



INDUSTRY HANDBOOK  
FOR  
SAFE PROCESSING OF NUTS

November 4, 2009

## **ACKNOWLEDGEMENTS**

The Grocery Manufacturers Association (GMA) gratefully acknowledges the contributions of GMA member and non-member companies that have shared materials and provided direction to the *Industry Handbook for Safe Processing of Nuts*, first edition.

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## CHAPTER 1 – 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, the Grocery Manufacturers Association (GMA), the American Peanut Council (APC), the Peanut & Tree Nut Processors Association (PTNPA), the American Council for Food Safety & Quality, the American Peanut Shellers Association (APSA), the National Pecan Shellers Association, the Administrative Committee for Pistachios, the California Pistachio Research Board, the Western Pistachio Association and the California Walnut Board have developed this publication, *Industry Handbook for Safe Processing of Nuts*, and the addenda or references, *Industry Handbook for the Safe Shelling of Peanuts* and *Good Agricultural Practices for California Pistachio Growers*. 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.

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.

### 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 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. 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.

It is recommended that raw materials provided to shellers, hullers, dehydrators, handlers, processors, and/or manufacturers be produced according to Good Agricultural Practices (GAP). *Good Agricultural Practices for Peanut Growing and Harvesting*, *Good Manufacturing Practices for Peanut Buying Points*, and *Good Agricultural Practices for Farmer Stock Storage and Handling* will be included with the *Industry Handbook for the Safe Shelling of Peanuts* for reference when available. *Good Agricultural Practices for California Pistachio Growers* is attached as an addendum to the *Industry Handbook for Safe Processing of Nuts*. Other references under development, such as GAP guidelines for pecans and walnuts will be provided when available.

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 remain 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 retrievals 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 obtain and maintain a duplicate sample of the lot examined by the external regulatory bodies.

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 about the Reportable Food Registry is available at <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm>).

## CHAPTER 2 – FOOD SAFETY PLAN

A commonly used framework for a food safety plan is the Hazard Analysis and Critical Control Point (HACCP) system. The HACCP system is a preventive approach to control food safety. Philosophically, HACCP involves a proactive, preventive approach to control potential 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. 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), which should be met to ensure the CCP is under control. Principle 4 involves establishing a system to monitor control of the CCP by scheduled measurements or observations. Principle 5 involves establishing the corrective actions to be taken when monitoring indicates a deviation from critical limit and that a particular CCP is not under control. Principle 6 is to establish 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.

It is recommended that all products and/or processes have an approved HACCP plan, as defined by the NACMCF or Codex guidance. At least one of the HACCP team members should be trained in HACCP, and one of the approvers should also be HACCP-trained. Trained approvers do not necessarily need to work at the same company as the creator(s) of the HACCP plan. The HACCP guidelines described here are intended for use by an expert, cross-functional team formed to develop a HACCP plan. The NACMCF and Codex documents, and examples provided in this Handbook are tools for the development, implementation, maintenance, and auditing of a HACCP plan. They also create common criteria for assessing hazards and identifying CCPs across shelling/hulling, processing, handling, or manufacturing to assure the safety of nuts and nut products.

### 2.1 Hazard Analysis and Risk Evaluation

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. A microbiologist should be involved during the

biological portion of the hazard analysis and risk evaluation step of HACCP plan development.

It is helpful for each facility to have a HACCP team leader who can take responsibility for the maintenance and upkeep of the plan documents. NACMCF and Codex 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.

### 2.1.1 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). Product safety hazards that are significant and should be controlled in the HACCP plan (CCPs) are identified by completing a risk evaluation.

### 2.1.2 Conduct a Hazard Analysis

During the hazard analysis, the HACCP 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.

#### 2.1.2.1 Hazard Identification

To identify the potential hazards, the following assessments should be completed and documented. The following information should be available to all developers, approvers, and reviewers of HACCP plans.

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 HACCP team creates a potential hazard list by reviewing information about:

- Raw materials and ingredients, processing aids, rework
- Packaging materials in direct contact with finished product
- Activities conducted at each process step, including handling and environmental conditions
- Equipment used to make the product

In the hazard identification process, the HACCP team may review the potential for undeclared allergens due to 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 include:

Biological:

*Salmonella* from incoming raw nuts/ingredients (e.g., peanuts, almonds, spices, dairy)  
*Salmonella* due to environmental re-contamination  
 Enteric pathogens from handling  
*Staphylococcus aureus* growth from time/temperature abuse  
*Salmonella* contamination from dust

	<i>Salmonella</i> due to re-contamination from condensate Pathogen growth during storage (if applicable)
<u>Chemical:</u>	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)
<u>Physical:</u>	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 or raw product packaging material

### 2.1.2.2 Hazard Evaluation

After listing of potential biological, chemical, and physical hazards, the HACCP 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.

Severity should be determined taking into consideration 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 PPs
- 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 GMPs

In the determination of whether a hazard is reasonably likely to occur, the HACCP team may consider the following: likelihood of presence at levels likely to cause illness or injury; whether the adverse effect of the hazard is a result of a single exposure (acute), or it takes multiple or chronic (i.e., long-term or lifetime) exposures. The HACCP team may also review applicable PPs that may be used to manage potential hazards, and ensure that the PPs are documented and implemented. Examples of applicable PPs:

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

Further elaboration of using the two-stage risk evaluation approach to conduct a hazard analysis can be found in published technical papers (Bernard et al., 2006; Bernard and Scott, 2007). Regulatory agencies have clarified that it is inappropriate to control significant hazards using PPs. If the hazard is reasonably likely to occur in the absence of control, then a CCP must be used to control the hazard.

### 2.1.3 Design Hazards Out

The most effective method to eliminate a hazard is to design it out of the product or process. Therefore, after identifying a hazard, each hazard should be assessed for the feasibility of designing it out. For example, wheat maltodextrin, an allergen, could be replaced with corn maltodextrin, thereby designing out the hazard.

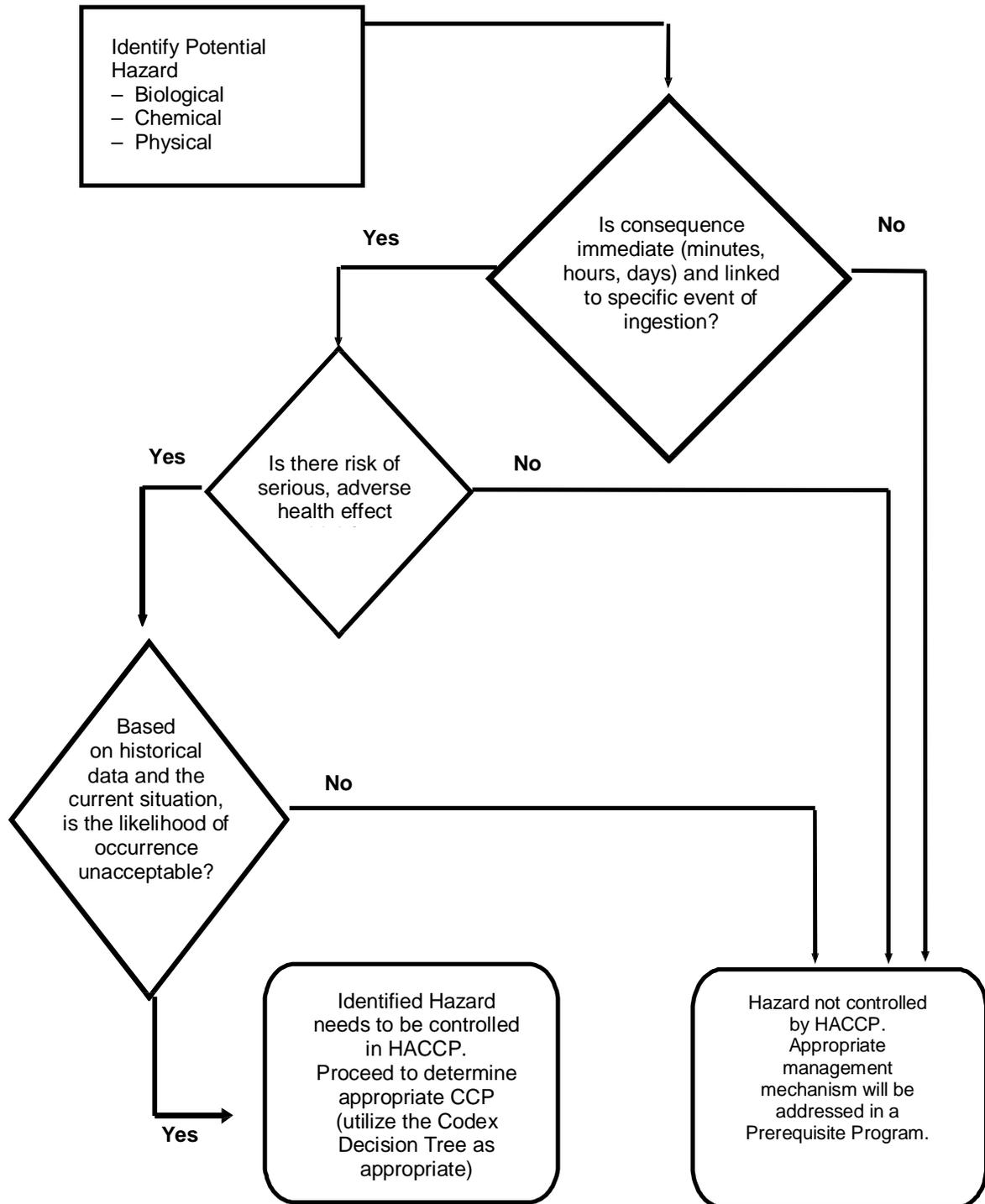
Hazards that cannot be designed out and are assessed as likely to be present in the finished product should be continuously and strictly controlled. These hazards are best managed by a CCP. Hazards that can be effectively prevented or are at levels not likely to cause the product to be unsafe are most effectively managed through prerequisite programs.

### 2.1.4 Hazard Evaluation Flow Chart

After a list of potential hazards has been identified, the HACCP team may use the Hazard Evaluation Flow Chart (Diagram 1, below) to aid in the determination of significant hazards that need to be controlled in the HACCP plan by a CCP, or potential hazards that can be managed outside the HACCP plan by a PP.

As described above, a key concept in assessment of the risk posed by a hazard is the nature of the identified hazard. For example, is the adverse effect of the hazard a result of a single exposure (acute), or does it take multiple or chronic (i.e., long-term or lifetime) exposures? Is the hazard likely to lead to significant illness or injury in a relatively short time frame (minutes, hours or days) or does it take much longer (months or years)? The answers to these questions will help determine if the hazard will be managed as a CCP or in a PP. For example, pathogens clearly are capable of causing serious, adverse health effect based on scientific evidence. However, other concerns such as molds, yeasts, and certain food intolerances are not known to cause serious, adverse health effect based on scientific evidence and should be addressed in a PP or a quality control program.

DIAGRAM 1. HAZARD EVALUATION FLOW CHART



## 2.2 Hazards and Hazard Management Criteria

Guidance for how to determine whether a process step is a CCP for a significant hazard identified in the hazard analysis is provided in the NACMCF document (NACMCF, 1998), the Codex document (CAC, 2003), and the GMA HACCP manual (Scott and Stevenson, 2006). The HACCP team may use a decision tree, such as the Codex Decision Tree (Diagram 2 below) to aid in the determination of whether a particular step on the process flow diagram is a CCP.

### 2.2.1 Hazards Controlled by CCPs

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

- Acute illness/injury;
- Occurrence of adverse effects within a predictable period of time following ingestion, e.g., minutes/hours/days.

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 and are most effectively managed as CCPs.

### 2.2.2 Hazards Managed by PPs

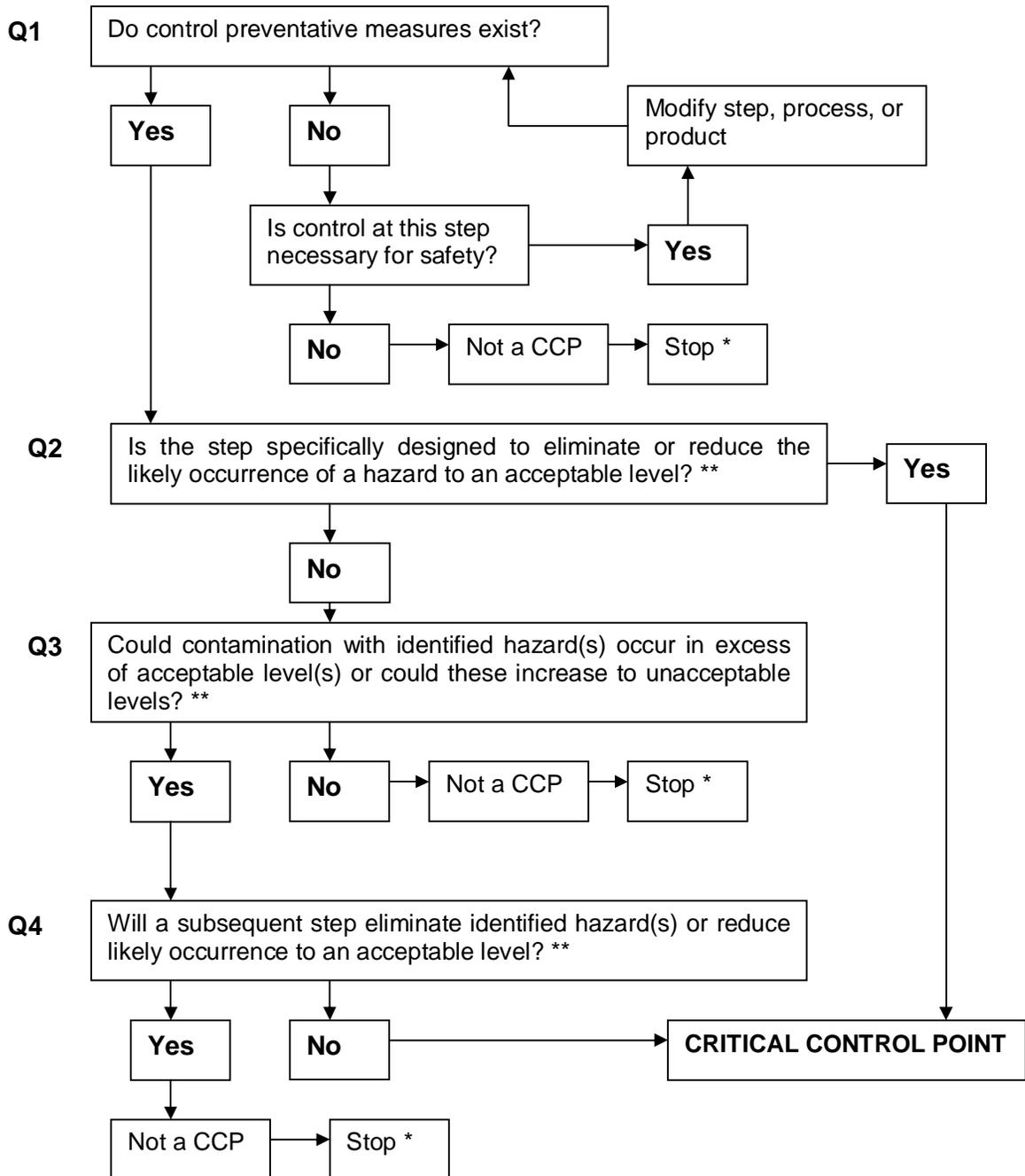
Potential hazards such as mycotoxins, and under some circumstances pesticides, tend to be viewed as having the following characteristics:

- Occurrence of illness after long term, chronic exposure (perhaps years) to the causative material; and,
- Difficulty in attributing a particular adverse effect to a specific event due to the widespread occurrence of the causative agent in the food supply.

These risks may be effectively managed by growers, using Good Agricultural Practices (GAPs), and shellers/hullers, using GMPs 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.

DIAGRAM 2. EXAMPLE OF DECISION TREE TO IDENTIFY CCPs (CODEX DECISION TREE)

(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 CCPs of HACCP plan.

## 2.2.3 Examples of Hazards Addressed by CCPs vs. PPs

### 2.2.3.1 Biological Hazards

For nuts, the organism of primary focus is *Salmonella*, as a result of this 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.

This organism need only be present in the food to cause illness. 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 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), as well as by implementing a program to prevent post-lethality recontamination prior to packaging (GMA, 2009).

Processors of a ready-to-eat nut product may or may not have a 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"), they will need to have a supplier approval program to ensure that *Salmonella* is not a hazard likely to occur in the ingredient.

Shellers/hullers who provide raw nuts as a non-ready-to-eat ingredient may not have a CCP to eliminate *Salmonella* in their process. However, they should have PPs in place to prevent *Salmonella* growth and minimize contamination.

COAs are managed in two ways. A COA is generated from the analysis of a sensitive ingredient and is used to designate that the particular lot of sensitive ingredient has been tested for the target pathogens(s) according to the defined sampling plan and testing method, and that the pathogen(s) were not detected. The receipt of COAs for this ingredient should only be managed as a CCP when the ingredient is used in a product with no lethal process step or when added after the lethal process step. There may be situations where a processor receives some sensitive ingredients that will receive a lethal process step, but others that do not, because they are added after the lethal step. In these situations, the COAs on the ingredients receiving a lethal process step 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. See Appendix 1 for sampling plans, sampling techniques, and results interpretation.

### 2.2.3.2 Chemical Hazards

Mycotoxins, antibiotics, pesticides, food allergens, and sulfites are potential chemical hazards. A major potential chemical hazard associated with nut processes is an allergen.

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

The exact prevalence of reactions to each of the allergens is unknown, but the occurrence of all true food allergies has been estimated to be about 2% of the adult population. Children tend to have a greater prevalence of allergic reactions (about 6-8%), but some of these may disappear with age (e.g., allergies associated with milk). The number of allergic individuals who are exquisitely sensitive to a particular allergen is unknown.

