.g., general public, age, adult, child, retail, food service, countries, regions, national)	
<b>Consumer/Customer Use</b> (e.g., Ready-to-consume, heat-and- consume, mix-and-consume)	
<b>Labeling/Label Instructions</b>  <b>List Only Those Ingredients Containing Allergens, Sulfites</b> (e.g., Preparation, storage needs, use by, best when used by)	
<b>Packaging</b> (e.g., Foil , plastic, glass, cup, can, hermetically sealed, gas permeable, tamper evident, modified atmosphere packaging)	
<b>Shelf Life</b> (e.g., Days and temperature conditions)	
<b>Transportation Practices</b>	
<b>Storage &amp; Distribution</b> (e.g., Ambient, refrigerated, frozen, relative humidity, high altitude)	

<b>HACCP/ Food Safety Plan</b> <b>Number:</b> Peanut 1 <b>Plant Name:</b> Company X <b>Address:</b> Anytown, US	Issue Date	21 - JUL - 09	PRODUCT:	DRY ROASTED NUT SNACKS
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**PRODUCT/PRODUCT CATEGORY DESCRIPTION**  
**Completed Example 1**

**Purpose:** To describe the product characteristics and storage and distribution factors as related to food safety.

<b>Product/Product Category</b> (e.g., Name, type, size)	Dry roasted peanut or almond snacks
<b>Raw Materials and Other Ingredients</b>	Raw peanuts, raw almonds
<b>Process</b> (e.g., oil roast, dry roast, steam, hot water, PPO-treated, ETO-treated)	Dry roasting
<b>Condition, Function and Design of the Facility and Equipment</b>	Facility built and equipment purchased with sanitary design in mind; well maintained
<b>Sanitation, Including Employee Hygiene</b>	Sanitation conducted according to SOP 123; Employee hygiene followed as per SOP 456; employees receive annual training and retraining as determined by verification
<b>Food Safety Characteristics</b> (e.g., pH, a <sub>w</sub> , % salt, pasteurization, cooking, preservatives, refrigeration)	Low water activity
<b>Intended Market</b> (e.g., General public, age, adult, child, retail, food service, countries, regions, national)	General public
<b>Consumer/Customer Use</b> (e.g., Ready-to-consume, heat-and-consume, mix-and-consume)	Ready-to-eat
<b>Labeling/Label Instructions</b> <b>List Only Those Ingredients Containing Allergens, Sulfites</b> (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
<b>Packaging</b> (e.g., Foil, plastic, glass, cup, can, hermetically sealed, gas permeable, tamper evident, modified atmosphere packaging)	Glass jar with plastic cap
<b>Shelf Life</b> (e.g., Days and temperature conditions)	270 days at ambient temperature
<b>Transportation</b>	Shipped on contracted trucks that are inspected before loading (SOP 789)
<b>Storage &amp; Distribution</b> (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:	

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**PROCESS FLOW DIAGRAM - EXAMPLE**

**Purpose:** A graphical representation of all processing steps from raw material receiving to finished product storage that are 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 & 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
- Numbered Critical Control Points (CCPs) shown at identified process steps

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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 ) VP = Vegetative Pathogen ( B ) SP = Spore forming Pathogen ( 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)	

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**INGREDIENT/PACKAGING ASSESSMENT – Completed Example**

INGREDIENT NAME	POTENTIAL HAZARDS INTRODUCED ( B ) VP = Vegetative Pathogen ( B ) SP = Spore forming Pathogen ( 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) or Preventive Control (PC)
Raw peanuts	(B) <i>Salmonella</i>	(B) Yes	(B) <i>Salmonella</i> may be present in raw material	(B) Roasting	CCP
	(C) Undeclared Peanut protein	(C) Yes	(C) Peanut is an allergen	(C) Bar code labeling (C) Label check at changeover	PC allergen program PC- allergen program
	(C) Aflatoxin	(C) No	(C) Supplier qualification plans and raw material screening eliminates the risk from aflatoxin		
	(P) Rocks	(P) Yes	(P) Plant experience has shown a history of rocks matter in this raw material	(P) Screens (P) Sifters	CCP
Roasted almonds	(B) None	(B) Yes	(B) Microbiologist has determined that roasting done by the supplier of this product eliminates the hazard from pathogens	(B) Supplier Program	PC supplier program
	(C) Undeclared Almond protein	(C) Yes	(C) Almond protein is an allergen,	(C) Bar code labeling	CCP
	(P) None	(P) No	(P) Based on plant history and experience, there is not a risk from extraneous matter in this material		
Herb blend	(B) VP	(B) Yes	(B) Pathogens(e.g., <i>Salmonella</i> , pathogenic <i>E. coli</i> ) may be present in raw material	(B) Supplier program	PC Supplier program
	(C) None	(C) No	(C) Toxicologist has reviewed this material and relevant scientific literature and has determined there is not a risk for allergens		
	(P) None	(P) No	(P) Based on plant history and experience, there is not a risk from extraneous matter in this material		
Rework	(B) None	(B) No	(B) All rework has been through a lethal kill step to eliminate pathogens		
	(C)Peanut, almond proteins	(C) Yes	(C) Peanuts and almonds are allergens and rework procedures are consistently followed	(C) Rework SOP addressing allergen management	PC allergen program
	(P) None	(P) No	(P) Based on plant history and experience, there is not a risk from extraneous matter in this material		
Process water	(B) VP	(B) No	(B) Chlorination of city water eliminates the risk for pathogens		
	(C) None	(C) No	(C) Toxicologist has reviewed this material and determined there is not a risk for allergens		
	(P) None	(P) No	(P) Filtration of city water eliminates the risk from extraneous matter		