Foods implicated in allergies are inherently safe and wholesome foods, or food ingredients, to most consumers, but pose a health risk to a small percentage of certain allergen-sensitive individuals. The list of foods which could be considered allergens can vary so check with regional authorities to determine which foods or ingredients could be managed as an allergen. A couple of examples of allergen lists are those from the FDA and CODEX.

In the U.S., the Food Allergen Labeling and Consumer Protection Act (FALCPA) defines a major food allergen as an ingredient that is one of the following foods or in the following food groups or is an ingredient that contains protein derived from one of the following:

1. Milk
2. Egg
3. Fish
4. Crustacean shellfish
5. Tree nuts
6. Wheat
7. Peanuts
8. Soybeans.

According to CODEX STAN 1-1985 (Revised 2008) Section 4.2.1.4, the following foods and ingredients are known to cause allergic reactions or hypersensitivity:

- Cereals containing gluten (i.e., wheat, rye, barley, oats, spelt, or their hybridized strains and products of these);
- Crustacea and products of these;
- Eggs and egg products;
- Fish and fish products;
- Peanuts, soybeans, and products of these;
- Milk and milk products (lactose included);
- Tree nuts and nut products; and
- Sulfites in concentrations of 10 mg/kg or more.

In these two examples, differences exist between the FDA allergen list and the CODEX allergen list. Since variations occur, refer to regional regulations when determining if a food or ingredient is considered an allergen.

A true allergic reaction involves the sensitive individual's immune system, and constitutes an immune response to a foreign protein. A small amount of food protein (i.e., the allergen) enters the body and elicits a reaction with certain immune system components (i.e., IgE immunoglobulins) that initiates the allergic response. The exact amount or level of these allergens necessary to elicit a serious reaction in sensitive individuals can vary, but is believed to be extremely small (milligram quantities or less) in those subpopulations that are exquisitely sensitive. A non-immunological reaction to foods, also known as food intolerance, is generally less severe but has been associated, in some instances, with

severe reactions. An example of such a reaction is sulfite-induced asthma. Since this is a non-immunological response, it is technically not a food allergy.

In addition to foods and ingredients known to cause allergic reactions, allergen lists may contain other materials that induce food intolerance reactions (e.g., sulfites and Yellow No. 5). If food intolerance materials are included in an allergen list, the term “allergen” will be used in a manner that includes all of the compounds listed.

In most cases, due to the low likelihood of occurrence and/or the nature of the hazard, chemical hazards (including allergens) are often managed by PPs. However, in certain instances a CCP may be the appropriate control for a food allergen. The following control measures and activities generally are part of a robust and thorough allergen control program.

- **Rework Handling:** Allergen-containing rework or holdover product must only be reincorporated into the same and/or appropriately labeled product.
- **Labeling:** Label controls should be in place for both the design and use/application of proper and accurate labeling. Processors should only have printed packaging material in the packaging area that is representative of the product being produced at that time. Processors should not keep packaging for items other than those immediately being produced in the packaging area.
- **Product Sequencing:** When possible, an allergen-containing product should never be followed by a product that does not contain an allergen. By scheduling the allergen-containing product at the end of the manufacturing run, the risk of cross-contact can be significantly reduced.
- **Product Changeover:** When changeover takes place from one allergen to another allergen, or non-allergen, there should be thorough, validated procedures in place for the removal of allergen-containing product prior to producing the non-allergen containing product. These activities may include cleaning, flushing, testing of subsequent product produced, surface swabbing, and inspection.
- **Traffic Patterns:** Traffic patterns should be carefully examined and controls put in place to prevent inadvertent cross-contact during the routine flow of materials and personnel. Controls may include covering belts that transport materials to prevent allergen-containing ingredients from falling from one belt to another.
- **Ingredient Assessment:** The ingredient specification should include a statement that the material being purchased is free of allergens except those listed on the ingredient declaration. Close cooperation and communication with suppliers is essential. A detailed review of allergen management practices and an on-site audit are recommended to verify that proper practices and procedures are in place and fully functioning.

While many companies address allergen management with a comprehensive PP, in certain operations the PP may not be adequate to justify that undeclared allergen is not reasonably likely to occur and, therefore, the hazard analysis outcome may dictate that certain aspects of an allergen management system may in fact be CCPs. For more detail on allergen management programs, see Chapter 3, Section 3.7.

### **2.2.3.3 Physical Hazards**

In general, extraneous matter is defined as any object/material 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 effect; 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, and preventive maintenance.

In some cases, the characteristics (size, shape and type) of the extraneous matter 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. If the hazard analysis determines that a potential physical hazard is likely to occur, it should be controlled by a CCP.

The HACCP team can use the Hazard Evaluation Flow Chart to help determine whether or not a potential physical hazard posed by extraneous matter needs to be controlled in HACCP. The following criteria may be used to establish the CCP(s) or PP(s):

- The CCP or PP for glass packaging is the clean-up of glass (following a breakage incident), post-filling (or after the glass cleaner/inverter), prior to package capping, if a detection/removal device for glass is not on the line. The inspection of the cleaning process should be documented. In addition, glass filling lines should have covered conveyors over exposed open jars after the jar cleaner/inverter (prior to filling and capping) to minimize the potential for extraneous glass falling into an open jar.
- An extraneous detection/removal device that is present on a line/process is a CCP if its primary purpose is to prevent, eliminate, or reduce to an acceptable level hazardous extraneous matter in the product and it is the last and/or most effective extraneous detection/removal device on that line/process.

Physical hazards removal/detection devices may include:

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

For example, within a manufacturing facility the HACCP team may determine that metal is likely to occur and, therefore, the final metal detectors are considered to be CCPs. Depending on the operations, one or more than one detection/removal device may be designated as CCPs.

## 2.3 Critical Control Points to Eliminate *Salmonella*

### 2.3.1 Objective

All facilities supplying processed tree nuts, peanuts, and/or associated products (e.g., nut pastes, marzipan, nut flours) should have effective processing conditions in place to control all significant hazards identified in the hazard analysis. This section focuses on CCP(s) designed to eliminate *Salmonella*.

*Salmonella* may be present in incoming raw nuts. As described above, thermal processing (oil roasting, dry roasting), gas treatment (e.g., propylene oxide (PPO) for certain nuts), and other control measures can be effective mechanisms to control this hazard. 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 the United States: processing conditions should 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 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, they will be included in updates to this document.

### 2.3.2 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.

### 2.3.3 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 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 or with a prescribed *Salmonella* reduction. The temperature of product entering the thermal process should be greater than the minimum initial temperature (lowest temperature) established during validation.

The scientific basis should be cited for the critical limit (e.g., regulatory guidelines, experimental studies, scientific publications). The following are examples of writing style conventions for scientific citation:

#### Scientific Publication

Smith, A.B. 1996. Thermal Processes for Foods. J. Food Sci. 47:650-657.

#### Regulatory Guideline

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 nut processor's process, such as a heat treatment, is lower than the prescribed process parameters recommended, then the process should be validated 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 section 2.7 of this Chapter.

#### Critical Limit Example - Oil Roasting

The values for critical times to achieve a 4- or 5-log kill in almonds were generated by Dr. Linda Harris at the University of California, Davis. In the U.S., for almonds, the

time/temperature conditions for oil roasting to achieve a 4- or 5-log kill are listed below. If the almond processor can achieve a 5-log kill, then the FDA allows the claim of “pasteurized.” 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.

Time/Temperature Conditions for Oil Roasting Almonds

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.

See Appendix 2 for additional examples for critical limits for other processes.

### 2.3.4 Monitoring Activity and Frequency

Examples of monitoring procedures for dry roasting, oil roasting, and steam pasteurization are provided below.

- 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. If the temperature cannot be measured between the nuts, a process validation should be performed to correlate oven/air/oil/steam temperature at the coldest spot with nut/nut bed temperature.
- 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.

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 and filed with the HACCP plan. For continuous oil roasters, belt speed should also be monitored to ensure the maximum speed is not exceeded as per process validation data.

Steam pasteurization:

Parameters should be monitored and recorded automatically for each batch. The system should stop the process if the critical limits are not met. Data should be reviewed at a frequency to demonstrate control.

### 2.3.5 Corrective Action Activity

In the event that a deviation is noted, the processor or supplier should have documented corrective actions in place to manage under-processed product and to sanitize all food contact surfaces exposed to under-processed product. In the event that a deviation is noted during processing, post-processing, or after packaging, all product since the last documented time that there was no deviation should be placed on quarantine hold pending product review and determination of product disposition. In cases where deviations from critical limits are detected during a review of records, after finished product is produced, all affected product should be placed on quarantine hold and the designated personnel notified to determine disposition. Hold/Release documentation should be available.

For example, 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 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).

### 2.3.6 CCP Verification Activities

Verification activities should be performed for each CCP to verify that the CCP critical limits are within control. These activities should be performed at a frequency sufficient to demonstrate control.

Examples of verification activities include:

- A designated plant employee review of records prior to release of product.
- 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.

### 2.3.7 Responsibility for Implementation of CCPs

Trained employees should be designated for monitoring and initiating corrective actions, and for CCP verification. It is recommended that appropriate members of the HACCP team be involved in corrective actions should a deviation to a critical limit occur, and in CCP verification as appropriate.

### 2.3.8 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.

## 2.4 Critical Control Points to Eliminate Metal

### 2.4.1 Objective

Nut manufacturers receive peanuts or tree nuts that, when harvested, may contain dirt, sticks, stones, nut grass, field glass, field metal, other nuts, and bone fragments. The majority of these potential hazards are managed at the sheller locations through PPs. This section focuses on CCPs designed to eliminate metal fragments, in an operation where the HACCP team concludes in the hazard analysis that metal fragments are reasonably likely to occur given PPs in place and, unless controlled, are likely to cause a significant injury.

### 2.4.2 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.

### 2.4.3 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. These parameters are examples only and must be validated for specific types of metal and magnets/metal detection equipment.

The scientific basis should be cited for the critical limit (e.g., regulatory guidelines, experimental studies, scientific publications). The following are examples of writing style conventions for scientific citation:

#### Scientific Publication

Author, Date. Title. Publication. Metal Detection in Nuts and Grains. J. Food Sci. Vol #: pages.

#### Regulatory Guideline

FDA (Food and Drug Administration). CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects. Available at:  
<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074554.htm>

#### Experimental Studies

Company X, Inc. Engineering and QA Depts, (City, Country). Product Study. Engineer and/or QA representative, Last name, First Initial, year. Notebook # or other identification.

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. As a guide, the detection sensitivity under production conditions should be capable of detecting and rejecting pieces equal to or less than:

- 1.5mm for ferrous
- 2.0mm for non-ferrous (brass)
- 2.5mm for stainless steel (316 grade)
- At no time should they be larger than 7mm for all metals

The FDA Health Hazard Evaluation Board “found that foreign objects that are less than 7mm, maximum dimension, rarely cause trauma or serious injury except in special risk

groups such as infants, surgery patients, and the elderly.”

<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074554.htm>

The reject mechanism should direct product rejects from the process flow automatically into an identified area, bin, or container. An action level should be defined on the basis of historical trend analysis.

- If this action level is exceeded, then all diverted rejected product should be evaluated to determine the cause for rejection.
- Where no action level is defined, 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.
- 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.

#### **2.4.4 Monitoring Activity and Frequency**

Examples of monitoring procedures for metal detection are provided below.

- Visual observation to ensure detector is working properly and product is passing through the detector should be taken at 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.
- Monitoring is generally performed by an equipment/line operator.

#### **2.4.5 Corrective Action Activity**

In the event a deviation is noted, the manufacturer should have documented corrective actions in place to manage product hold and disposition, equipment repair, calibration and verification, and/or line clean-up, inspection, and restart, depending upon the reason for the deviation. In the event a deviation is noted during or after operations, all product produced since the last documented time that there was no deviation should be placed on hold pending product review and determination of product disposition. In cases where deviations from critical limits are detected during a review of records, after nuts are packaged, all affected product should be placed on hold and the designated personnel notified to determine disposition. Hold/Release documentation should be available.

For example, corrective action for deviations to critical limits at the metal detector may include repair or re-calibration of metal detector or replacement of 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 or controlled disposal of rejected nuts/finished product.

### 2.4.6 CCP Verification Activities

Verification activities should be performed for each CCP to verify that the CCP critical limits are within control. These activities should be performed at a frequency sufficient to demonstrate control.

Functionality verification for electronic detection and rejection devices should take place during production with the normal product flow. As an example, frequencies for system verification should occur at the following times:

- 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 changeover
- 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, 2 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. 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.

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 once/shift
- QA and/or production management review and sign metal detector records daily
- QA performs HACCP system audit annually, reviewing procedures and paperwork for compliance and effectiveness
- Metal detector calibration per manufacturer's recommendation (e.g., annually)

### 2.4.7 Responsibility for Implementation of CCPs

Trained employees should be designated for monitoring and initiating corrective actions, and for CCP verification. It may be beneficial to involve members of the HACCP team in corrective actions should a deviation to a critical limit occur, and in CCP verification as appropriate.

### 2.4.8 Record Location

All records should have a designated, secure location. Examples of records include: metal detector calibration logs, metal detector verification records, hold and release records, corrective action records, traceability records.

## 2.5 HACCP Plan Administration

A completed HACCP plan should contain the following components:

- Product/Product Category Description
- Process Flow Diagram

Ingredient/Packaging Assessment  
 Processing Step Evaluation  
 Allergen Cross-contact Production Assessment  
 Critical Control Point (CCP) Documentation  
 HACCP Plan Approval

Forms are acceptable if they follow NACMCF and/or Codex principles and guidelines. Example forms can be found in Appendix 3. Format of the forms is optional as long as the appropriate content is present. Retention time for HACCP records should be at least as long as the shelf-life of finished product, or as designated in company policies, FDA regulations, or other appropriate regulatory standards.

## 2.6 HACCP System Validation Procedures

HACCP plan validation ensures that all hazards have been identified, every hazard is being effectively controlled to the degree necessary, and only significant hazards are controlled within the HACCP system. HACCP system validation involves the collection and evaluation of scientific, historical, and technical information to assess whether the HACCP plan, when properly implemented, efficiently identifies and controls all food safety hazards and emerging issues associated with the product or process.

As described above, a CCP for a kill step must be validated and the validation (both laboratory studies and in-plant studies) should be performed by qualified personnel such as a process authority.

### When to validate a HACCP plan

- New plans or significantly changed existing plans
- Whenever there is a systematic or recurring product safety issue, or industry recall of similar product
- Existing plans (no changes), on a schedule determined by the processor or supplier that is no longer than two years or per regulatory requirement

### 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 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

**Using the information gathered when creating the plan (refer to Sections 2.1 – 2.5)**

Review CCP documentation for each CCP to determine:

- Are all hazards that need to be addressed in HACCP addressed?
  - The Hazard Evaluation Flow Chart may be used (refer to Section 2.1)
- If addressed by CCP, is the CCP the right one?
  - The modified Codex Decision Tree may be used (refer to Section 2.2)
- 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 HACCP team to determine if the HACCP plan needs to be changed.**

- Documentation of the validation process can be done using a validation check list (see an example below from the National Conference on Interstate Milk Shipments (NCIMS) to identify new food safety information.
- New information, if identified, should be evaluated by the HACCP team and documented.
- If needed, the plant HACCP coordinator should update the HACCP plan, as determined by the HACCP team.

It should be noted that whenever there are changes to product, package or process, as appropriate, the HACCP team should be convened to review the effect on the existing HACCP plan. The review during validation is intended only to verify that all changes made since the last validation are reflected in the hazard analysis and, as needed, in the HACCP plan itself.

**Example from the NCIMS HACCP Program: HACCP Validation Checklist**

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

**Validation Type (check one):**

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

Date Conducted:

Conducted By:

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"/>			

## 2.7 Process Validation

### 2.7.1 Introduction

Processors use various technologies to process tree nuts and peanuts including oil roasting, dry roasting, blanching, PPO, ethylene oxide (ETO) for black walnuts, 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. These include environmental controls, basic GMPs, zoning requirements, and adherence to validated nut processing requirements. Appendix 4 describes acceptable uses and residue levels for PPO and ETO.

*Salmonella* has been identified as a potential biological hazard in incoming raw tree nuts and peanuts. Thermal and chemical processing (e.g., roasting and PPO, respectively) can be effective control mechanisms. To be effective, the process must consistently deliver a minimum degree of lethality of 4 logs (should defer to legal requirements if needed) of a target organism, typically *Salmonella*, as demonstrated by a process-specific validation study. Validation should be audited a minimum of every 12 months, or as dictated by a HACCP reassessment, and be reviewed against existing lethality in published literature, such as the documents identified in the “Scientific Basis” Section below (Section 2.7.8).

### 2.7.2 Validation Study Design Requirements

For all processes designed to reduce the numbers of potential hazards such as *Salmonella*, experiments should be conducted to validate the log kill in each piece of equipment for each nut type. These experiments are of two types: 1) an inoculation challenge study of the process with the appropriate *Salmonella* strains or a surrogate organism of equal or greater (thermal/chemical) resistance than *Salmonella*, and 2) a time/temperature profile determination of the process, measuring the temperature throughout the process in the coldest spot. Either method is acceptable for validation, although local regulatory requirements may differ. For oil roasting and blanching, for example, a processor can use time and temperature data from pilot plant or laboratory studies (*Salmonella* can be used to do these studies), followed by a study in the plant with thermocouples to validate that the process delivers the required time/temperature profile. For dry roasting and other processes, for example, the surrogate challenge in the commercial equipment is recommended. Ideally, for roasting and steam pasteurization, inoculated challenge studies and the time/temperature profiling should be conducted simultaneously. If there are no changes to the process, or no new products, time/temperature profiling could be conducted on an annual basis to verify that the scheduled process is being achieved. If there is new roaster/oil/steam equipment, or a design change of processing equipment or conditions (e.g., new air source or a different type of gas or a different type of nut), validation using both a surrogate and/or temperature profiling is required.

The 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, and lowest concentration PPO/ETO. For thermal processes, temperature readings are collected at various points in the process, e.g., across the belt, left, middle, right. Unevenness of the degree of roasting (e.g., color) may indicate a variation in moisture loss and/or a variation in the temperature profile in the roaster. A review of the design of the roaster and the heat distribution in the roaster should take place prior to the validation to indicate the correct location for probe placement. If the control/indicating probe connected to the equipment setting cannot be located at the coldest spot, a correlation should be developed experimentally to account for this difference.

The validation studies are conducted in triplicate, e.g., the temperature sensor has to run three times through the equipment. Validation studies conducted in production areas must not use a pathogenic bacterial species. Surrogate organisms should be substituted if their sensitivity to temperature is well documented from a reliable source/process authority.

The minimum elements of the study are listed below and all should be included in any process validation report (Section 2.7.7). Validation reports should be available for review by customer auditors.

### 2.7.3 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.

### 2.7.4 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™, or equivalent. 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. An example procedure for calibration check or verification of data loggers can be found in Appendix 5.

### 2.7.5 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* on the incoming raw peanuts and tree nuts.

The validation runs should only begin once the roaster settings are equilibrated. When a validation study is conducted, all elements of the Validation Study Requirements (Section 2.7.7) should be included.

#### 2.7.5.1 Time/Temperature Profile Validations

Using a data-tracking unit, record the temperature of the nuts throughout the entire run, and the time through the 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 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. 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. Retrieve the unit as it exits the roaster or at the end of the roasting time.

For roasters, such as drum roasters and belt roasters with baffles, where the use of thermocouples is not attainable, a surrogate inoculation study may be warranted.

For situations where the data-tracking device would be exposed to damaging heat, e.g., submerged in an oil bath, the use of a handheld temperature measuring device may be

warranted. For a batch oil process, the handheld device would need to relay the temperature throughout the process in all corners of the roasting tank or any predetermined cooler areas within the tank. For a continuous, belt, oil roaster, the time in roaster would need to be marked on the side of the roaster, coinciding with maximum 30-second intervals. The temperature would be read at each of these locations in the center of oil bed.

Review the profile data for consistency between 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 confirm the results.

The profiles should meet the minimum criteria documented in the initial validation profile performed at the time the process was established. 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 a qualified person such as a process authority to ensure the minimum criteria are met.

### 2.7.5.2 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 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). When time and temperature conditions of a 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, if the processing conditions cannot be reproduced, a surrogate organism can be used for the plant roaster. The surrogate must be characterized and must demonstrate heat resistance comparable to or greater than the target *Salmonella*. In studies with almonds, *Enterococcus faecium* NRRL B-2354 was found to be an appropriate surrogate for *Salmonella* Enteritidis PT 30 in dry processes (Wang, 2008). In studies with several varieties of peanuts, *E. faecium* was again shown to be a conservative surrogate for *Salmonella* PT 30 in thermal inactivation studies (Goodfellow, 2009).

All cultures are grown in Tryptic Soy Broth at 35°C for 24 hours. The broth cultures (1.0 ml /plate) are then spread over 15mm x 150mm plates of Tryptic Soy Agar (TSA) and incubated for 24 hours at 35°C. Five plates of *Salmonella* cultures or *Enterococcus* cultures are prepared per a pre-determined amount of nut sample, e.g., 400 g (the amount of nut needed is pre-determined by experimental design). After incubation, 5-6 ml of 0.1% peptone is added to each plate and the bacterial lawn loosened with a sterile spreader. Sterile pipettes are used to collect the loosened cells and the collections are pooled into approximately a 25 ml inoculum preparation for each 400-g batch. Each inoculum is kept mixing on a stir plate until all nuts have been inoculated. For example, for peanut inoculation, separate 400-g portions of each nut type are weighed into Cryovac® or Whirl Pak® bags and 25 ml pooled inoculum is added to the bag. The bags are closed and mixed by hand by repeated inversion for 1 minute and the inoculated peanuts are poured out onto filter paper over a metal rack in a sterile plastic tub. The inoculated peanuts are loosely covered and allowed to dry for 24 hours at room temperature (~ 24°C). Prior to the roasting tests, samples of each batch are plated onto the appropriate agars to confirm that the inoculation level is at least 7 logs per gram. The agars employed are TSA and Bismuth Sulfite Agar (BSA) for *Salmonella*, TSA and Dextrose Tryptone/Yeast Extract Agar (DTYE) and KF supplemented with TTC Agar (KF) for the *Enterococcus* (Goodfellow, 2009; Harris, 2005). The inoculated nuts should be placed in a gauze-type bag or similar containment and placed at the predetermined cold spot of each process for the entire process. The initial inoculation level of the surrogate on the nuts should be determined after initial drying

(usually 24 hr to make sure the moisture level after inoculation is the same as the original nuts), prior to use in the study, and after the study to account for die-off if not used right away. The surrogate population on the nuts should be enumerated after the process and the log reduction calculated accordingly. The surrogate runs should be conducted in triplicate, and the microbiological sampling in duplicate. For PPO processes, inoculation data can be obtained using MPN (Most Probable Number) methodology. Another critical aspect of the validation study is to measure moisture of the nuts after drying following inoculation and after roasting to ensure that the analytical values are similar to those of uninoculated nuts, during routine processing.

Oil and dry roasting parameters have been published for almonds. It is important to recognize that, at the time of this writing, the science behind several factors contributing to comprehensive process validation remain under discussion and are being studied: the selection of an appropriate surrogate for a specific nut type and process, the optimal preparatory culturing methodology for the surrogate, the appropriate inoculation procedure for the surrogate on the tree nuts/peanuts, 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. It is important to establish the correlation between the surrogate and *Salmonella* in the nut under validation, if such data are not already available.

Examples of a challenge study with *Salmonella* and a time/temperature profile validation study can be found in Appendix 6.

### 2.7.6 Lethality Computation

For thermal processes, *Salmonella* heat resistance values are provided below (Example Table, not to be used for processing critical limits. Processors need to determine heat resistance parameters for their own CCP.)

	Temp (°F)	Time (min) 4-log	Time (min) 5-log	z value (°F)	Reference
DRY ROASTING	284	16	19.3		Goodfellow (2009)
DRUM ROASTING	248	17	21.3	98	Experimental data
OIL ROASTING	260	1.6	2.0	NA	Harris and Du (2005)
BLANCHING	190	1.6	2.0		Almond Board of California supporting documents
	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 CCP models, the thermal process equation in Appendix 7 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 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. Surrogate studies would be recommended in these situations.

For some processes, such as steam pasteurization/vacuum or PPO treatment, each processing unit at each specific location should be validated individually.

### **2.7.7 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:

#### **2.7.7.1 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, 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

##### PPO Processes

Type and brand of equipment (attach diagram)

Processing conditions - grams of PPO/cm<sup>3</sup>

Amount of product treated per chamber

Shutdown/alarm features

Calibration practices and schedule

##### Steam Pasteurization Processes:

Type and brand of equipment (attach diagram)

Processing conditions – steam pressure or vacuum achieved

Amount of product treated per chamber

Shutdown/alarm features

Calibration practices and schedule

#### **2.7.7.2 Product Description Processed in the Above Equipment**

Nut type

Initial form of nuts (raw, or pre-processed)

Final form of nuts (nut paste, pieces, whole)

#### **2.7.7.3 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.

#### **2.7.7.4 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 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.

#### **2.7.7.5 Establishment of Worst Case Conditions – Other**

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.

#### **2.7.7.6 Target Parameters for Monitoring**

Determine target parameters to assure process variability remains above critical limit. 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.

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

Describe confirmation of worst case assessments and achievability of at least a 4-log reduction (FDA currently suggests minimum 5-log for peanuts and pistachios, unless data are available to support that less than 5-log is adequate) using a data logger (cal. +/- 0.5°C).

#### **2.7.7.8 Corrective Action**

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

#### **2.7.7.9 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.

#### **2.7.7.10 Monitoring Records**

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

### 2.7.7.11 Validation of Process Capability (Lethality)

For processes where the CCP Model is 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.

### 2.7.8 Scientific Basis

ABC (Almond Board of California). 2007. The efficacy of hot water on the reduction of *Salmonella* in almonds in a hot water bath. Documents DOC002 and DOC 005. Almond Board of California. Modesto, CA. Available at [www.almond-board.com](http://www.almond-board.com).

Beuchat, L. R., and E. K. Heaton. 1975. *Salmonella* survival on pecans as influenced by processing and storage conditions. Appl. Microbiol. 29:795-801.

GMA (Grocery Manufacturers Association). 2009. Control of *Salmonella* in low-moisture foods. Element 6: Validate control measures to inactivate *Salmonella*. Available at <http://www.gmaonline.org/science/SalmonellaControlGuidance.pdf>. Accessed July 8, 2009.

Goodfellow, S. J. 2009. Fate of *Salmonella* species and *E. faecium* cultures inoculated onto peanuts subjected to oil and dry roasting conditions. Report prepared for APC council.

Harris, L., and W.-X. Du. 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. (On file at KFNA Corporate Microbiology, East Hanover, NJ).

Jeong, S., B. Marks, and A. Orta-Ramirez. 2009. Thermal inactivation kinetics for *Salmonella* Enteritidis PT 30 on almonds subjected to moist-air convection heating. J. Food Prot. 72:1602–1609.

Larkin, J. W. 2008. *Salmonella* factors affecting resistance to non-thermal processes. IAFP Symposium S8 – Validating processes for reducing *Salmonella* in low water activity foods, IAFP annual meeting, August 3 – 6 Columbus, Ohio.

Wang, G. 2008. Surrogate selection strategy. IAFP Symposium S8 – Validating processes for reducing *Salmonella* in low water activity foods, IAFP annual meeting, August 3 – 6 Columbus, Ohio.

## CHAPTER 3 – PREREQUISITE PROGRAMS AND PREVENTIVE CONTROLS

### 3.1 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.

List of Key Prerequisite Programs

Facilities*	Allergen Management Program*
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	Training
Pest Control	

\* Additional information available in appendices.

### 3.2 Facilities

#### 3.2.1 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.

### 3.2.2 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, test may be done for total chlorine (minimum 0.2 ppm) or per state and/or local regulations.

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

### 3.2.3 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 should be separated from the production areas (minimum 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 environment) 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 between 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 9 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.

### 3.2.4 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.

### **3.2.5 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 below. 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 element removal will not result in contaminant 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.

## **3.3 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 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, 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 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).

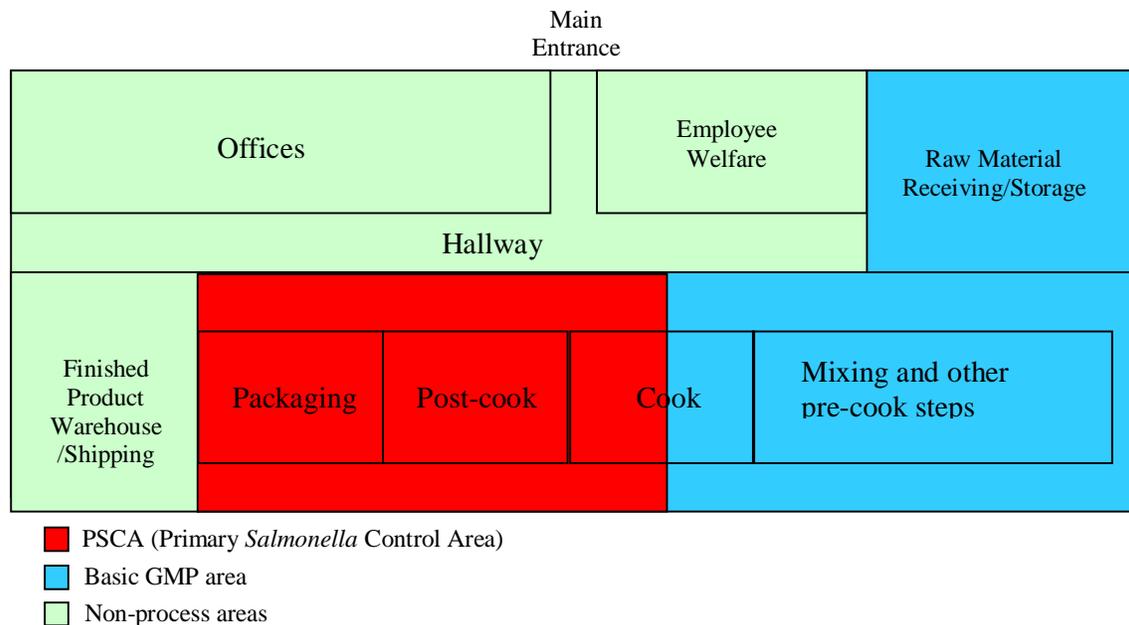


Figure 1. Example of a conceptual plant layout showing two process areas with different hygiene control: a Primary *Salmonella* Control Area (PSCA) in red and a basic GMP area in blue. The need for GMPs in non-process areas should be assessed on a case-by-case basis.

### 3.3.1 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.

### 3.3.2 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.

### 3.3.3 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

### 3.4 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, sweepings, scrapings, and other types such as dust collected by a vacuum cleaner. Analysis of samples (e.g., floor debris, fines, sweepings) and sponge swabs taken of 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 critical 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.

This section focuses on detection of *Salmonella* and predicting its presence in the processing environment. It does not address non-pathogen (indicator organism) sampling or air quality monitoring, which are performed to verify the effectiveness of cleaning and sanitation programs (see Section 3.6 below for more information). However, it is important to trend this type of environmental monitoring data and take appropriate actions based on trend. Each processor should establish a baseline for what can be achieved under effective cleaning and sanitation programs. An upward trend or sudden increase in monitoring data should initiate an investigation that could impact the design, characteristics, and implementation of the PEMP.

#### 3.4.1 Designation of Pathogen Monitoring Sampling Sites

A facility segregated area assessment is done to determine risk and necessary control programs to prevent spread of contamination from raw areas and other potential contamination sources to process areas including the PSCA (see section 3.3 above).

Environmental monitoring for *Salmonella* is routinely conducted on non-product contact surfaces (non-PCSs). Product contact surfaces (PCS) are generally only swabbed for pathogens under certain circumstances such as in response to possible pathogen contamination issues (e.g., roof leaks), investigation of a positive finished product, verification of cleaning, or commissioning of new equipment upon installation.

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 the physical facility structure. 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 process area into four sampling zones based on proximity to the process equipment. Examples of sampling sites within each zone are detailed in Table 1. Process areas should be mapped and swab/sampling locations numbered within each zone. Pathogen monitoring programs should include, at minimum, documented best practices, action/reaction criteria, and historical trending (if evaluating quantifiable data).

Table 1. Pathogen monitoring sites are categorized into four sampling zones based on proximity to process equipment

Zone	Examples of Sampling Sites	Test For	Frequency
I	<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	Indicator organisms (e.g., Aerobic Plate Count; Enterobacteriaceae); <i>Salmonella</i> only when special circumstances dictate.	Post-sanitation or as needed for investigational, validation or verification purposes
II	<b>Environmental surfaces immediately adjacent to product-contact surfaces</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, HVAC vents, vacuum cleaners if used near PCSs, air filters, etc.	<i>Salmonella</i>	Weekly, twice monthly, or monthly
III	<b>Environmental surfaces further removed from product contact surfaces in production areas</b> , e.g., hand trucks, forklifts, walls, ductwork, drains, floors, ceilings, equipment legs, fork truck and cart wheels, tools, brooms, squeegees, floor scrubbers, drains, 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
IV	<b>Outside process area</b> , e.g., warehouses, bathrooms, cafeteria, plant entrance, locker room, mechanical room, hallways, offices, and refuse/recycle areas	<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.

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 contamination to the product, the likelihood that condensate will form on the surface and contaminate the product below, the regulatory requirements associated with the Zone 1 designation, 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 in consultation with Sanitation, Quality, and Microbiology managers.

### 3.4.2 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. Products produced without a process lethal to pathogens that are intended for direct consumption (e.g., trail mix) would dictate a more comprehensive swabbing program. 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 thermal process are swabbed more regularly to monitor for possible product recontamination potential. In general, a greater number of samples are taken in Zone 2 than Zone 3 and in Zone 3 than Zone 4. It should be noted that 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.

Zone 1 PCS samples are viewed in the same way as finished product, and are not routinely taken since testing the first product produced at start-up is a more representative sampling of the entire process for the assessment of pathogen risk. Direct product contact swabbing risks contamination of the process while in operation and the introduction of moisture from hydrated sponge swabs. 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 satisfactory test results are received.

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. 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, equipment exterior). Sampling points for Zone 2 should not represent areas that may be indirect Zone 1 sites, and therefore present no direct immediate process risk and do not implicate product.

Zone 3 sites are non-PCS within a process area 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 outside processing areas. Contamination in this zone could spread to the processing area via foot or equipment traffic (e.g., waste carts picking up contamination in 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.

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.

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.

### 3.4.3 Pathogen Monitoring for Special Circumstances: Plant Construction or New Equipment Installation

Swabbing and testing for *Salmonella* are performed in construction areas and adjacent areas during construction. The frequency of swabbing should be increased after construction, after equipment installation, and after major repairs are completed. 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

### 3.4.4 Environmental Sampling Procedures

Swabbing procedures and methods should be consistent with standard industry practices and performed by trained Quality Assurance personnel.