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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 ) VP = Vegetative Pathogen ( B ) SP = Spore forming Pathogen ( 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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**PROCESSING STEP EVALUATION**  
**Completed Example**

PROCESS STEP	POTENTIAL HAZARDS INTRODUCED OR ENHANCED AT THIS STEP ( B ) VP = Vegetative Pathogen ( B ) SP = Spore forming Pathogen ( 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	(B) Yes	(B) Raw peanuts may contain Salmonella	(B) Roasting	CCP
	(C) Undeclared allergens	(C) Yes	(C)	(C) Labeling	PC
	(P) Rocks	(P) No	(P)	(P) Screens and Sifters	CCP
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	(B) Yes	(B) Roasting is used to inactivate Salmonella	(B) Roasting	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) VP – Human Handling	(B) No	(B) Strict adherence to GMPs by employees reduces the risk of contamination	(B) GMP's	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 GMPs by employees reduces the risk of contamination		
Rework addition	(B) VP – Human Handling	(B) No	(B) Strict adherence to GMPs 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		
Packaging into foil packages	(B) Salmonella	(B) Yes	(B) Post process contamination during packaging peanuts may introduce Salmonella	(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		

**INGREDIENT/PACKAGING/PROCESSING ASSESSMENT**  
**EXAMPLE 2 (Developed by the Food Safety Preventive Controls Alliance)**

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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, substances such as 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

<b>Hazard Analysis</b>								
(1) Ingredient / Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
	B							
	C							
	P							
	B							
	C							

Hazard Analysis								
(1) Ingredient / Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
P								
B								
C								
P								

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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. 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)

<b>A</b>	<b>B</b>	<b>C</b>
List all ingredients containing allergens per Food Allergen List. List any processing aids that may come in contact with product contact surfaces or product itself.	List identified allergens of ingredients	List identified carryover allergens

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**INGREDIENT ALLERGEN ASSESSMENT**  
**Completed 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. 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)

<b>A</b>	<b>B</b>	<b>C</b>
List all ingredients containing allergens per Food Allergen List. List any processing aids that may come in contact with product contact surfaces or product itself.	List identified allergens of ingredients	List identified carryover allergens
Raw peanuts	Peanut	
Roasted almonds	Almond	
Rework nuts	Peanut, almond	



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**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 etc.	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)?		If "No" identify control mechanism(s) ( _ - PC) ( _ - P P )
	<b>YES</b> (list allergens)	<b>NO</b> (list allergens)	
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

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**CRITICAL CONTROL POINT (CCP) DOCUMENTATION EXAMPLE**

**Purpose:** To define food safety limits and monitoring and corrective action requirements.

Critical Control Point 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 such as “shall” and “must.”

**CRITICAL CONTROL POINT ID/PROCESS STEP:** Oil roasting time and temperature for almonds

**HAZARD:** Biological (vegetative pathogens – Salmonella spp.)

**CRITICAL LIMIT:**

Time/Temperature conditions to achieve a 4- or 5-log kill for Salmonella spp. are listed below. If the processor wishes to achieve a 5-log kill, then the Almond Board of California allows 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: flow rate shall be recorded continuously or belt speed setting is 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.

All measuring devices used to monitor critical control parameters shall be calibrated at a frequency sufficient to demonstrate control (minimum every 6 months), by designated trained employee(s).

**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. 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.	<p>Products conveyed through metal detector.</p> <p>Metal detector is operable and reject mechanism capable of rejecting:                      _____mm                      (_____) ferrous,                      _____mm                      (_____) nonferrous and                      _____mm                      (_____) stainless steel spheres from product stream*.</p>	<p>Visual observation to ensure that the detector is on and product is conveyed through detector.</p> <p>Challenge detector with product samples seeded with the appropriate size metal in accordance with SOP #MD101</p>	<p>Approximately once every 2 hrs; At the start and end of production</p> <p>Approximately once every 2 hrs; At the start and end of production</p>	<p>Wrapper or Relief Operator</p> <p>Wrapper or Relief Operator</p>	<p>When an inoperable metal detector or reject mechanism is found, wrapper is shutdown 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.</p> <p>Wrapper will not be started until the detector/reject mechanism is repaired and verified to be working.</p> <p>QA or Manufacturing will file Incident Reports when critical limits are exceeded.</p>	<p>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</p> <p>QA and Production management review and sign records daily</p> <p>Plant QA performs HACCP system audit annually, reviewing procedures/paperwork for compliance and effectiveness.</p> <p>Annual metal detector calibration per manufacturer's recommendation. (Manufacturer should be contacted for maintenance procedures specific to make/model in use.)</p>	<p>Wrapper production form (which contains records of monitoring and verification activities: visual observations, challenge and sensitivity tests by operator or QA, and record review)</p> <p>Incident reports describing the deviation, corrective action, and results of evaluation and product disposition.</p> <p>Metal detector calibration logs</p>

\* Note: Sensitivity to be specified based on product and equipment capability and specific line set-up. Sensitivity of new products needs to be determined.