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 neutralizing buffer. Floor sweepings and debris from vacuum collection points also provide excellent samples for pathogen monitoring and should be collected with sterile collection tools such as scoops and scrapers, then placed into a sterile Whirl-Pak® bag.



Figure 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.
3. Using sterile gloves, remove the sponge from the Whirl-Pak® bag or equivalent.
4. Sponge an area as large as reasonably possible. For example, 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 Cultiurette (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 Cultiurette tube.
6. Change gloves between sponge samples. The use of an alcohol-based hand sanitizer 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 negative control sample 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. Optimally, 50 g of material should be collected; however, even small quantities are useful for assessment.

#### 2.4.5 Methods of Analysis for Environmental Samples

An official or validated method should be used to test samples taken from the environment.

- The FDA BAM method (2007) and the ISO 6579 method (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 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 the FDA (2007), 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.
- *Salmonella* isolates should be serotyped. Genetic fingerprinting (e.g., Ribotyping, pulsed field gel electrophoresis (PFGE), and repetitive sequence polymerase chain reaction (Rep-PCR) methods) of the *Salmonella* isolate is a recommended procedure for a more discriminating characterization of the strain. These subtyping methods may be used for tracking and troubleshooting purposes.
- 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.

- 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 comes up 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. 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.

### 3.4.6 Corrective Actions

Corrective actions must be taken when *Salmonella* is detected in an environmental monitoring sample. In most cases, corrective actions are triggered by presumptive *Salmonella* test results, since waiting for the final confirmation could take up to a week.

- A facility should have a predetermined plan of action ready to initiate should a positive pathogen result be reported for an environmental swab. 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 and potential causes investigated. It may be advantageous to have a pre-assigned team to assist in the investigation and to help direct corrective actions.
- 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, should be documented.

Table 2. Examples of corrective action procedures following positive *Salmonella* findings in the plant environment

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### **Zone 2, 3, or 4: Response to a Single Positive**

Corrective actions must be taken when a *Salmonella*-positive is found in any zone. Corrective actions should be initiated based on presumptive positive test results. The actions should aim to eliminate potential sources of the contamination.

Corrective actions common to Zone 2, 3, and 4 may include the following:

- Initiate pre-assigned response team to conduct a preliminary investigation to determine potential cause or source for the contamination (e.g., water leaks, maintenance activity, construction). The suspect site and surrounding areas should be examined as part of the investigation.
- Take immediate actions to correct any GMP deficiencies based on findings. These may include:
  - Quarantine the suspect area and limit access to the area.
  - Reinforce hygienic practices with appropriate employees (retrain if necessary).
  - Re-examine cleaning frequencies and revise, as appropriate.
  - Eliminate water and water collection points, if present.
  - Repair damaged floors/walls and other structural damage, as appropriate.
  - Re-examine traffic patterns. Where necessary and feasible, limit traffic flows (both employees and mobile equipment) through the area, restrict fork truck movement, redirect high-risk traffic patterns from adjacent areas, etc.
- If desired, conduct investigational sampling of the suspect and surrounding areas prior to cleaning. Precaution should be taken to avoid spreading potential contamination from the suspect area to other areas in the plant.
- Thoroughly clean/sanitize and dry the positive site and the surrounding area. Use dry, controlled wet, and/or wet cleaning, as appropriate, according to guidelines described in Section 3.6 below and the GMA 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, 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, is 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.

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Table 2. (Continued)

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**Special Circumstances: Consecutive Positives (all Zones)**

When a sound control program for *Salmonella* is in place, finding multiple and/or consecutive positives may indicate that the primary source is a harborage site, where the organism may have become established and is multiplying. This can lead to an increased risk for spreading the organism and, ultimately, process line contamination. Corrective actions outlined below may be followed for problem resolution.

- Map the contamination sites on a layout of the facility to aid in locating the source of contamination, or at least suggest additional sites to sample. It is critical that a harborage site, if one exists, be found and eliminated. This usually means taking more samples than those taken during routine monitoring in the affected and traffic flow areas.
- Reinforce GMP training and hygienic practices and provide additional attention to sanitation procedures.
- Visually inspect areas for potential niches. Intensify cleaning activities around these areas.
- Visually inspect handling practices (production, sanitation, maintenance, material handling) and correct non-hygienic employee practices.
- Review equipment cleaning and preventive maintenance protocols and revise, if necessary.
- Examine processing equipment and consider equipment redesign, if necessary.
- PCS or product testing may be necessary or need to be intensified for 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. 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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### 3.5 Personnel

#### 3.5.1 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. In the Food Code (<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/default.htm>) and in guidance for the voluntary use of HACCP principles for retail establishments (<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Operators/default.htm>), the FDA recommends that the managers of food operations be assigned the responsibility for assuring compliance by good personnel hygiene practices. To accomplish this, management should assume active managerial control with 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 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. Exposed piercings should be removed.
- Effective hair covering and 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 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 10 describes more detailed recommendations for personal hygiene practices for nut processors to consider in their operations.

### **3.5.2 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, using the bathroom, and 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
6. Discard used towels in trash
7. Sanitize hands with an appropriate sanitizer, e.g., hands-free dispenser
8. Dry hands

The following list shows the currently recognized pathogens/diseases that can be transmitted by food that has been contaminated by an infected person, according to the 2008 CDC list (accessible at <http://edocket.access.gpo.gov/2008/pdf/E8-27165.pdf>).

<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>

### 3.6 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 environment.

#### 3.6.1 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.

### 3.6.2 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

### 3.6.3 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 11 (the “7-Steps of Dry Sanitation”) and Appendix 12 (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 13.

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, or CO<sub>2</sub>-blasting) 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.

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 4, below.

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.

### 3.6.4 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.

Post-cleaning or pre-operational inspections could be performed to confirm that equipment is clean, properly assembled, free from chemical residues, sanitized, 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 (controlled wet cleaning or full wet cleaning) 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 are specified below.

#### Cleaned Equipment - Guidelines only

		Post-heat treatment - taken before sanitize		Post-heat treatment - pre-op taken after sanitize	
		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 monitoring data 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 to ensure the action taken has been effective. One technique would be to repeat and rotate swabs until three (3) consecutive acceptable results are obtained.

Swabbing should be performed after cleaning, but before sanitizing procedures. This will monitor the effectiveness of the cleaning process. If swabs must be 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. 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).

### **3.6.5 Clean Equipment Swab Program for Dry Product**

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

- 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 cleaning the equipment but prior to the addition of sanitizer.
- Examples of swabs that could be used include Culturette Transwab™, Cotton, Rediswab™, Quickswab™.
- See chart above for 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.
- 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.

### **3.7 Allergen Management**

The facility 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.

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.

#### **3.7.1 Avoid Allergens**

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. Introduction of unintended allergens during manufacturing can be avoided by preventing manufacturing cross-contact via proper rework handling, product sequencing, and change-over cleaning or change-over flushing. As example, do not add peanuts to a tree nut mix for the purpose of avoiding an allergen clean-up.

Supplier control programs can also aid in managing the risk of unintended allergens entering the nut manufacturing facility and assure correct handling and storage of allergens that are received. The nut processor should review their supplier's allergen control programs to assure that the potential for allergenic proteins to be included in products where they are not labeled is minimized. This requires each supplier to have their own established policies and procedures 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.

#### **3.7.2 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 cross-contact with products that do not declare these allergens on their labels. Below are various individual programs that, 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.

### 3.7.2.1 Segregation of Allergens

One component to managing allergens is keeping allergenic ingredients and products separate, as reasonably possible, from other ingredients and products. The segregation of allergens begins when ingredients are received at the dock door and ends when product leaves the facility. The following are practices that can be used to manage the segregation of allergens:

- a. Process and Product Design
  - i. Run allergen-containing products on lines or equipment dedicated to that specific allergen profile, whenever possible, to reduce the risk of cross-contact. Consider erecting a physical barrier, for lines in close proximity, to reduce the risk of allergenic cross-contact (e.g., walls, curtains, partitions).
  - ii. 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. The sanitation protocol could be validated to determine its effectiveness. See the Sanitation section (Section 3.6 above) for further details.
  - iii. When adding an allergenic ingredient, add it as late in the process as possible to limit the amount of equipment that comes in contact with the allergen.
- b. Receiving
  - i. Separate incoming nuts intended for further processing in separate storage containers, segregated by nut types (e.g., almonds received in totes are separated from peanuts received in totes.)
  - ii. Clearly identify incoming minor ingredients that contain allergens, including allergens as sub-components (e.g., spice blends). Identify the specific allergen(s) that are contained in the ingredient in an easy to identify manner (e.g., a flavoring that contains whey is labeled with a color-coded label that states "Allergen: Milk").
  - iii. Handle damaged allergen containers in such a manner as to prevent cross-contamination of other materials.
- c. Storage
  - i. Store raw materials, ingredients and work-in-process in such a way that allergenic materials do not come in contact with other materials. Examples:
    - Separate storage areas for peanuts, pecans, almonds
    - Minor ingredients are stored on the lowest level of pallet storage racks.
  - ii. Visibly designate the storage area.
  - iii. Allergen materials are not stored above non-allergens or allergens of a different type.
  - iv. Store allergens in closed, tightly sealed containers whenever possible.
- d. Traffic Patterns of People and Materials

- i. Limit traffic patterns of people, raw materials, forklifts, and packaging supplies, into and out of a room that is processing an allergen containing product, to avoid cross-contact in higher risk areas. Example: Brush a spill of allergen material off of a fork truck prior to it leaving the allergen area.
  - ii. 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. Examples include different colored outer clothing or different colored hair nets. If this is not practical, establish procedures for personnel movement to minimize the potential for cross-contact in higher risk areas. Examples include hand washing and a change of outer clothing.
  - iii. Manage employees' outer clothing to avoid cross-contact of allergens in common areas within the plant (e.g., cafeterias, break rooms, locker rooms).
    - Examples: Dedicated outer clothing (e.g., lab coat) 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.
  - iv. Immediately clean up any spills or damaged containers of allergen-containing raw materials, ingredients, or finished product to avoid the potential for allergenic cross-contact.
  - v. 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.
  - vi. If a process reuses materials (e.g., cleaning solutions, cooking or cooling water, oils), careful consideration must be made before reusing these materials after an allergen containing product was run.
- e. Tools and Utensils
- i. Dedicate tools used during production of an allergen-containing product to that allergen profile.
  - ii. Clearly identify the dedicated tool, for use with a particular allergen, through color coding or other easily identifiable system.
  - iii. Store the dedicated tool separately from other non-allergen use tools and tools used for a different type of allergen.
  - iv. Thoroughly clean and inspect the tool prior to the tool's next use, if the tool cannot be dedicated to a particular allergen profile.
- f. Production Scheduling
- i. When scheduling multiple products on the same equipment, plan to run the allergen-containing product last or after non-allergenic products have been processed. 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 just wheat second, and the product with wheat and walnuts third. This sequence should not present a risk of allergen cross-contact.
  - ii. Overall risk is reduced by minimizing the number of allergen changeovers. This can be accomplished by scheduling longer production runs of allergen-containing products.
  - iii. Schedule sanitation of the equipment immediately after a production run that contains an allergen. This should be done prior to running product that

doesn't contain allergens or products that do not contain the same allergen profile.

g. Allergen Matrix

- i. To aid employees and production scheduling, an Allergen Changeover Matrix may be created. 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. The following is an example of an Allergen Changeover Matrix:

		<b>TO</b>				
		<b>Product #1 (wheat)</b>	<b>Product #2 (wheat)</b>	<b>Product #3 (None)</b>	<b>Product #4 (wheat, soy, almond)</b>	<b>Product #5 (wheat, whey)</b>
<b>F</b>	<b>Product #1 (wheat)</b>		Non-allergen clean	<b>Allergen clean (wheat)</b>	Non-allergen clean	Non-allergen clean
	<b>Product #2 (wheat)</b>	Non-allergen clean		<b>Allergen clean (wheat)</b>	Non-allergen clean	Non-allergen clean
<b>O</b>	<b>Product #3 (None)</b>	Non-allergen clean	Non-allergen clean		Non-allergen clean	Non-allergen clean
<b>M</b>	<b>Product #4 (wheat, soy, almond)</b>	<b>Allergen clean (soy, almond)</b>	<b>Allergen clean (soy, almond)</b>	<b>Allergen clean (wheat, soy, almond)</b>		<b>Allergen clean (soy, almond)</b>
	<b>Product #5 (wheat, whey)</b>	<b>Allergen clean (whey)</b>	<b>Allergen clean (whey)</b>	<b>Allergen clean (wheat, whey)</b>	<b>Allergen clean (whey)</b>	

**3.7.2.2 Control of Rework and Work In Process (WIP)**

Rework practices should be evaluated as part of the HACCP risk evaluation. If rework is identified as a possible risk, the following control requirements should be considered.

- **Policy:** A common policy is for processors to only use rework for “like-into-like” applications, as soon as possible, preferably on the same day or shift.
- **Storage:** In the event that allergen-containing rework must be placed into storage, it should be stored in a manner that avoids the risk of 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 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.)

- Labeling of rework: 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 in a product. This can be accomplished by using labels or color schemes, or a combination thereof. If labels are used, they could contain the following information, at a minimum:
  - Name of the rework, or work-in-process (WIP) material
  - Name of the allergen
  - Date/time of manufacture
  - Date/time put into storage
  - Date/time for using rework/WIP, where appropriate
  
- Usage: 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.
  - Transfer: The transfer of rework or WIP from the staging area to the processing line should be accomplished without cross-contact with other ingredients or products. If the use of lifting equipment, such as lift trucks, is unavoidable, care should be taken to prevent the spread of allergen-containing debris to other parts of the plant.
  - Staging: 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: If at all feasible, re-entry equipment, utensils, and tools should be dedicated for handling a specific allergen. Where this is not feasible, the tools should be cleaned using an allergen-clean sanitation procedure to lower the risk of incidental cross-contact.
  - Usage procedures: Procedures for using rework or WIP may 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 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.
  
- Documentation and recordkeeping: The introduction of rework into the process stream should be documented to reduce the risk of accidental product mixing. If cross-contact does occur, then the documentation can help track and verify 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 operator's initials and the time of the activity.

- During add-back, the following information may be entered on the batch sheet: a) Identity of the allergen; b) amount of rework/WIP material added; c) time of addition; d) batch number, and e) 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.
- Other possible elements of effective rework and WIP allergen control:
    - Corrective action requirements: 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 document corrective action.

### 3.7.2.3 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 to preventing 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 form or allergen and the equipment design.

When cleaning or flushing is used to restrict allergen carry-over (and thus not declare the allergen on the product label), the effectiveness of the sanitation procedure should be validated. This changeover procedure may be considered a CCP in the HACCP plan.

### 3.7.2.4 Cleaning Expectations, Responsibilities, and Procedures

The effectiveness of allergen cleaning procedures (wet or dry) should be validated and the results should be acceptable (see the validation procedure below). No allergen-containing piece, particulate, accumulation, or clump should carry over into the next product from food contact surfaces of from adjacent areas. The goal is to reduce and manage allergic consumer health risk.

#### Allergen Changeover Procedures

- Empty the system, remove hand-weighed ingredients, recoup materials and any previous labels or pre-printed packaging materials.
- Clean all food contact surfaces and niches of any size piece of debris, particulate, or deposits of product. Various cleaning methods may be used to remove these materials in a manner that does not distribute them to other locations (e.g., uncontrolled use of compressed air).
- Cleaning methods may include vacuuming, brushing, wet wash, and wipe down, as needed.
- All product zone surfaces are visibly clean of any piece, particulate, accumulation, or clump of material.
- Separation, covering, or disassembly and removal of allergen-contacted equipment from non-allergen contacted equipment are 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 analytical testing or by authorized individuals. 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 water to what would otherwise be a dry system as it may create a microbiological hazard.

In some cases, a flushing changeover may be sufficient to reduce consumer risk. In these cases, an allergen risk evaluation should be completed to determine if this is the appropriate method and if the resultant product must be cross-contact labeled. Allergen-containing pieces, particulates, accumulations, or clumps do not carry over into the next or non-allergen product from product zones or adjacent areas. The goal is to reduce and manage allergic consumer health risk without dismantling the production line. This method should be used only after careful consideration.

### Flushing Changeover Procedure

- Hand-weighed ingredients, rework, and previous product labels should be removed.
- The line is flushed with non-allergen containing product to remove residual allergens. Flushing agents that can be used should be compatible with the products and not create a cross-contact or labeling issue. Agents such as flour, sugar, and salt are commonly used.
- 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.

Flow-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.

**Expectation:** Product carried over to the next product does not present an allergen or labeling risk to that product.

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

- Hand-weighed ingredients, rework, WIP, and previous product labels should be removed.
- Labeling programs should be in place to avoid misbranding.
- Quality concerns could determine that a set amount of product is discarded as it may not meet the quality requirements of either product.

### 3.7.2.5 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.

#### 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.
- 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 a pre-operational inspection. Some firms find that using a documented pre-op checklist is helpful.
- Ensure the “visibly clean” standard. If the visible clean standard has been achieved, consider performing any applicable allergen analytical testing.
  - If visibly clean or acceptable allergen analytical results are not attained:
    - Revise plant SSOPs
    - Consider if equipment modifications are needed
    - Re-clean the line
  - Re-inspect the line
  - Continue this cycle until acceptable results have been met.
  - If allergens cannot be effectively removed after repeated attempts, alternate strategies such as product/ingredient reformulation, redesign of equipment, dedicated equipment/lines, or cross-contact labeling options could be considered.
- The inspector should document the approved sanitation SOP cleaning validation.
- Following SSOP validation, responsibility reverts to the existing line inspector(s) for the ongoing allergen cleaning and verification process.
- Validation documents could be part of the facility’s record retention program.
- Consider re-validation when there are changes in: formula, allergen or allergen form, equipment, line configuration, product, process, significant personnel changes or sanitation procedures.