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Process Preventive Controls – Landscape Layout	Process Controls			
	Hazard(s)			
	Parameters, values or critical limits			
	Monitoring	What		
		How		
		Frequency		
		Who		
	Corrective Action			
	Verification			
	Records			

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Allergen Control	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records					
			What	How	Frequency	Who								

**Form Name: Food Allergen Preventive Controls**

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**Form Name: Food Allergen Ingredient Analysis**

Raw Material Name	Supplier	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, then there is 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 not only allergens, but also 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” 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.

<b>PLANT NAME</b>	<b>ISSUE DATE</b>	<b>PAGE</b>
<b>ADDRESS</b>	<b>SUPERSEDES</b>	<b>PRODUCT CODE</b>

**Form Name: Food Allergen Label Verification Listing**

<b>Product</b>	<b>Allergen Statement</b>

<b>PLANT NAME</b>	<b>ISSUE DATE</b>	<b>PAGE</b>
<b>ADDRESS</b>	<b>SUPERSEDES</b>	<b>PRODUCT CODE</b>

**Form Name: Production Line Food Allergen Assessment**

<b>Product Name</b>	<b>Production Line</b>	<b>Intentional Allergens</b>							
		<b>Egg</b>	<b>Milk</b>	<b>Soy</b>	<b>Wheat</b>	<b>Tree Nut (market name)</b>	<b>Peanut</b>	<b>Fish (market name)</b>	<b>Shellfish (market name)</b>

**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.

<b>PLANT NAME</b>	<b>ISSUE DATE</b>	<b>PAGE</b>
<b>ADDRESS</b>	<b>SUPERSEDES</b>	<b>PRODUCT CODE</b>

**Form Name: Sanitation Preventive Controls**

<b>Location</b>		
<b>Purpose</b>		
<b>Frequency</b>		
<b>Who</b>		
<b>Procedure</b>		
<b>Monitoring</b>		
<b>Corrections</b>		
<b>Records</b>		
<b>Verification</b>		<b>Date</b>

<b>PLANT NAME</b>	<b>ISSUE DATE</b>	<b>PAGE</b>
<b>ADDRESS</b>	<b>SUPERSEDES</b>	<b>PRODUCT CODE</b>

<b>Corrective Action Form</b>	
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:

<b>PLANT NAME</b>	<b>ISSUE DATE</b>	<b>PAGE</b>
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### Food Safety Plan Reanalysis Checklist

**Reason for reanalysis:**

<b>Task</b>	<b>Date Reviewed and Initials</b>	<b>Is Update Needed? (yes/no)</b>	<b>Date Task Completed</b>	<b>Signature or Initials of Person Completing the Task</b>
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 \_\_\_\_\_

## 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 4-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 FDA based upon prevalence/enumeration studies and other studies such as a quantitative risk assessment (under development) as appropriate. In the absence of such studies, FDA has suggested a 5-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 FDA completes its tree nut risk assessment, results will be included in updates to this document.

#### Management Responsibility

All facilities supplying processed tree nuts and/or peanuts should ensure that instructions are developed, documented, communicated, and followed, and that responsible employees are designated and adequately trained, in order to meet the minimum processing standards outlined in the plan.

#### Critical Limits for Nut Process 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.

FDA requires that the scientific basis be cited for the critical limit (e.g., regulatory guidelines, experimental studies, scientific publications) in the food safety plan. 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

FDA (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. Available at <http://www.cfsan.fda.gov/~dms/pnutguid.html>.

### Experimental Studies

Company X, Inc. Microbiology Dept, (City). Product - Challenge Study. Microbiologist, Last name, First Initial, year. Note book # or other identification.

If the process, such as 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, in order 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 U.S., for almonds, the time/temperature conditions for oil roasting to achieve a 4- or 5-log kill are in Table 1. Through a letter of determination issued to the Almond Board of California, FDA has not objected to use of the term “pasteurization,” if the almond processor can achieve a 5-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 between 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:

- 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 both batch and continuous systems, 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. Please note: Under the preventive controls rules, 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.

#### Continuous dry roasting:

Bed depth and belt speed should be monitored and controlled to ensure that 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 such as size/density, moisture, and incoming nut temperature may be critical; if they are, they need to be monitored.

#### Oil roasting:

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 also 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.

#### Steam/moist heat pasteurization:

Parameters should be monitored and recorded automatically for each batch. 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 rechecking readings to ensure compliance with the critical limits. In addition, 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:

- 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, traceability records.

## Illustrative Example: Critical Control Points 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 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 that instructions are developed, documented, communicated, and followed, and that responsible employees are designated and adequately trained, in order to meet the minimum metal detection and control standards outlined by this section.