### 3.7.2.6 Analytical Allergen Testing for Validation

While many foods are classified as allergens, reliable analytical tests for both products and equipment are available for only a few allergens.

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:

- o Equipment swabs
- o First product after start-up
- o Intermediate or in-process product
- o 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 lanes are used, sample all lanes.
- 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 may be determined to constitute an insignificant risk. Examples may include trace ambient dust from products, but may not include dust from allergenic ingredients or “dust” with significant dimension. In summary, these exceptions are rare and must be individually evaluated by experts on a case by case basis.

### **3.7.2.7 Verification of Allergen Cleaning**

Verification is the process used to assure that the validated sanitation procedures are accurately being followed on an ongoing basis. Verification should be completed by whatever method has been designed into the validated program, either visually clean or allergen analytical testing. Verification should occur periodically, after running an allergenic product, but before processing products that do not contain the same allergen profile.

The verification activities 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 checklist steps should document that they have been completed. Many firms perform the verification by using a person that is not associated with the SSOP procedure. Records could be reviewed by a qualified person as further verification that the line was cleaned appropriately and cleaned according to the validated sanitation procedure. This record should be retained according to the facility’s record retention program.

### **3.7.2.8 Sanitary Design of Allergen Equipment**

The value of well-designed equipment should not be underestimated. Equipment that has been built to sanitary principles is easier and faster to clean, exhibits more effective cleaning, requires fewer employees to clean, and better meets GMP/regulatory guidelines. In general, 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.

### 3.7.3 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 and customer specifications. Two important aspects of label management include controls for design, and controls for inventory and label application.

#### 3.7.3.1 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 for art work and labeling copy
- Prior to printing labels, labels are reviewed by someone with sufficient knowledge of regulatory requirements, including declaration of allergens, to ensure compliant label and package designs
- The use of commonly understood terms in consumer friendly language for all allergenic ingredient declarations (e.g., milk, not whey or casein)
- 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 (color and/or numerical) of printed labels and packages

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

#### 3.7.3.2 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/package at the end of a run to assure that the next run of materials is not inadvertently mislabeled. Only labels or pre-printed packaging for the product currently being packaged should be staged in the packaging area. Samples of packaging should be checked for accuracy before it is placed into packaging machinery. During processing, product containers and labels should be inspected to reconcile allergen-related label information on the containers with the ingredient specifications of the product. Unused packaging and labels should be removed after the production run. Unused packaging materials that are returned to the warehouse at the completion of a production run should not be mixed with other packaging materials during storage. Proper inventory control procedures should be in place and effective. Packaging stored in boxes, such as plastic cups and lids, should have the boxes sealed shut.

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. Labels and pre-labeled packaging should not be co-mingled inside shipping and storage containers.

Another technique to consider is 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 for confirming correct product and label changeover may be warranted.

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.

### 3.7.4 Allergen Training

The successful control of allergens depends on employees and managers doing the right thing at the right time. Their proper action is based on their understanding of what their responsibilities are, but also why they have those responsibilities. Understanding allergens and the facility's allergen control procedures is aided by a strong allergen training program.

- a. All employees of a facility should receive General Allergen Awareness training when new to the facility and at least annually.
- b. 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. Some examples of specific topics for training are:
  - i. HACCP Verification Duties
  - ii. Sanitation Cleaning Procedures for Allergen Changeovers
  - iii. Production Procedures for Allergen Changeovers
  - iv. Label Controls
  - v. Allergen Cleaning Validation/Testing Procedures
  - vi. Allergen Ingredient Spill Procedures
  - vii. Allergenic Ingredient Receiving Procedures
  - viii. Allergen Tool Cleaning and Handling Procedures
  - ix. Allergen Changeover Matrix
  - x. Rework Controls

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

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, pipe, 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 requirement) 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.

### 3.9 Control of Raw Materials and Products

#### 3.9.1 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.

This Handbook can be used as a guideline for supplier approval. For further reference for supplier management see GMA's *Food Supply Chain Handbook* (available at: [http://www.gmabrands.com/publications/GMA\\_SupplyChain2.pdf](http://www.gmabrands.com/publications/GMA_SupplyChain2.pdf)).

##### 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 HACCP). 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.
- **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.

#### **3.9.2 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 due to possible extraneous, microbiological, or allergen contamination without an evaluation. 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 14 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.
- 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.
- 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.

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.

### 3.9.3 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, accessible at <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm>) 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.

### **3.9.4 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.

The hold procedure should address 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 visually 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 visually 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 that lot/code of product or any ingredients used in that product, it should be done before the release of a 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.

### **3.9.5 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 limits of a CCP
- 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.

### **3.9.6 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.

### **3.10 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 program 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 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 15.

#### 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.

### 3.11 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

### 3.12 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 of pathogens:
  - o The lab for pathogen testing should be in a building separate from production.
  - o 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.
  - o Any potentially infectious material should be sterilized prior to disposal.
  - o 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) 4th Edition” (available at <http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm>).

### 3.13 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. They should evaluate the effectiveness of training and maintain appropriate records of education, training, skills, and experience.

Training for production employees should include a general awareness of the principles of food safety and quality, and topics such as HACCP, allergens, diseases that are communicable via food, GMPs, 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 monitoring CCPs should receive specific training including monitoring, documentation, verification, and corrective actions if the critical limits are not met. Specific training to meet the requirements of this document should be provided as required.

## CHAPTER 4 – PRINCIPLES OF EQUIPMENT DESIGN

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, 2002) 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.

### Principle 1: Cleanable

Equipment should be constructed to be cleanable to a 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, based on 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 or sampled. In other words, in a non-clean-in-place environment, processors should have access to 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 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 by sanitation employees, the easier it is for them 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. 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 stagnant 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 ability 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 manufacturer's. 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 must be compatible with the equipment and the manufacturing environment. These procedures must 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 everyday, 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 single line or equipment should be properly separated to prevent cross contamination based on a risk assessment.

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 a RTE area.

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

All plant personnel, contractors, and visitors to processor 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 must 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.

## GLOSSARY

**Accuracy:** The repeatability of closeness to the target value of a certified reference or other standard.

**Allergen:** Food causing an adverse reaction that is mediated by an immunological response.

**Allergen Profile:** The totality of the allergens which are present in a product by design, or likely to be present by cross contact. The complete allergen profile must be included appropriately on the label.

**ATP:** adenosine triphosphate, used for environmental monitoring, to determine organic load present on equipment post cleaning and sanitation.

**Audit:** Systematic and functionally independent examination to determine whether activities and related results comply with a conforming scheme, whereby all the elements of this scheme should be covered by reviewing the suppliers' manual and related procedures, together with an evaluation of the production facilities.

**Auditor:** Person qualified to carry out audits for or on behalf of a certification body.

**Calibration:** The adjustment of measuring and monitoring equipment to assure that: 1) For equipment that measures across a range of values, the measurements are accurate across the entire range, to the degree of accuracy stated. 2) For equipment that is used to measure a single point, that the measurement reaches the degree of accuracy stated.

**Certificate of Analysis (COA):** A document provided by the Supplier which indicates results of specific tests/analysis performed on a defined lot of the Supplier's product. The tests are done either by the Supplier or an external testing firm, and must be based on protocols/methods that have been approved and agreed by technical experts. A COA should contain:

- Supplier name, address, phone number, and contact person
- Material name, lot identity, production date and customer raw material identification number
- Supplier purchase order number, if available
- Specification number (or purchase agreement) and issue date
- Signature of authorized agent of the Supplier and date of signature
- Statement that the results are actual lot analysis results or composite results commonly used in commodity industries
- Test and Analysis results for each lot, including customer specification target and range
- Parameter being tested, Test method, sample size and sampling method being used
- Laboratory name and location performing the testing

**CODEX:** An international organization of scientists chartered by the United Nations World Health Organization to address food safety issues worldwide. The membership is composed of delegates from industry, academia and government.

**Critical Control Point (CCP):** A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

**Cross Contact (allergen):** Allergens which are not part of the intended formulation, introduced into products during manufacturing. This may arise from either: 1) Traces of

product from the previous production run that cannot be adequately cleaned from the production line due to technical limitations. 2) When contact is likely or probable to occur, in the normal manufacturing process, with products or ingredients that are produced on separate lines, or in the same or adjacent processing areas.

**Disposition:** Determining and authorizing what must be done with non conforming product that has been placed on hold.

**Evaluation:** Examination of production facilities, in order to verify that they conform to requirements.

**Extraneous Material/Matter:** Any object or matter that may become part of the product being produced, which is not designed to be part of such product. Extraneous matter may be a foreign object, foreign material or an aberration in the product or product ingredient. Examples may include: metal; stones; wood; animal parts; plastic; paper and extraneous matter inherent to raw materials (bone, nut shells, etc.).

**Flow-through/Push-through Changeover:** A changeover from one product to another in a relatively closed manufacturing system that involves sending a predetermined quantity of the next subsequent product through the system. The product formulation typically contains the same ingredients as the previous product to avoid product labeling concerns. The friction from the next product removes material from the system and “cleans” the production equipment. This is typically only part of a larger cleaning protocol and may include discarding a set amount of the subsequent product at the beginning of the run.

**Flushing Changeover:** A changeover from one product to another in a relatively closed manufacturing system that involves sending a predetermined quantity of a food ingredient through the system. This ingredient is typically abrasive in nature and can be found in the products that are run on that production process (e.g., salt, sugar). The friction from the ingredient removes material from the system and “cleans” the production equipment. This is typically only part of a larger cleaning protocol.

**Food Allergy:** An abnormal immune system response to a food protein.

**Food Regulatory Agency:** State or Government body appointed or authorized to oversee activities of the food manufacturing and supply industry. Examples include European country specific Food Standards Agencies, Trading Standards Agencies, USA agencies such as FDA, USDA, and in Canada CFIA.

**HACCP:** Hazard Analysis Critical Control Point.

**HACCP Team:** A cross-functional team of experts responsible for the development of a food safety plan.

**Hazard:** A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

**Hazard Analysis:** The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be controlled in the HACCP plan.

**Hold:** A status assigned to a specified product indicating it must all remain stopped from normal handling processes until further notice. Synonyms include: quarantined, blocked, segregated, contained, embargoed, etc.

**Category I Product Hold:** The product / material will be placed in a segregated and secured area when possible. All affected product will be visually identified and physically obstructed. For example, hold stickers / tags on pallets and chains placed across the bay / rack, or hold tape wrapped around the cases, or product placed in caged / fenced area that is locked. These controls also apply to facilities that use automated or computerized storage / inventory systems. Inventory is confirmed daily.

**Category II Product Hold:** The product / material will be placed in a segregated area when possible. All affected product will be visually identified and / or physically obstructed, as long as the method adopted effectively prevents inadvertent movement. These controls also apply to facilities that use automated or computerized storage / inventory systems. Inventory is confirmed monthly.

**Like into Like:** Products/rework that have a certain allergen profile can be added into products/rework that have the same allergen profile.

**Lot (Lot Number):** A unique identity given to a defined quantity of a material usually based on time and location of manufacture. For continuous processes, a lot cannot exceed the amount of material produced in one 24 hour period. For non-continuous processes, the batch, blend, shift, or other time segment may be used to identify a lot. For materials received in bulk, the lot would usually be identified as the contents of the bulk vehicle.

**LOTO:** Lock-Out-Tag-Out

**Manufacturing Plant:** Any facility where products are manufactured

**Microbiologically Sensitive Materials:** (also, "Sensitive Ingredient") An ingredient that may contain zero-tolerance pathogens or support the growth of any pathogen. Sensitivity of an ingredient is based on origin, the manner in which it is processed, and/or on epidemiological and historical data.

**Mock Recall:** A simulated recall process of tracing a material back to the Supplier through the process and/ to the customer or a finished product back to all of the components in the product (lot numbers and suppliers) and the next customer where the product was shipped. This exercise helps to ensure that traceability procedures are adequate and identify opportunities for improvement in the event of a real recall situation.

**Non-conformity:** Deviation of product or process from specified requirements, or the absence of, or failure to implement and maintain, one or more required management system elements, or a situation which would, on the basis of available objective evidence, raise significant doubt as to the conformity of what the supplier is supplying.

**Oil-Free Compressed Air:** The term is used to describe compressed air generated by oil-free compressors. In these types of compressors lubricants are not used within the compression chambers and therefore the compressed air generated is "oil-free." ([http://www.fluidenergy.com/market/closer\\_look\\_oil\\_free\\_air.htm](http://www.fluidenergy.com/market/closer_look_oil_free_air.htm)). The use of an oil-free compressor does not eliminate the need for down stream treatment, depending on individual circumstances.

**Overflow:** Product obtained directly at the processing line and that meets all food safety requirements. (e.g. generated by unbalanced ratio between processing line and packaging line capacities). Overflow includes in-process products that are returned directly into the process or recirculated, such as nuts or nut products, chocolate, or cereal. Product which meets this definition of Overflow will not be treated as rework if it

is used on the same line during the same shift or production run. However, if Overflow is stored, or moved for use on a different line, then it shall be treated as rework. Traceability must be maintained.

**Pathogen:** A foodborne microorganism recognized as a public health hazard that can cause illness or death in humans.

**Prerequisite Program (PP).** The universal procedures used to control the conditions in the plant environment which contribute to the overall safety of the product.

**Process Authority:** A person or organization having expert knowledge of the processing requirements of a food under review. A Process Authority may be an in-plant employee, an outside consultant, other professional or professional body who has specialized training for the process under review.

**Refrigeration:** Temperature conditions target 40°F not to exceed 45 °F (8 °C).

**Rinsate:** A fluid sample from a closed or self-contained cleaning system (i.e., Clean-In-Place – CIP) that can be tested for the presence of residual chemicals or allergens. This fluid sample is typically taken from the latter portion of the final rinse stage and before the sanitizer stage of the CIP cycle.

**Risk:** A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

**Recall:** Removal of a product from the market due to a non-conformity that poses a potential or real violation of a regulation.

**Release:** The action to discharge a product from hold status for usage after the cause has been investigated, and disposition determined.

**Rework:** Any product or product component that fails to make it completely through the manufacturing process 1st pass, but is suitable to be returned to the process stream. Rework can result from liquid or solid semi-finished product as well as from all finished products. Rework may include non conforming product (finished or semi finished), intermediate material or product used to flush ingredient and product delivery lines.

**Sanitation:** All actions dealing with cleaning or maintaining hygienic conditions of the facility. This ranges from cleaning/sanitizing specific equipment to periodic cleaning activities throughout the facility, including building, structural, and grounds cleaning activities.

**Tolerance:** Allowable deviation from the target value of a certified reference or other standard.

**Traceability:** The ability to track a specific lot of ingredient/component to the product that contains it; and to track a finished product to the primary external customer(s) or destination(s).

## Appendix 1

### 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 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. For components of a supplier approval program, see the GMA guidance on "Control of *Salmonella* in Low Moisture Food" available at <http://www.gmaonline.org/science/SalmonellaControlGuidance.pdf>, 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>

<b>Category I</b>	<b>Category II</b>	<b>Category III</b>
<b>Number of samples: 60 Amount tested per sample: 25 g</b>	<b>Number of samples: 30 Amount tested per sample: 25 g</b>	<b>Number of samples: 15 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>

<b>Conditions of use reduce concern</b>	<b>Conditions of use cause no change in concern</b>	<b>Conditions of use increase concern</b>
<b>Case 10 n=5, c=0</b>	<b>Case 11 n=10, c=0</b>	<b>Case 12 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 n=15, c=0</b>	<b>Case 14 n=30, c=0</b>	<b>Case 15 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.

## 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 and Hammack, 2007), 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, 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*, the tested lot is considered adulterated and should not be released into commerce. 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 the GMA guidance on “Control of *Salmonella* in Low-Moisture Food” (available at <http://www.gmaonline.org/science/SalmonellaControlGuidance.pdf>, p. 63).

References (for Appendix 1)

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## Appendix 2

Examples for Guidelines for Time/Temperature Parameters to Meet a 5-log Reduction in *Salmonella*

Type of Processing	Critical Reference Parameters				
	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

**Appendix 3**  
**Examples of HACCP Forms**

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  
HACCP Plan Approval

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**PRODUCT/PRODUCT CATEGORY DESCRIPTION - EXAMPLE**

**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>Process</b> (e.g., oil roast, dry roast, steam, hot water, PPO-treated, ETO-treated)	
<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>Storage &amp; Distribution</b> (e.g., Ambient, refrigerated, frozen, relative humidity, high altitude)	

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## PRODUCT/PRODUCT CATEGORY DESCRIPTION

### Completed Example

**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 walnut snacks
<b>Process</b> (e.g., oil roast, dry roast, steam, hot water, PPO-treated, ETO-treated)	Dry roasting
<b>Food Safety Characteristics</b> (e.g., pH, $a_w$ , % 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 walnuts (on walnut 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>Storage &amp; Distribution</b> (e.g., Ambient, refrigerated, frozen, relative humidity, high altitude)	Ambient

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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**

**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 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 prevent or eliminate the hazard, or to reduce the hazard to an acceptable level in the HACCP plan?)	Is the control measure a critical control point (CCP) 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 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 prevent or eliminate the hazard, or to reduce the hazard to an acceptable level in the HACCP plan?)	Is the control measure a critical control point (CCP) or a prerequisite program (PP)?
Raw peanuts	(B) VP, e.g. <i>Salmonella</i>	(B) Yes	(B) Pathogens may be present in raw material	(B) Roasting	CCP
	(C) Peanut protein	(C) Yes	(C) Peanut and walnuts are allergens	(C) Bar code labeling (C) Label check at changeover	CCP PP
	(C) Aflatoxin	(C) No	(C) Supplier qualification plans and raw material screening eliminates the risk from aflatoxin	(C) Supplier qualification (C) Mycotoxin testing	PP PP
	(P) Extraneous matter	(P) Yes	(P) Plant experience has shown a history of extraneous matter in this raw material	(P) Screens (P) Sifters	PP CCP
Roasted walnuts	(B) None	(B) No	(B) Microbiologist has determined that roasting of this product has eliminated the hazard from pathogens	(B) None	NA
	(C) Walnut protein	(C) Yes	(C) Peanut protein is an allergen, but all products produced on the line are peanut only, and all products are labeled as containing peanut	(C) Bar code labeling (C) Label check at changeover	CCP PP
	(P) None	(P) No	(P) Based on plant history and experience, there is not a risk from extraneous matter in this material	(P) None	NA
Herb blend	(B) VP	(B) Yes	(B) Pathogens may be present in raw material	(B) Certificate of Analysis	CCP
	(C) None	(C) No	(C) Toxicologist has reviewed this material and relevant scientific literature and has determined there is not a risk for allergens	(C) None	NA
	(P) None	(P) No	(P) Based on plant history and experience, there is not a risk from extraneous matter in this material	(P) None	NA
Rework	(B) None	(B) No	(B) All rework has been through a lethal kill step to eliminate pathogens	(B) None	NA
	(C)Peanut, walnut proteins	(C) Yes	(C) Peanuts and walnuts are allergens	(C) Rework handling procedures	PP
	(P) None	(P) No	(P) Based on plant history and experience, there is not a risk from extraneous matter in this material	(P) None	NA
Process water	(B) VP	(B) No	(B) Chlorination of city water eliminates the risk for pathogens	(B) City chlorination testing	PP
	(C) None	(C) No	(C) Toxicologist has reviewed this material and determined there is not a risk for allergens	(C) None	NA
	(P) None	(P) No	(P) Filtration of city water eliminates the risk from extraneous matter	(P) Water filtration	PP

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**PROCESSING STEP EVALUATION  
EXAMPLE**

**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 HACCP 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 prevent or eliminate the hazard, or to reduce the hazard to an acceptable level in the HACCP plan?)	Is the control measure a critical control point (CCP) or a prerequisite program (PP)?
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C)	(C)	
	(P)	(P)	(P)	(P)	
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C)	(C)	
	(P)	(P)	(P)	(P)	
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C)	(C)	
	(P)	(P)	(P)	(P)	
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C)	(C)	
	(P)	(P)	(P)	(P)	
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C)	(C)	
	(P)	(P)	(P)	(P)	

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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 HACCP 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 prevent or eliminate the hazard, or to reduce the hazard to an acceptable level in the HACCP plan?)	Is the control measure a critical control point (CCP) or a prerequisite program (PP)?
Raw Peanut Receiving	(B) None	(B) No	(B) The act of receiving peanuts does not introduce any biological hazards	(B) None	NA
	(C) None	(C) No	(C) The act of receiving peanuts does not introduce any chemical hazards	(C) None	NA
	(P) None	(P) No	(P) The act of receiving peanuts does not introduce any physical hazards	(P) None	NA
Raw Peanut Storage	(B) None	(B) No	(B) The act of storing peanuts does not introduce any biological hazards	(B) None	NA
	(C) None	(C) No	(C) The act of storing peanuts does not introduce any chemical hazards	(C) None	NA
	(P) None	(P) No	(P) The act of storing peanuts does not introduce any physical hazards	(P) None	NA
Peanut Roasting	(B) None	(B) No	(B) The act of roasting peanuts does not introduce any biological hazards	(B) None	NA
	(C) None	(C) No	(C) The act of roasting peanuts does not introduce any chemical hazards	(C) None	NA
	(P) None	(P) No	(P) The act of roasting peanuts does not introduce any physical hazards	(P) None	NA
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	(C) None	NA
	(P) Extraneous metal from seasoning container	(P) No	(P) Strict adherence to GMPs by employees reduces the risk of contamination	(P) GMP's	PP
Rework addition	(B) VP – Human Handling	(B) No	(B) Strict adherence to GMPs by employees reduces the risk of contamination	(B) GMP's	PP
	(C) Tree nut protein	(C) Yes	(C) Addition of incorrect rework could result in addition of undeclared tree nut allergen	(C) Rework Handling	CCP
	(P) None	(P) No	(P) The act of rework addition does not introduce any physical hazards	(P) None	NA
Packaging into foil packages	(B) None	(B) No	(B) The act of packaging peanuts does not introduce any biological hazards	(B) None	NA
	(C) None	(C) No	(C) The act of packaging peanuts does not introduce any chemical hazards	(C) None	NA
	(P) None	(P) No	(P) The act of packaging peanuts does not	(P) None	NA



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## INGREDIENT ALLERGEN ASSESSMENT Completed Example

**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 Critical Control Point (CCP) or prerequisite program (PP).

PER MANUFACTURING LINE: (There should be as many forms 1 and 2 as manufacturing lines present in the plant)

A	B	C
List all ingredients containing allergens per Food Allergen List. List any processing aids that may come in contact with product contact surfaces or product itself.	List identified allergens of ingredients	List identified carryover allergens
Raw peanuts	Peanut	
Roasted walnuts	Walnut	
Rework nuts	Peanut, walnut	



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## ALLERGEN CROSS-CONTACT PRODUCTION ASSESSMENT COMPLETED EXAMPLE

**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) ( _ - CCP) ( _ - PP )
	<b>YES</b> (list allergens)	<b>NO</b> (list allergens)	
Roasted peanuts snack pack		Walnuts	Barcode Labeling – CCP, Label Check at Changeover – PP, Rework Handling - CCP
Roasted walnuts with cranberries		Peanuts	Barcode Labeling – CCP, Label Check at Changeover – PP, Rework Handling - CCP
Roasted peanuts seasoned with herbs		Walnuts	Barcode Labeling – CCP, Label Check at Changeover – PP, Rework Handling - CCP
Roasted peanuts with mixed fruit		Walnuts	Barcode Labeling – CCP, Label Check at Changeover – PP, Rework Handling - CCP

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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.”

<u>Minimum Temperature*</u>	<u>Minimum Time</u> 4-log kill	<u>Minimum Time</u> 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 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 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 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	Metal 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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PLANT NAME:	Supersedes	DD-MMM-YY	Page Number
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### HACCP PLAN APPROVAL EXAMPLE

**Purpose:** Provides documentation of final approval to assure that the HACCP plan was developed using a cross-functional team approach.

Reason for Approval Request

NEW PLANS, e.g., new product, new process, new package

MODIFICATIONS TO EXISTING PLAN, e.g., product line extension, new or changed ingredients, modified/relocated process, addition of Critical Control Point(s), elimination of Critical Control Point(s)

CHANGE DESCRIPTION Describe all change(s), reason for change(s) and their location in the documentation

List and attach (or reference) the following documents

Document	Date Issued	Page Number
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		
HACCP Plan Approval		

Identify hazard analysis team members by name.

Signature of person(s) **approving** plan:

## Appendix 4

### 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 5

### Example of Calibrating 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 6

### Examples of Roaster Thermal Process Validation

#### Example A

#### VALIDATION OF PEANUT ROASTING PROFILES FOR 4-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. There is currently no information available on the lethality of roasting against *Salmonella* on peanuts.

Raw peanuts are likely to be contaminated with *Salmonella* at low levels (< 10 CFU/g). 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 published it as a proposed rule in the Federal Register (AMS, 2006), based on risk assessments (Danyluk et al., 2006). The appropriate log-reduction for *Salmonella* in peanuts is being determined by further studies such as a risk assessment.

In this example, it was assumed that roasting peanuts with a 4-log *Salmonella* reduction would provide the appropriate lethality. (Note: whether or not a 4-log reduction is adequate is yet to be determined by further studies on the incidence and concentration of salmonellae in raw peanuts and/or additional scientific data and information.)

The traditional roasting practice may not be fully effective in *Salmonella* inactivation and must be evaluated for its adequacy. As the water activity ( $a_w$ ) of the product decreases, the lethality of the heat will be less against *Salmonella* (Shachar and Yaron, 2006). As the peanut loses moisture and  $a_w$  gets lower, the heat will be less effective to inactivate *Salmonella*. 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. Therefore, the maximum lethality against *Salmonella* may not be delivered during roasting for a given time/temperature profile. In this study, an innovative approach was used to deliver the maximum lethality of heat against *Salmonella*. That is, roasting starts at the highest temperature of the profile and is lowered during roasting, as opposed to the traditional 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 are likely to be increasing 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.

The objective of this study is to determine and validate the peanut roasting time/temperature profiles with specified roasting operational parameters to achieve >4-log *Salmonella* log-reduction and produce high quality roasted peanuts. The goal is to meet the safety requirement before meeting the roasting quality requirement.

## 2. MATERIALS & METHODS

### 2.1 Inoculum preparation & peanut inoculation

In this study, two test organisms (*Salmonella* Enteritidis BAA-1045 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 level.

Raw peanuts on the trays were put into the biohazard hood. The culture was then sprayed evenly onto the single layer raw peanuts using a spray bottle. The inoculated peanuts were air-dried overnight in the hood before using them for the experiments.

### 2.2 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.

### 2.3 *Salmonella* log-reduction determination

#### 2.3.1 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.

### 2.3.2 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.

### 2.3.3 Calculation of Log-*Salmonella* Reduction

Log-*Salmonella* reduction (LSR) was calculated based on the log average of ten pre-roast samples and ten post-roast samples.

## 2.4 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.

## 3 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.

Traditionally, peanuts are roasted either with same temperature or with the temperatures increasing with time. In this study, an innovative approach was taken. That is, as opposed to traditional roasting, the roasting temperature at the beginning of the roasting was the highest and at the end of the roasting was the lowest to maximize the lethality of the heat. Peanuts were roasted at various time/temperature profiles.

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 with 3" bed depth was able to achieve >5.0-log reduction in both *Salmonella* Enteritidis and *Salmonella* Tennessee. *Salmonella* Enteritidis and Tennessee appear to have comparable heat resistance.

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. Three experimental trials were performed. The log-reduction ranged from 5.12 to 5.72 log CFU/g.

#### 4 SUMMARY & CONCLUSION

The results of this study can be summarized as:

- 4.1 Lethality of roasting can be maximized by starting roasting with highest temperature and reducing it as roasting progresses, as opposed to the traditional roasting with single temperature or increasing temperature as roasting progresses.
- 4.2 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 lowest profiles.
- 4.3 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.
- 4.4 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.

4.5 *Salmonella* Enteritidis BAA-1045 and *Salmonella* Tennessee ATCC 10722 appeared to have comparable heat resistance.

4.6 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 *Salmonella* log-reduction and roasting quality such as color.

4.7 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 will be smaller ( $\leq 5^{\circ}\text{F}$ ).

4.8 The log-reductions between the two peanut types were comparable.

In conclusion, > 4-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.

## 5 RECOMMENDATIONS

5.1 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 information provided in this study.

5.2 The following operational parameters are recommended to produce high-quality roasted peanuts in addition to producing safe roasted peanuts.

5.2.1 Incoming hot air flow rate must be secured at  $\geq 190$  fpm during entire production time.

5.2.2 Hot air flow direction (up or down) for each zone should be opposite to the air flow direction of the zone before.

5.2.3 Even air flow distribution across the belt should be ensured at each zone.

5.2.4 Three-inch peanut bed depth is optimum bed depth for food safety and quality standpoint. It must be  $\leq 3.5$  inches to meet the requirement for both food safety and highest quality roasted peanut production with more uniform roasted peanut color.

5.2.5 Roaster air temperature should be adjusted appropriately to achieve required *Salmonella* log-reduction (>4.0-log) and to produce roasted peanuts at the required color specification (L-value:  $48 \pm 2$ ). Roaster air temperature must be set highest at the beginning and reduced as the roasting progresses to achieve the maximum lethality.

- 5.2.6 Belt speed must be adjusted accurately to assure the roasting time required for safe and quality roasting (not including cooling time)

## 6 NEXT STEPS TO COMPLETE THE VALIDATION PROCESS

Peanut time/temperature profiles of the actual production (roasting) must be validated by following the procedure below:

- 6.1 Three thermocouples with multiple peanut-penetrating and air probes (3–4 peanut penetrating probes and 3–4 air probes) must be used. Total 6–8 probes per thermocouple must be embedded into the middle of the peanut bed. One 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.
- 6.2 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 should be approximately one inch.
- 6.3 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.
- 6.4 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.
- 6.5 Once the time/temperature roasting profiles are determined, the time/temperature profiles must be compared to those of the roasting experiments in this study and evaluated whether >4-log *Salmonella* reduction can be achieved based on the results of this study.
- 6.6 The following microbiological sampling and testing is necessary to evaluate the overall microbiological quality of the roasted peanuts and to finalize the validation process.
  1. Take five samples (raw peanuts) before roaster and 5 samples after roaster per production shift.
  2. Take samples at equal time-intervals throughout the shift.
  3. Take samples for 30 production shifts.
  4. Test 25 g of each sample for APC, coliforms, and *E. coli*.

## 7 REFERENCES (for Appendix 6 Example A)

Danyluk, M.D., L.J. Harris, and D. W. Schaffner. 2006. Monte Carlo simulations assessing the risk of salmonellosis from consumption of almonds. *J. Food Prot.* 69:1594-1599.

Kirk, M.D. C. L. Little, M. Lem, M. Fye, D. Genoble, A. Tan, J. Threlfall, A. Paccagnella, D. Lightfoot, H. Lyi, L. McIntyre, L. ward, D.J. Brown, S. Surnam, and I. S. T. Fisher. 2004. An Outbreak due to Peanuts in their shell caused by *Salmonella* enterica serotypes Stanley and Newport-sharing molecular information to solve international outbreaks. *Epidemiol. Infect.* 132:571-577.

Shachar, D., and S. Yaron. 2006. Heat tolerance of *Salmonella* enterica serovars Agona, Enteritidis, and Typhimurium in peanut butter. *J. Food Prot.* 69:2687-2691.

USDA Agricultural Marketing Service (AMS). 2006. Almonds grown in California; outgoing quality control requirements and requests for approval for new information collection. Proposed Rule. Federal Register. 71:70683-70692.

**Example B**

**VALIDATION OF ROASTER IN 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 \_\_\_\_\_:

Table 1. Comparison of Time/Temperature Profile Data for Validated and Verified Processes

Validation	Time/Temperature Profile		
	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 ≥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 \_\_\_\_\_ indicate that the \_\_\_\_\_ roaster delivered a process (air temperature delivered to peanuts) with microbial lethality in excess of the validated minimum process

## Appendix 7

### 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)

$$F_{125^\circ\text{C}} = 19.3 \times 10^{[284-270]/78}$$

$$F_{125^\circ\text{C}} = 19.3 \times 10^{0.179}$$

$$F_{125^\circ\text{C}} = 19.3 \times 1.51$$

$$F_{125^\circ\text{C}} = 29.2 \text{ min at } 270^\circ\text{F}$$

## Appendix 8

### 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 a 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 Lethen 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 9

### 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 10

### 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 micro 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 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 neck, earplugs with rigid attachment worn around neck, earmuffs attached by 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: before entering a production area, upon re-entering the 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 11

### 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 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 12

### 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
  - Lock out all equipment requiring disassembly
- LOTO - 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 to drain, not drain to the trash

#### Step 3 - Soap and Scour

- Foam/Soap the floors, walls and equipment – PPE required
  - Work from bottom to top
    - Foam the floors
      - 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 13

#### Sanitation Good Manufacturing 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>
Sanitary Mats	<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> <ul style="list-style-type: none"> <li>• Live plants, flowers, or animals should not be brought into: <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> </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 14

### 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>
<p>Rework Handling &amp; Storage</p>	<p>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.</p>

## Appendix 15

### 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.
  - f. Third party metal detection technology vendors should not be used. X-ray can be considered as alternative but approval shall be obtained from Corporate Quality.
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 ConAgra 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.
      1. 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.
      2. 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.
      3. 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

- a. Verification of detection/rejection system effectiveness
  - i. Test standards shall be used to verify detection and system effectiveness. The test standard shall be diverted by the unit.
  - ii. Each facility shall have procedures for standard checks verifying units are detecting appropriately.
  - iii. All verification tests shall be documented and recorded.
- b. Once per week a plant Quality designee reviews the foreign material control documents to ensure completeness and accuracy.
- c. A certified outside company or trained internal maintenance person shall ensure accurate calibration according to manufacturer’s specification on an annual basis.
- d. Any changes or new products that may affect metal detection performance shall require the metal detection system to be qualified for that change or product.

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.cfsan.fda.gov/~dms/dalbook.html>
- Inspecting Incoming Food Material by FDA <http://www.cfsan.fda.gov/~dms/insp-toc.html>
- 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:

<b>Aperture Height</b>	<b>Product Classification</b>	<b>Sensitivity Standards</b>
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	1.5 mm Diameter (Ferrous & Non)
	Wet Conductive Product	2.0 mm Diameter (Ferrous & Non)
	Wet Non-Conductive Product	2.5 mm Diameter (Ferrous & Non)
125 to 200 mm	Dry Product	2.0 mm Diameter (Ferrous & Non)
	Wet Conductive Product	2.5 mm Diameter (Ferrous & Non)
	Wet Non-Conductive Product	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.*

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# Industry Handbook for the Safe Shelling of Peanuts

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## *Addendum to Industry Handbook for the Safe Processing of Nuts*

9/21/2009

[This is a guidance document for the peanut shelling industry and provides examples of prerequisite programs that can be used in ensuring the safe shelling of peanuts. The handbook is part of a broader nut industry initiative to provide food safety guidance for the supply chain.]