### Critical Limits for Nut Process 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 also be a useful resource. These parameters are examples only and must be validated for specific types of metal and magnets/metal detection equipment.

The detecting limit for an end-point 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

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 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**

It is the responsibility of each facility to determine the appropriate monitoring activities and frequency of those activities. The food safety plan must document, in writing, the monitoring activities and corresponding frequencies selected by the facility. Monitoring is generally performed by an equipment/line operator. Examples of monitoring procedures for metal detection are provided below.

- Visual observation to ensure that the detector is on and that product is passing through the detector should be performed and documented at the start-up and end of each shift and approximately once every 2 hours during the shift.
- The reject mechanism should be tested at start-up and end of each shift and approximately once every 2 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 re-calibration 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.

### **CCP Verification Activities**

Functionality verification for electronic detection and rejection devices such as 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
  - This includes changes in primary packaging and/or formulation, whether between shifts or within a shift
- Following any repairs, maintenance, or adjustments
- On a regular basis 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 non-magnetic 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 that 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 also 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, for example 3 consecutive ones, to ensure that devices with pneumatic rejection mechanisms have enough air capacity to blow off a third consecutive sample.

Examples of verification activities include:

- 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
- QA and/or production management review and sign metal detector records within 7 working days of their generation (this is the timeframe required by FDA), and preferably daily or before product release
- QA performs system audit annually, reviewing procedures and paperwork for compliance and effectiveness
- Metal detector calibration per manufacturer's recommendation (e.g., annually), with calibration records reviewed and signed by the PC QI.

### **Record Location**

Examples of records include: metal detector calibration logs, metal detector verification records, hold and release records, corrective action records, traceability records.

## Appendix F. Pesticide Registration Information for Propylene Oxide and Ethylene Oxide

Please note that the registrations listed below are for the United States. Other countries may not allow the use of these chemicals or have different tolerances.

1. Propylene oxide (CAS Reg. No. 75-56-9; 40 CFR 180.491). Registered as a postharvest 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).
2. Propylene chlorohydrin. This is a reaction product from the use of propylene oxide as a postharvest fumigant; general residue tolerance is 10 ppm for tree nuts in crop group 14.
3. Ethylene Oxide (CAS Reg. No. 75-21-8; 40 CFR 180.151). Registered as a postharvest fumigant; general residue tolerance is 50 ppm in black walnut meats. Tolerance of 50 ppm in walnut is pending (proposed 12/31/08).

Sources: Pesticide Chemical News Guide, Edition of 7/1/09, Patrick D. Duggan, editor. Agra Informa, Inc. 2200 Claredon Blvd., Suite 1401, Arlington, VA 22201 ([www.foodregulation.com](http://www.foodregulation.com)).

IR 4 Detailed Report PR # 07903 C. IR-4 Project Headquarters,  
Rutgers, The State University of NJ.  
[http://ir4.rutgers.edu/FoodUse/food\\_Use2.cfm?PRnum=07903](http://ir4.rutgers.edu/FoodUse/food_Use2.cfm?PRnum=07903)

### **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 data is observed. If the offset in 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

##### 1. INTRODUCTION

Since peanut is a raw agricultural commodity, *Salmonella* is likely to be present. Peanut roasting, a dry heating process, is considered as a critical control point (CCP) to inactivate *Salmonella* on raw peanuts. 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 not likely to grow on raw peanuts with 6–8% moisture ( $a_w \leq 0.65$ ), but may survive some period of time. The Almond Board of California recommended 4-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 4-log reduction is adequate or if 5-log is needed) is being determined by on-going industry-led survey and further studies such as a risk assessment.

Each roasting operation must be evaluated for its efficacy in *Salmonella* inactivation. As the peanut loses moisture and the water activity ( $a_w$ ) of the product decreases, the lethality of the heat will be less effective against *Salmonella* (Shachar and Yaron, 2006). 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* that is consistent with the desired product characteristics. That is, roasting starts at the highest temperature of the profile and is lowered during roasting.

The roasting time/temperature profiles of the peanuts are affected by operational parameters such as peanut bed depth, air flow rate, air distribution, total roasting time (associated with belt speed), in addition to roaster air temperature. The peanut temperature and air temperature between peanuts typically increase at the slowest rate in the middle layer of the peanut 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.

In this study, the experiments were carried out with inoculated and un-inoculated 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 >5-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 & METHODS**

### **Inoculum Preparation & 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 TSB from the stock culture slants and incubated at 35°C for 22-24 hr. The TSB culture was centrifuged at 10,000 rpm for 10 min. After decanting the supernatant, the cell pellet was re-suspended 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<sup>10</sup> CFU/mL.

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 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 & 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, it is recommended that a higher number (e.g., 10-15) of probes be used to assess temperature uniformity and differences and to verify cold spot(s), especially when conducting temperature measurements in*

processing equipment. It is important to ensure that there are peanuts 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 Butterfield's Phosphate Buffer (BPB) for 2 min to obtain 1/10 dilution. After making serial dilutions with BPB, the appropriate dilutions were plated on duplicate XLD plates. The plates were incubated at 35°C for 48 hr 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 down 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 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 ten pre-roast samples and ten 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 that all of the nuts in the experimental trials received the same treatment and, 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 either calibrated with black/white tiles or calibrated 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 & DISCUSSION

**NOTE:** Tables and Figures are not included as part of 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 un-inoculated 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, it was expected that the variation in time/temperature profiles would be greater across the peanut bed as the peanut depth increases. 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 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 min 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 both *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 & T4 were the only temperatures plotted. The average log-reduction was >5.44-log (CFU/g). This result shows that that the log-reduction was comparable in 50/50 blend peanuts and the medium runners.

Final set of experiments were performed with medium runners inoculated with *Salmonella* Enteritidis BAA-1045 by roasting peanuts at 3.5” bed depth. The peanuts were roasted at this time 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 & CONCLUSION

The results of this study can be summarized as:

- 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 were both able to achieve  $\geq 5$ -log *Salmonella* reduction. The color (L-values) of the roasted peanuts was lighter than the target L-value ( $48 \pm 2$ ) 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 such as 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 all affect LSR and roasting quality such as color.
- There is a good correlation between the air temperature between peanuts and the peanut temperature. Toward to the end of the roasting, the difference between these two temperatures was smaller ( $\leq 5^{\circ}\text{F}$ ).
- 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 such as 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 such as 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 safe roasted peanuts, taking into account the equipment used in this study.
  - Incoming hot air flow rate must be secured at  $\geq 190$  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:  $48 \pm 2$ ).
  - 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 distance across the belt.
- Peanut-penetrating probes inserted into peanuts need to be embedded in the middle of the peanut bed 2 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 3 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 whether >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 5 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 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 3-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 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 that all peanuts are roasted using a process exceeding an equivalent of 5-log *Salmonella* reduction. Roaster temperature settings are calibrated for accuracy, and 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 that 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
--	--------------------------

<b>Validation</b>	First roaster zones	Second roaster zones	Third roaster zones
Minimum Equivalent Process Validated (Air Temp Delivered to Peanuts)	X min Y °F	X min Y °F	X min Y °F
<b>Verification</b>			
Critical Limits for Aeroglide Roaster (Air Temperature Settings)	X min Y °F	X min Y °F	X min Y °F
Roasting Process - Verified 12-04-08 (Air Temperature Settings)	X min Y °F	X min Y °F	X min $\geq$ Y °F
Roasting Process - Verified 12-04-08 (Air Temp Delivered to Peanuts)	X min Y °F	X min Y °F	X min Y °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 CCP Models:

$$F = F_R \times 10^{[(T_R - T)/z]}$$

T = temperature (°F)

F = the equivalent time required at actual applied temperature T

F<sub>R</sub> = the time required at given T<sub>R</sub> (i.e., the reference time/temp stated in Model 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 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<sub>R</sub> = 19.3 min (reference Model CCP, above)

T<sub>R</sub> = 284°F (reference Model CCP, above)

z = 78°F (reference Model CCP, above)

$$F = 19.3 \times 10^{[284-270]/78}$$

$$F = 19.3 \times 10^{0.179}$$

$$F = 19.3 \times 1.51$$

$$F = 29.2 \text{ min at } 270^\circ\text{F}$$

<b>Appendix J. Critical Factors Summary Sheet</b>					
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 Scalding 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. Scalding Temperature	198.0°F (minimum)		Continuously	Built in Temp Probe Chart Recorder/PLC	
3. Scalding Speed Setting	23.0 Hz (maximum)		Continuously	Chart Recorder/PLC	
4. Product Loading (Conveyor Setting)	25.0 Hz (maximum)		Continuously	Chart Recorder/PLC	
General Description/ Deviation Instructions					
<b>Product Identification:</b> Blanched Almonds					
<b>Product Segregation:</b> Incoming raw almonds are stored upon arrival in a separate warehouse; Blanched product is segregated in a finished product storage warehouse.					
<b>Product Packing:</b> 50 lbs cartons , bulk bins,					
<b>Deviation Instructions:</b>					
<ul style="list-style-type: none"> <li>• All involved product segregated immediately upon identification of a deviation</li> <li>• Production ceased immediately if deviation occurs and is noted during a run</li> <li>• All involved product to be further treated, re-blanched, and/or reviewed by Process Authority for disposition determination.</li> <li>• Production to resume once deviation is corrected and equipment has been properly cleaned and sanitized</li> </ul>					
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 0.3 $\mu$  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., 1 $\mu$  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. The water should meet potable water standards set by the Environmental Protection Agency (<http://www.epa.gov/safewater/contaminants/index.html>).
- 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.