## CHAPTER 1 - PREREQUISITE PROGRAMS FOR PEANUT SHELLERS

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## Introduction

Peanut shellers 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” (PPs) are the foundation and will provide operating conditions conducive to the implementation of HACCP. 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.

Prerequisite programs should be documented and will be audited as part of food safety audits and include Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs) and Sanitation Standard Operating Procedures (SSOPs). GMPs are a series of general principles that must be observed during manufacturing and their guidelines outline the aspects of production that would affect the quality of a product. Encompassed within GMPs are Good Handling Practices, Good Laboratory Practices and other best practice principles.

SOPs and SSOPs work in conjunction with GMPs and are prescriptive instructions on how to manufacture, sanitize and operate. Examples of an SOP would be a written procedure for sheller equipment operation, magnet check, or shipping inspection. Examples of an SSOP are sanitizing procedure for sheller/gravity or a procedure for cleaning of floors.

An example of an SSOP is on Page 8, Cleaning and Sanitation, and an example of an SOP and its format can be found in Appendix AA.

This guidance material is not intended to be an all inclusive reference on PPs. Included are a number of key PPs that will provide a strong basic foundation for the shelling of safe nut products.

This document is a compilation of information from the *Industry Handbook for Safe Processing of Nuts*, GMA, 2009, and *Good Manufacturing Practices for Shelling Plant Operations*, M. Spooner, J. Trice, S. Calhoun, APC, 2008, as well as from referenced material listed at the end of the Guidelines. The *Industry Handbook for the Safe Shelling of Peanuts* was drafted by M. Arline, JLA Global; R. Starling, Golden Peanut Company; D. Cowart, Ph.D., JLA USA, now with Birdsong Peanuts; and, E. Plowden, Jr., WatsonSpence LLP, and endorsed by the American Peanut Shellers Association in October 2009.

### List of Key Prerequisite Programs (PPs)

Facilities	Personnel Practices
Receiving, Storage, and Distribution	Training
Pest Control	Labeling
Chemical Control	Allergen Management Program
Production Equipment	Extraneous Material Control
Specifications	Use of Outside Laboratories
Supplier Control	Product Hold and Release
Cleaning and Sanitation	Complaint Investigations
Preventive Maintenance	Traceability and Recall

**Facilities** - The facility should be located, constructed and maintained according to sanitary design principles. There should be linear product flow and traffic control to minimize cross-contamination from raw incoming to cleaned and shelled peanuts. Facilities should be well-ventilated and designed to prevent moisture and extraneous matter contamination in shelled peanuts.

Bathrooms, water fountains and handwashing facilities should be convenient to product areas, while not providing a potential product contamination source.

**Receiving, Storage and Distribution** – All raw materials and products should be stored under sanitary and secure conditions, with the proper temperature and humidity conditions to assure their safety and wholesomeness.

The sheller should use designated storage areas or stock rooms 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.

Storage facilities should be neat, orderly, and include considerations for:

- Sanitation and pest control (e.g., spacing equipment or material storage away from walls, guideline 18 inches for multiple pallet applications; sealed doors and windows; cleanable floors, walls and overhead structures).
- Damaged bags, totes, boxes should be sealed to prevent product spillage and contamination. Raw materials damaged during the shelling process should be separated and a determination made as to the proper disposition. Spills should be cleaned up to prevent potential for contamination and infestation.
- Identification and tracking of shelf life of raw materials and release status of shelled peanuts. An effective stock rotation system should be in place.
- Temperature/humidity-controlled versus ambient conditions, as required per specification. Storage temperatures and humidity (where applicable) should be measured and documented using calibrated recording equipment.
- Storage off the floor on pallets or slip sheets. Pallets, slip sheets, 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.
- All peanut storage facilities must be dry, free of moisture build-up and leaks.
- Glass should not be allowed in storage areas. Light bulbs should be shatterproof.
- Products with strong odors should be segregated to avoid odor migration.
- Where packaging materials are not sealed 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, no off odors.

The transportation program should encompass the following minimum requirements:

- 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).
- 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. This information should be documented.
- Temperature-controlled vehicles should carry suitable on-board temperature monitoring devices. The devices should be verified at defined intervals. This information should be documented.
- 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.
- Inbound and outbound bulk containers should be sealed. Acceptable seals include:

For Federal-State tags:

- For totes, the two ties should be “tied off” and then the Federal-State Tag (which has 2 ends) double wrapped around the ties and sealed with clear plastic poly tape.
- For 2200 pound boxes, the box should be poly taped (tamper evident) around the entire box 4 times, and the Federal-State Tag poly taped to the top of the box.
- The tags should have company name and logo printed on them.

Seals, meeting customer and regulatory requirements, should be secured on railcars and export containers.

Large bags such as super-sacks or totes containing plastic liners should have a bag closure that will readily reveal any tampering and will not permit removal and reinstallation without breaking the seal.

In cases where third party warehouses are used to store raw materials, packaging materials, or shelled products, periodic assessments should be conducted to assure that the sheller’s requirements are met.

**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. Pest control activities should be performed by certified pest control contractors or personnel with a valid commercial applicator’s license, or operating under the supervision of a licensed pesticide applicator. In the first case, a valid contract and a copy of the license given by the relevant local authority, including insurance coverage, should be in place.

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

Exclusion should be the first line of defense and primary method of controlling pests. Efforts should be made to keep pests out of the building by using good exterior controls including:

- Eliminate all possible entrances into the facility (note that a mouse can enter through a ¼" (1 cm) opening)
  - All doors, dock doors, windows, and screens should fit tightly
  - Doors should be kept closed
  - Pipe openings through facility walls should be sealed
- Product pipes should be capped when not in use
- Areas around farmer stock storage facilities should be free of grass, weeds, debris, and any extraneous material to prevent rodent harborage. A program must be in place to maintain the areas surrounding storage facilities (mowing and spraying).
- A clear border (approximately 3-ft wide/3-ft vertical), free of vegetation from the ground to above the roof should be maintained around the building perimeter (including tree limbs and shrubs).
- Scrap, pallets, pipe, 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 rodent holes and burrows should be closed.
- All raw materials, equipment, and supplies received should be inspected upon receipt for rodent excreta or any signs of gnawing and chewing on the containers or peanuts. Mice often enter the facility in incoming loads.
- All openings on wall and roof penetrations should be screened to prevent insect or rodent ingress. Ventilation systems should be louvered and screened to prevent entrance of insects and birds into farmer stock storage facilities.

Rodent traps are set in three perimeters of control (lot line, exterior of the building, and interior of the building). Rodent traps should be used on interior ground level floors 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. Secondly, food and harborage sources should be controlled through proper sanitation, housekeeping, and storage practices.

Chemicals used for pest control should be accurately labeled, inventoried and, when not in use, securely stored (by locked door/gate) with access granted to authorized and designated personnel only. 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.

Bait stations should be installed at approximately 50-ft intervals around exterior of buildings and maintained with approved bait. Stations should be secured and locked to prevent entry of unauthorized personnel. Stations should also be numbered and a master listing maintained to monitor rodent activity at each station. All stations should be checked routinely to document activity. Tin Cats (no poison) should be used in outside area exposed

to product (e.g., dump pits) at approximately 25-ft intervals. Rodenticides used should be in block form only (rodenticidal granulates, pellets or powders should not be used).

Light bulbs from the insect light traps should be replaced regularly (as per manufacturer requirement) 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.

Routine inspections should be conducted at a frequency necessary to identify pest activity, harborages, and entry points. Pest activity inspection results should be recorded. 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. If pest activity is noted, controls should be increased appropriately. Documentation should include a map of the facility traps and bait stations, copy of license of pesticide applicator, MSDS sheets and check lists of activity with any corrective action, plus all training.

**Chemical Control** – Documented procedures should be in place to assure the segregation, security and proper use of non-food chemicals in the plant. These include cleaning chemicals, fumigants, and pesticides or baits used in or around the plant.

**Production Equipment** – All equipment should be constructed and installed according to sanitary design principles. Preventive maintenance and calibration schedules should be established and documented. All testing, recording and monitoring devices should be checked at specified intervals to assure accuracy. Results should be recorded and signed.

**Specifications** – There should be written specifications for all incoming and shelled peanuts and packaging materials. Shelled peanut specifications should meet regulatory and customer requirements.

**Supplier Control** - Each facility should assure that its suppliers have in place effective GMP and food safety programs. Shellers who receive shelled peanuts from a seed sheller, toll sheller or other contract sheller should assure that their supplier's food safety programs are also in compliance with these guidelines.

**Cleaning and Sanitation** – All procedures for cleaning and sanitation of the equipment and facility should be documented and followed. The sanitation procedures should be written using the following information: Description of the area to be cleaned; equipment needed for cleaning including tools, chemicals, etc.; work instructions or procedures to be followed; person responsible for cleaning the assigned area; and, frequency of cleaning the area. Documentation using a master sanitation schedule should be in place.

An **example of a sanitation procedure** follows:

#### SHELLER/GRAVITY AREA

Description of Area: The shellers are used to remove hulls from the farmer stock peanuts. Hulls are sent to an outside facility and used for animal feed. Shelled

peanuts are moved forward in the process. The gravity separators are used to remove foreign material of different density from the peanuts.

Equipment needed for cleaning: broom, dust pan, trash can, air hose, shovel.

Procedure: Keep area around the shellers clean. Do not store parts, tools, or chemicals on the equipment and keep all items in a locked storage cabinet. On an as needed basis, keep all spills swept up and keep area neat and well-maintained. On a daily basis, blow down all equipment. On a weekly basis, clean out all peanuts from the elevators. Spray elevators as needed and required by label. Sweep up the entire area after blowing down.

Frequency of Cleaning: Weekly – Equipment, Elevators  
Daily – Floors, Spills

Person Responsible: Operator

Documentation: Master Sanitation Schedule must be signed by the person completing the sanitation procedure.

### **Preventive Maintenance**

Equipment and materials selected for production should be suitable for the purpose intended, and well-maintained. A documented, planned maintenance program should be defined for preventive and corrective maintenance. 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.

Appropriate measures should be in place to protect products in the event that repair or maintenance activities occur during production. A documented program should be in place to isolate maintenance work areas from active production lines and for line/area release to production after completion of maintenance work (equipment and area to be cleaned and sanitized as applicable prior to release for food production).

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

Food-grade lubricants should be used on food cleaning and shelling equipment where direct and/or indirect contact between lubricant and food products is possible.

All metal welds in product contact areas should be non-toxic, cleanable, free from pits, folds, cracks, crevices or inclusions.

Tools should be cleaned and kept off of floors and walking surfaces (e.g., decks, stairs). Tools should be maintained in a locked tool box or other secure container.

Equipment repairs are intended to be permanent and should be performed using proper materials. Temporary fixes that may adversely impact the food safety/quality of a product

should be replaced in a timely manner (typically within 30 days) by permanent repairs. Plastic, tape and paperboard used in temporary repairs should be dated until replaced.

**Personnel Practices** – All employees, contractors and guests who enter the shelling plant should follow the requirements for personal hygiene and food safety practices.

From American Peanut Council GMP's June 2009 pages 5-6:

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 has assigned to the managers of food operations the responsibility for assuring compliance by all personnel with this part of the GMPs. To accomplish this, management has been given the responsibility for training personnel in food protection principles and food handling techniques. A written training program should be established, routinely evaluated, and updated as necessary. It is important to note that training must be applied as stringently to temporary personnel as with permanent employees. Contract service personnel must be trained in quality and food safety before being placed into positions that may affect the product.

There are several personnel practices with which peanut shellers should be diligent:

- Disease Control - Personnel with contagious illnesses, open lesions, boils, sores or infected wounds which could contaminate foods or food contact surfaces with microorganisms should be excluded from areas where contamination may occur. 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 risk to the work environment. A comprehensive health policy outlining employee restrictions should be developed by each organization.
- Cleanliness - (a) Employees need to wear clean garments which 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) it should be assured that any outside clothing be clean and sanitary if allowed in production areas, (e) personal cleanliness needs to be maintained by washing hands prior to work, when they are soiled, after eating, and after using restrooms.
- No jewelry should be worn or otherwise allowed in the plant.
- Effective hair covering and beard 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, and medicines applied to the skin.
- Education and training - 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 and significant potential consumer impact 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. 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.

- Each worker's responsibility and accountability as to job expectations should be documented in a clearly understandable manner.
- Personnel practices should be monitored through internal audits.
- Visitors should follow the same rules as employees and be so instructed when entering a facility.
- No glass containers should be allowed inside a shelling facility, including break areas, and food and food products should not be allowed in production areas.
- For handling any chemicals or pest control, only impermeable gloves should be used and be kept clean and sanitary during use or disposed of after use.

#### Educate workers 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 peanuts. 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, using the bathroom, and 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 30 seconds)
4. Rinse off soap thoroughly with clean water
5. Dry hands with single-use towels
6. Discard used towels in trash
7. Sanitize hands with an appropriate alcohol-based sanitizer
8. Dry hands before or after sanitizer use, as per sanitizer supplier directions.

**Training** – All employees should receive documented training in personal hygiene, GMPs, cleaning and sanitation procedures, personal safety and their role in HACCP and other food safety and food quality programs.

The peanut sheller should:

1. Determine the necessary competence for personnel performing work affecting food safety across all functions, e.g., production, maintenance, logistics, etc., and provide training or take other actions to satisfy these needs
2. Evaluate the effectiveness of the actions taken

3. Maintain appropriate records of education, training, skills and experience
  - a. Training for production employees should include a general awareness of the principles of quality, HACCP, allergens, diseases that are communicable via food, GMPs, foreign object prevention and food defense.
  - b. Refresher training should be provided annually. Training should be performed for new employees before starting work. Site-specific programs should include any necessary information and instruction for visitors and contractors prior to performing activities which may affect product safety.
  - c. Employees monitoring CCPs should receive specific training including monitoring, documentation, verification and corrective actions if the critical limits are not met.
  - e. Specific training to meet the requirements of this document should be provided as required.

**Labeling** – The sheller 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 and customer specifications.

The labels should accurately describe the material. It should clearly exhibit the name and address of the sheller, lot number, net quantity, storage conditions, and/or other information, as specified.

**Allergen Management Program** – While it is well-known that some consumers are allergic to peanuts, pecans also produce allergic reactions in some consumers. Peanut shellers should have allergen management programs to eliminate pecans from the raw peanut stream prior to receipt or during the shelling and cleaning process.

**Extraneous Matter Control** – Product cleaning, screening, separation and detection systems should be designed to remove extraneous material from incoming raw product. Inspection programs should be established to verify that the systems are working within specifications and as designed.

The sheller should have effective programs to prevent, detect and control extraneous matter in the shelled product. A risk assessment should be performed to determine potential sources of extraneous matter, including:

- Incoming raw material and primary packaging materials
- Equipment design, processing and packaging equipment, and utensils
- Plant environment (e.g., ceilings, walls, floors)
- Contamination from personnel or other operations such as cleaning and sanitation, contractor work, etc.
- Rework/work-in-progress
- Maintenance or repair of equipment
- Historical information of types of extraneous matter previously found or reported by consumers.

The assessments should consider all types of extraneous matter. Periodic reassessments should be conducted, particularly following changes to the plant environment and instances of non-conformances (e.g., customer or consumer complaints, CCP failures, etc.).

Based on the assessment, an appropriate strategy for minimizing extraneous matter should be developed, including:

- Designing the risk of extraneous matter out of the process (e.g., eliminating metal-to-metal contact on equipment)
- Preventing introduction of extraneous matter into the product (e.g., GMP, 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

The sheller should manage detection and removal devices in such a way to maximize the effectiveness of these devices. Focus should be put on the following points:

- Location of the devices in the production line
- Procedures to manage the devices
- Start-up set up (e.g., check if magnet is in place; screen is properly seated in its housing; centrifuge is operating at required rpm's; metal detector is detecting and rejecting specified metal test pieces)
- Frequency of detection and rejection mechanism verification checks
- Limits of acceptable and unacceptable results
- Abnormal findings (should be reported and documented)
- Corrective actions are taken where necessary
- Devices are calibrated as per supplier specifications or sheller experience to assure optimum effectiveness

The detection devices installed throughout the production line should be adequate to address the risks identified in the risk evaluation. These include the type of device and established detection limit.

#### Device Operation for an end-point metal detector

The detecting limit for an end-point metal detector will depend on 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. **As a guide**, the detection sensitivity under production conditions should be capable of detecting and rejecting pieces equal to or less than:

- 1.5mm for ferrous
- 2.0mm for non-ferrous (brass)
- 2.5mm for stainless steel (316 grade)
- At no time should they be larger than 7mm (0.28 in) for all metals

Functionality verification for electronic detection and rejection devices should take place during production with the normal product flow. Minimum frequency for system verification should occur at the following times:

- 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 (recommended minimum every 4 hours)

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, each test piece (ferrous, non-ferrous and stainless steel) should be passed through the detection device and detected and rejected, as defined by the particular facility's food safety program. 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 Reject mechanism should direct product rejects from the process flow automatically into an identified area, bin or container. An action level should be defined on the basis of historical trend analysis. If this action level is exceeded, then all diverted product (rejects) should be evaluated to determine the cause for rejection. Where no action level is defined, 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 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, ceramics and/or hard plastics 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., screens). Appropriate and timely corrective action should be implemented in case of any source of extraneous matter with the potential of falling into the product stream.

Other materials resulting from peanut harvesting are also found in raw peanut streams, such as nut grass, wood and stems. Peanut cleaning and shelling equipment should be properly maintained and monitored to assure removal or reduction to an acceptable level of these materials.

### **Use of Outside Laboratories**

Shelled peanuts are required under the marketing order to be certified by lot that each meets the USDA aflatoxin requirements for edible peanuts prior to entering the market place. Shellers must use USDA-certified laboratories that are inspected by USDA and participate in the USDA quality assurance systems.