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 acceptance 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™ [model 25020-50] HACH Free chlorine test [Model CN-70 or CN-66] LaMotte Colorimeter [Model 1200 CL] HF Scientific DPD chlorine photometer Helige DPD Merck Co. Aquamerck chlorine test 14760	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] <u>BAM Chapter 3.</u>	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:

- Is a plant lay-out map in place, designating each manufacturing area accordingly and showing traffic flow patterns between areas in order to prevent the transfer of microorganisms from the contaminated to the non-contaminated areas?
- Is there a structural separation in place between different areas (e.g., compartmentalization, closed pipes, and tanks of product)?
- Is there physical separation between raw product handling and other manufacturing areas?
- Are common coolers for storing raw ingredients and finished products or packaging/supplies prevented/adequately controlled?
- Are common docks for receiving of micro-sensitive ingredients and shipping of finished product prevented/adequately controlled?
- Are waste areas physically separated from production areas?
- Are common CIP systems between raw liquids and processed product prevented/adequately controlled?
- Is contamination via packaging material prevented?

### Traffic control:

- Are traffic patterns of people, trucks, materials, and equipment defined and controlled to prevent cross contamination?
- Are common elevators, hallways, etc., between different classified areas prevented/adequately controlled?
- Are separate vestibule facilities used as entrance/exit 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 missing floor grout repaired?
- Are floors maintained 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? Any water seepage noted between rooms/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:

- 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/hr 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 effective 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?

GMP measures:

- 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 GMP rules enforced for visitors and outside contractors?
- Are hand wash & 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/door foamers in place and maintained where applicable?
- Are sanitizer concentrations in foot baths/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/tools cleaned/sanitized after usage or dedicated to one area?
- Are common pipe connections for receiving or unloading of different liquid ingredients prevented or adequately controlled?

Sanitation controls:

- Are cleaning/sanitation procedures in place after equipment downtime and after maintenance activities (including activities of external contractors/suppliers) have been completed? Are sanitation controls/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 should not be decorated in any way (including decals, nail polish, etc.)
- Carrying objects above the belt or waistline (e.g., pens, flashlights, thermometers, etc.).
- Expectorating (spitting) in production areas
- Rings, watches, earrings, necklaces, other jewelry (including ornaments in exposed pierced body areas such as tongue and nose) should not be 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, but 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

### Clothing and personal equipment

- All clothing should be kept in good repair. 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, etc.). 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 GMP 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 walked 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 such as cigarettes, notepads, food, pens, etc.
- 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, 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.
- In addition, 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, 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 should not be decorated (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 provided 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 5 cm or 2 inches long), clasps, scarves or bandannas may be worn neatly under the hair net, but should not contain gem stones or decorative attachments.

Plant-supplied hair restraints should be worn in production areas.

- Hairnets/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/mustache restraint.
- Sideburns should be trimmed and be no longer than the bottom of the ear.

## **Appendix N. The 7-Steps of Dry Sanitation**

Many techniques and principles exist for cleaning food equipment, including the “7-Steps of Dry Sanitation.” The 7 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.

### Step 1: Sanitation Preparation

- Purge all systems – empty all product reservoirs
- Remove all ingredients, packaging, garbage
- Gather and stage safety gear, cleaning tools and supplies, sanitation chemicals, etc.

### Step 2: Secure and Disassemble Equipment

- Lock-out-tag-out (LOTO) - Secure equipment and de-energize
- Remove guards, release belt tension from all conveyors
- Remove parts such as belts, rollers, catch pans and take them for off-line cleaning
- Disassemble all other components: socks, dividers, molds, etc.
  - 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 – 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 – do not damage equipment)
- Detail brush down equipment – use correct brush
- Vacuum all remaining product fragments and hard to reach areas
- Wipe down equipment as necessary
- Clean framework and equipment legs
- Clean guards/parts off line as necessary
- Wipe excess grease from fittings

### Step 5: Post Inspection and Re-clean

- Run equipment for at least one cycle to dislodge any remaining soils
- LOTO - Self inspect equipment and area with flash light
- Ensure all food contact surfaces are free of all residues
- Re-clean as needed

### Step 6: Pre-operational Inspection Reassembly

- LOTO - Complete and document pre-operational inspection with flash light
- Correct any noted deficiencies and document
- LOTO - Reassemble equipment
- Remove Lockout lock and tag

Step 7: Sanitize and Final Release

- Document pre-operation inspection process and all corrective actions
- Sanitize – allow dry time, if necessary, to ensure complete drying
- Release to production

## Appendix O. The 7-Steps of Wet Sanitation

Many techniques and principles exist for cleaning food equipment, including the “7-Steps of Wet Sanitation”. The 7 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.

### 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
  - LOTO- Lock out all equipment requiring disassembly
- Disassemble equipment
  - Set up to handle equipment only twice (e.g., racks, stands)
  - NEVER place food contact equipment directly on floor
- Dry Clean
  - Remove gross soils from all equipment and floors
  - Take care with removal of allergens – Do Not Use Air
  - Work top down, side-to-side – use best tools for job

### Step 2 - Pre Rinse

- Remove/rinse visible gross soils (130°F) – personal protective equipment (PPE) 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 – one side to the other
- Use squeegees to clean up piles of debris
- Clean debris from drains - bring trash receptacles to drain, not carry drain materials across production areas to the trash receptacles.

### Step 3 - Soap and Scour

- Foam/Soap the floors, walls and equipment – PPE required
  - Work from bottom to top
    - Foam the floors
    - Foam the walls
      - Minimum of 5 feet from the floor
      - Working from bottom to top
    - Foam the equipment – working from bottom to top.
- After foam/soap is applied, allow 5 – 10 minutes set time
- While soap is setting, scrub surfaces to remove fats, protein films, and/or bio films
- DO NOT ALLOW FOAM/SOAP TO DRY – dry foam supports the development of bio-films
- 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-op

- 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
- Remove water from ceiling and overheads if applicable
- Re-lubricate where appropriate
- Sanitize parts/components that are not accessible once assembled – PPE
- Remove sanitation outerwear and put on appropriate GMP clothing
- Assemble applicable parts

#### Step 6 - Pre-Operation Inspection

- Complete the pre-operation inspection per plant procedure – LOTO
  - Use a powerful flashlight
  - Should be completed by someone other than the employee(s) performing the cleaning
- 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 - Sanitizing

- Ensure no standing or pooling water before beginning
- Flood-sanitize the equipment at no rinse concentrations – 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 (5' 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 Quat).
  - Do not rinse with water. Allow to drain and air dry.
  - Work your way out of the room
- Squeegee pooling sanitizer to drain
- Release line to production or maintenance

**Appendix P. Examples of Sanitation and Good Housekeeping Practices**

Water Handling	<p>Water should not be splashed from the floor or from unclean equipment onto cleaned equipment or processes during operation.</p> <p>Water from cleaning operations in one area should be prevented from flowing into areas where product is being produced.</p>
Sanitary Handling of Sanitation Tools and Equipment	<p>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 <i>used, dedicated, handled and/or stored</i>:</p> <ul style="list-style-type: none"> <li>• In raw areas</li> <li>• In ready-to-eat areas</li> <li>• According to allergen control programs</li> <li>• According to color code programs</li> </ul>
Gaskets Handling	<p>Gaskets should be handled and stored in a sanitary manner:</p> <ul style="list-style-type: none"> <li>• Product-contact gaskets should be cleaned or replaced at a defined frequency.</li> <li>• Used or damaged/worn gaskets should be discarded to prevent inadvertent later use.</li> <li>• New gaskets should be washed before use.</li> <li>• Clean gaskets should be stored in a designated sanitary container.</li> </ul>
Cleaning and Handling of Product Equipment	<p>Cleaned equipment should be handled in a manner that maintains its sanitary condition and that prevents damage, including:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Cleaned equipment should not be dragged across the floor or walking surfaces.</li> <li>• Clean parts should not be stored in unclean containers.</li> <li>• Clean parts should not be stored with dirty parts.</li> </ul>

<p>Sanitary Mats</p>	<p>Designated sanitary mats should be handled to maintain sanitary conditions, including:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• When not in use, mats should be stored off of the floor in a manner that allows them to dry (e.g., on a hanger designed to hold mats).</li> </ul> <p><i>Note:</i> Rubber mats used for employee comfort at workstations should be distinguishable (e.g., by color) from sanitary mats.</p>
<p>Good Housekeeping</p>	<p>General Do’s and Don’ts</p> <ul style="list-style-type: none"> <li>• Avoid spillage and damage to product by careful handling.</li> <li>• Maintain bagged product in a neat and orderly manner.</li> <li>• Avoid product overhang on pallets.</li> <li>• Damaged bags or drums should be immediately sealed to prevent product spillage and contamination.</li> <li>• Contaminated ingredients should not be used.</li> <li>• Littering or practices that cause poor housekeeping or other unsanitary conditions should be prohibited.</li> <li>• All waste and refuse should be placed in trash containers, which should be labeled as “trash” or otherwise identified by specific plant programs and training.</li> <li>• Trash containers should be maintained in a sanitary condition by using liners and/or routine cleaning of the containers.</li> </ul>
<p>Accessories Brought into Production Area</p>	<p>Radios, cameras, televisions, cell phones, books, and magazines should not be allowed in production areas unless permitted by local policies.</p> <p>Other areas where these items are allowed should be defined by site-specific rules.</p> <p>Live plants, flowers, or animals should not be brought into:</p> <ul style="list-style-type: none"> <li>• Production areas</li> <li>• Production area offices</li> <li>• Corridors opening directly into production areas</li> <li>• Areas connected by a common air supply to production</li> </ul>
<p>Preventing Aerosols on Finished Product and Product Contact Surfaces</p>	<p>Near sanitized equipment and in areas of exposed finished product, water hoses or compressed air hoses should not be used to clean the floor or equipment due to the formation of aerosols.</p> <p>Use of high-pressure water greater than 100 psi/7 bar should be restricted to use 2 hours prior to sanitizing and should not be used during operation.</p>

**Appendix Q. Proper Storage**

<p>Designated Storage Practices</p>	<p>Product or ingredient containers should <u>not</u> be stored immediately adjacent to containers for waste or non-product items (e.g., cleaning compounds, laboratory solvents).</p> <p>Non-product items should be stored in separate, designated areas.</p> <p>All items should be stored to avoid direct contact with the floor or walking surfaces (e.g., on pallets, slipsheets, or racks).</p> <ul style="list-style-type: none"> <li>• Where slipsheeting operations are used, the slipsheeted product may be stored directly on the floor, provided there are no sources of contamination.</li> <li>• Sitting or standing on product shipping cases should not be allowed.</li> <li>• Over-stacking of product should be avoided. Product should be stacked to appropriate heights.</li> </ul>
<p>Ingredient Storage Practices</p>	<p>Ingredients should be adequately protected and stored in a sanitary manner.</p> <ul style="list-style-type: none"> <li>• In the original, labeled container, or</li> <li>• In another authorized sanitary container that is clearly marked for the use of the specific ingredient (e.g., sanitary pails or tote bins).</li> <li>• Ingredient identification and lot number/ traceability should be maintained.</li> <li>• Containers should be properly closed/sealed/covered.</li> <li>• When returning ingredient containers to storage, ingredients should be stored in the proper temperature environment.</li> </ul> <p>Bulk pre-weighed ingredients should be stored in appropriate approved containers.</p>
<p>Packaging Storage Practices</p>	<p>Packaging materials, in full or partial quantities, should be adequately protected and stored in a sanitary manner.</p> <ul style="list-style-type: none"> <li>• Material should be covered to prevent contamination (e.g., closures, films, etc.)</li> <li>• Packaging material should be removed from the area during wet cleaning.</li> <li>• Packaging materials should not be stored directly on walking surfaces.</li> <li>• Maintain the identification and traceability of packaging materials.</li> </ul>

Rework Handling & Storage	Rework product should be adequately covered/protected during breaks, lunch periods, downtime, etc. with clean plastic or other suitable material. Traceability of rework should be maintained.
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## 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.”

### I. 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.

### II. RESPONSIBILITY:

**Corporate and Plant Operations** 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** 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 and shall further ensure that the responsibilities are clearly defined, documented, understood, and implemented.

**Plant Quality Lead** 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.**

**Platform Quality** provides assistance and support, as needed, and periodically assesses state-of-the-art capabilities of metal detection.

**Corporate Engineering** provides technically-based recommendations regarding metal detection systems with the capabilities to reduce or eliminate metal contaminants.

### III. DEFINITIONS:

**Metal Detection System** – Personnel, procedures, and equipment designed to work together to reduce or eliminate metal contaminants in finished products.

**Foreign Material** – An object, either extraneous or indigenous, that is not intended to be part of the product formulation, non-edible, such as but not limited to 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 kicked off when a positive is detected.

### IV. 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/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. Metallic test samples shall be detected according to the supplied table in Section VII below. Deviations from these minimum detection sizes shall be documented in writing by the facility and evaluated by Corporate Quality.
  - 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 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 not available, the list shall be generated by the responsible implementation team. 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 such as 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 in close proximity or alongside other metal detectors in the facility shall be calibrated to operate at different frequencies in order 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 3 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 8 feet per minute.
3. Metal detection system sanitary and safety requirements:
  - a. Metal detection system must meet the sanitary design requirements (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/state regulations for metal detection systems are in compliance (certification, registration, annual audits, etc.).
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.
  - c. Specified detection capabilities shall be verified on the production line following installation and start up.
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 temperature and rate through the metal detector.
  - b. Consistent product flow through the center of the metal detector aperture.
  - c. Consistent product speed (at or above 8 ft/min) through the center of the metal detector aperture.
  - d. Consistent product effect (background sensitivity of each unique product)
  - e. 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. A test product/package to which a test sample contaminant is attached or inserted shall be passed through the detector three times and be successfully rejected.
  - ii. The test sample shall be placed on top of the package, or inserted in the package as near to the center of the test package and metal detector aperture as possible.
  - iii. The contaminated test sample package used must be consistently identical to the products being run on the line and at the sensitivity appropriate to the detection limits set for the line.
  - iv. At Corporate Quality Assurance's discretion, the testing procedure can be simplified 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 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 2 additional times.
  - iii. If the package passed through all 3 times without being rejected, the package can be considered acceptable; if it did not pass, then the package is rejected, taken apart, and the source of the rejection is identified.
- b. If a metal detection system is not working properly, the following is to 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 period 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 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.

10. Metal detection system verification activities

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.

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 are available upon request.
- c. The Corrective Action Records shall be located in a designated location and are available upon request.
- d. Verification records shall be located in a designated location and are available upon request.
- e. Calibration records and x-ray test standards shall be located in a designated location and are available upon request.

V. RELATED DOCUMENTATION:

- The Food Defect Action Levels by FDA  
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/sanitation/transportation/ucm056174.htm>
- FDA CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects.  
Available at:  
<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074554.htm>

VI. REVISION HISTORY:

Date	Revision	Reason	By

VII. SENSITIVITY REQUIREMENTS:

Aperture Height	Product Classification	Sensitivity Standards
Up to 50 mm	Dry Product	1.0 mm Diameter (Ferrous & Non)
	Wet Conductive Product	1.5 mm Diameter (Ferrous & Non)
	Wet Non-Conductive Product	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 to be in compliance with above noted sensitivities shall be brought to the attention of Corporate Quality for further review and action.*