For peanuts, the following protocol is used for testing finished shelled good lots:

Finished lots  $\leq 15$  ppb

\*1AB  $\leq 8$  ppb, If  $>8$  ppb and  $<45$  ppb

then run the 2AB

\*1AB + 2AB avg.  $\leq 12$  ppb, If  $>12$  ppb and  $<23$  ppb,

then run 3AB

\*1AB + 2AB + 3AB avg.  $\leq 15$  ppb

Accept the lot

### **Product Hold and Release**

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

The program should include controls for non-conforming raw materials, materials pending testing or rework, packaging, labels, and shelled peanuts. Records should be maintained to enable reconstruction of each hold event's history.

Products/materials that are on hold must be controlled via a defined and effective system which is intended to prevent inadvertent movement. Inventory reconciliation must occur to verify proper control.

When any material produced for the customer is either inadvertently released from hold or is suspected of non-conformance but has already been shipped to the customer, the customer representative should be notified immediately by phone, followed by notification in writing.

**Complaint Investigations** – Shellers should have procedures in place to receive, document, investigate, respond to and correct, if necessary, customer and consumer complaints.

**Traceability and Recall** – All raw materials and products should be lot-coded and a recall/retrieval system in place so that rapid and complete traces and recalls can be done when a product retrieval is necessary.

Companies should have an effective program for traceability of all raw materials used and shelled products produced. A recall team should be defined and contact information readily available. If requested, the sheller must 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. In general, the sheller should be able to identify the warehouse in which the peanuts were stored immediately prior to shelling. The traceability program should include identification of all raw materials, process parameters (for the specific lot), rework, and primary packaging materials, as well as the customers to whom the lot was distributed or the method of disposal.

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, shelled product.

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.

Appendix AA

**EXAMPLE**

**Magnet Check – Packaging  
Standard Operating Procedure**

**Purpose**

To remove ferrous metal from the inshell product flow after the shelling and sorting process prior to packaging and document findings.

**Scope**

This procedure covers the last magnet in the process prior to packing raw inshell edible peanuts.

**Responsibility**

1. The Packout Team Lead Person will be responsible for cleaning, maintaining and documenting findings for the magnet located on the exit spout of the elevator supplying the bagging bin.
2. The appropriate Shift Supervisor will be responsible for ensuring the Packout Team Leader is trained to follow this procedure.

**Procedure**

1. The Magnet will be cleaned by the Packout Team Lead Person after each cut on shelled good are packed
2. The Lock Out Procedure for locking out equipment will be followed, if the Lead Person is working near moving parts or electrical connections.
3. The Lead Person will ensure that there are no safety hazards which will prevent the task from being performed safely. If there are questions about the safety aspect of the task, contact your Supervisor before proceeding with the magnet check.
4. The Packout Team Lead Person will stop the flow of the product going into the Elevator.
5. The Packout Lead Person will remove metal from the magnet, log findings on the magnet findings chart, and discard findings in the appropriate waste container, being careful to ensure that metal does not enter the finished product stream.
6. If metal exceed action level, Packout Lead Person will inform the Supervisor who will evaluate and determine corrective action.

**CONFIDENTIAL**  
Inshell Control Point #1

Packing Line Magnet

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Revised 8/19/09

## CHAPTER 2 – FOOD SAFETY PLAN

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## Introduction

A commonly used framework for a food safety plan is the Hazard Analysis and Critical Control Point (HACCP) system. The HACCP system is a preventive approach to control food safety. Philosophically, HACCP involves a proactive, preventive approach to control potential 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 are specified, methods for control are identified and criteria for compliance are clearly defined. 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), which should be met to ensure the CCP is under control. Principle 4 involves establishing a system to monitor control of the CCP by scheduled measurements or observations. Principle 5 involves establishing the corrective actions to be taken when monitoring indicates a deviation from critical limit and that a particular CCP is not under control. Principle 6 is to establish 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.

It is recommended that all products and/or processes have an approved HACCP plan. Approval is determined by an internal or external reviewer trained in a HACCP course endorsed by the International HACCP Alliance. The HACCP guidelines described here are intended for use by an expert, multi-disciplinary team formed to develop a HACCP plan. The NACMCF and Codex documents and examples provided in this handbook are tools for the development, implementation, maintenance, and auditing of a HACCP plan. They also create common criteria for assessing hazards and identifying CCPs across peanut shelling operations to assure the safety of peanuts and peanut products.

### 1. Hazard Analysis and Risk Evaluation

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 shelling operation should be formed. A microbiologist should be involved during the biological portion of the hazard analysis and risk evaluation step of HACCP plan development.

It is helpful for each facility to have a HACCP team leader who can take responsibility for the maintenance and upkeep of the plan documents. NACMCF and Codex recommend the team take the following preliminary steps:

1. describe the food and its distribution;
2. describe the intended use and consumers of the food;
3. develop a flow diagram that describes the process; and,
4. 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.

### **1.1 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). Product safety hazards that are significant and should be controlled in the HACCP plan (Critical Control Points or CCPs) are identified by completing a risk evaluation.

The following steps are taken in determining whether a hazard needs to be controlled within a HACCP plan:

1. Identify potential hazards, using the flow diagram as a guide (see 1.2.1 and Diagram 1, below)
2. From the potential hazards, determine which are significant hazards that require control within a HACCP plan (see 1.2.2 and Diagram 2, below)
3. For each significant hazard, identify the CCPs to be used to control, minimize or eliminate the hazard (see 2.0, 2.1 and 2.2, plus Diagram 3, below)

### **1.2 Conduct a Hazard Analysis**

During the hazard analysis, the HACCP team should determine all potential biological, chemical, and physical hazards that can be introduced, enhanced, or controlled in the raw materials and during shelling operations. 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.

#### **1.2.1 Hazard Identification**

To identify the potential hazards, the following assessments should be completed and documented. The following information should be available to all developers, approvers, and reviewers of HACCP plans.

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 HACCP team creates a potential hazard list by reviewing information about:

- Raw materials, processing aids, rework
- Packaging materials in direct contact with shelled product
- Activities conducted at each process step, including handling and environmental conditions
- Equipment used to make the product

In the hazard identification process, the HACCP team should review the potential for undeclared allergens due to contamination (most likely pecan) during harvesting and handling. It is also helpful to review plant layout to assess each area or room in the shelling facility to determine the potential for cross-contamination from dust or other environmental conditions. Examples of potential hazards could include:

Biological: *Salmonella* from incoming raw nuts<sup>1</sup>  
*Salmonella* due to environmental contamination (e.g., roof leaks, dust from bird-infested staging areas)  
 Enteric pathogens from handling

<sup>1</sup> *Salmonella* is not eliminated at the sheller, but through heat or other approved processing methods at the manufacturer. The sheller should focus on prerequisite programs that do not increase the microbiological load.

Chemical: Allergen(s) due to incoming pecan contamination  
 Aflatoxin

Physical: Metal due to metal-to-metal wear of equipment (e.g., sorters, sizers, screens) or field metal  
 Field glass  
 Sticks, stones, nut grass, bone fragments  
 Plastic

For assistance in **identifying potential hazards**, the HACCP team may use **Examples of Questions to be Considered When Conducting a Hazard Analysis** (Example 1, below)

**Diagram 1****APPENDIX C: Examples of Questions to be Considered When Conducting a Hazard Analysis (modified for shellers)**

Modified for peanut shellers from NACMCF J. Food Prot., Vol. 61, No. 9

**The hazard analysis consists of asking a series of questions that are appropriate to the process under consideration. The purpose of the questions is to assist in identifying potential hazards.**

- A. Ingredients
  1. Does the food contain any sensitive ingredients that may present microbiological hazards (e.g., *Salmonella*, *Staphylococcus aureus*); chemical hazards (e.g., aflatoxin, antibiotic or pesticide residues); or physical hazards (stones, glass, metal)?
  2. Are potable water, ice and/or steam used in formulating or in handling the food?
  3. What are the sources (e.g., geographical region, specific supplier)?
- B. Intrinsic factors – physical characteristics and composition (e.g., water activity) of food ingredient
  1. What hazards may result if the food composition is not controlled?
  2. Does the food permit survival or multiplication of pathogens and/or toxin formation in the food during processing?
  3. Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps in the food chain?
  4. Are there other similar products in the marketplace? What has been the safety record for these products? What hazards have been associated with the products?
- C. Procedures
  1. Is there a controllable process step that destroys pathogens?
- D. Microbial content of the food
  1. What is the normal microbial content of the food?
  2. Are there areas within the facility where pathogens can enter the product or can grow if already present in the raw product?
  3. Does the subsequent change (if any) in microbial population alter the safety of the food?
- E. Facility design
  1. Does the layout of the facility provide an adequate separation of raw materials from shelled peanuts? If not, what hazards should be considered as possible contaminants of the shelled product?
  2. Is positive air pressure maintained in shelled product packaging area? Is this essential for product safety?
  3. Is the traffic pattern for people and moving equipment a significant source of contamination?
- F. Equipment design and use
  1. Will the equipment provide the cleaning needed for safe food?
  2. Is the equipment properly sized for the volume of food that will be shelled and cleaned?
  3. Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?
  4. Is the equipment reliable or is it prone to frequent breakdowns?
  5. Is the equipment designed so that it can be easily cleaned and sanitized?
  6. Is there a chance for product contamination with hazardous substances; e.g., glass, metal?
  7. What product safety devices are used to enhance consumer safety?
    - a. Metal detectors

- b. Magnets
  - c. Sifters
  - d. Filters
  - e. Screens
  - f. Thermometers
8. To what degree will normal equipment wear affect the likely occurrence of a physical hazard (e.g., metal) in the product?
  9. Are allergen protocols needed in cleaning raw product and protecting shelled product?
- G. Packaging
1. Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?
  2. Is the package clearly labeled with storage conditions, if required for safety?
  3. Does the package include instructions for the safe handling and preparation of the raw product when sold directly or indirectly to a consumer?
  4. Is the packaging material resistant to damage, thereby preventing the entrance of microbial contamination?
  5. Are tamper-evident packaging features used?
  6. Is each package, tote or case legibly and accurately coded?
  7. Does each package contain the proper label?
- H. Sanitation
1. Can sanitation have an impact on the safety of the peanuts being shelled?
  2. Can the facility and equipment be easily cleaned and sanitized to permit the safe handling of food?
  3. Is it possible to provide sanitary conditions consistently and adequately to assure safe foods?
- I. Employee health, hygiene, and education
1. Can employee health or personal hygiene practices impact the safety of the food being processed?
  2. Do the employees understand the process and the factors they must control to assure the shelling and packaging of safe food?
  3. Will the employees inform management of a problem that could impact food safety?
- J. Conditions of storage between packaging and manufacturer and/or end user
1. What is the likelihood that the peanuts will be improperly stored at the wrong temperature/humidity?
  2. Would an error in storage lead to a microbiologically unsafe food?
- K. Intended use
1. Will the peanuts be further processed (heat-treated) by the manufacturer or customer?
- L. Intended consumer
1. Are the peanuts intended for the general public?
  2. Are the peanuts intended for consumption by a population with increased susceptibility to illness (e.g., infants, the aged, the infirmed, immunocompromised individuals)?
  3. Is the food to be used for institutional feeding or home use?

### 1.2.2 Hazard Evaluation

After listing of potential biological, chemical and physical hazards, the HACCP 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.

Severity should be determined taking into consideration susceptibility of intended consumers to foodborne illness or injury, 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
- Frequency of association of potential hazard with the food (e.g., glass contamination in product, likely to be low)
- Method of cleaning and inspection/detection within the shelling facility
- Storage and transportation conditions
- Historical experience within the shelling facility
- Design of cleaning and shelling equipment
- How the likely occurrence is affected by normal adherence to GMPs

In the determination of whether a hazard is reasonably likely to occur, the HACCP team may consider the following: likelihood of presence at levels likely to cause illness or injury; whether the adverse effect of the hazard is a result of a single exposure (acute), or it takes multiple or chronic (i.e., long-term or lifetime) exposures. The HACCP team may also review applicable prerequisite program(s) that may be used to manage potential hazards, and ensure that the prerequisite programs are documented and implemented. Examples of applicable prerequisite programs:

- Building Structure/Utility Systems (e.g., walls, barriers, airflow)
- Employee Hygiene/Practices (e.g., traffic patterns)

Further elaboration of using the two-stage risk evaluation approach to conduct a hazard analysis can be found in published technical papers (Bernard, et al., 2006; Bernard and Scott, 2007). Regulatory agencies have clarified that it is inappropriate to control significant hazards using prerequisite programs. If the hazard is reasonably likely to occur in the absence of control, then a CCP must be used to control the hazard.

### 1.3 Design Hazards Out

The most effective method to eliminate a hazard is to design it out of the product or process. Therefore, after identifying a hazard, each hazard should be assessed for the feasibility of designing it out. For example, shatterproof light bulbs should be utilized to reduce or eliminate the likelihood of glass in product; pecan trees that are located around peanut staging areas can either be cut/moved or staging areas can be covered to eliminate pecan contamination; and, peanut staging areas that are exposed to bird contamination can be protected to eliminate bird roosting and associated product contamination.

Hazards that cannot be designed out and are assessed as likely to be present in the shelled product should be continuously and strictly controlled (e.g., metal fragments that pass through screening equipment). These hazards are best managed by a CCP. Hazards that can be effectively prevented or are at levels not likely to cause the product to be unsafe are most effectively managed through prerequisite programs (e.g., sticks, stones, nut grass, glass from shelling mill light fixtures or fork trucks).

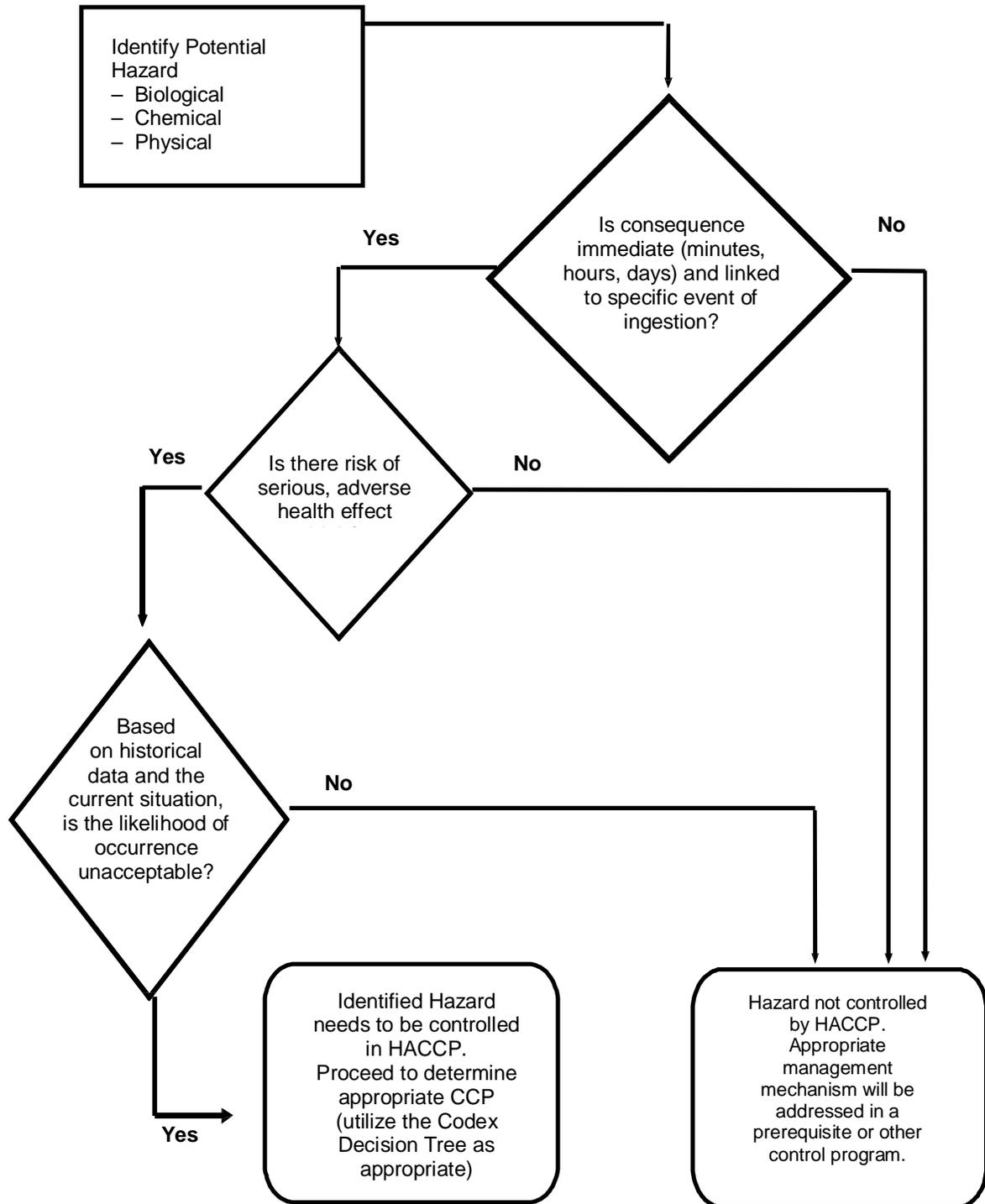
#### **1.4 Hazard Evaluation Flow Chart**

##### **How to determine whether potential hazards are “significant hazards”:**

After a list of potential hazards has been identified, the HACCP team may use the **Hazard Evaluation Flow Chart** (Diagram 2, below) to aid in the determination of significant hazards that need to be controlled in the HACCP plan by a Critical Control Point (CCP), or potential hazards that can be managed outside the HACCP plan by a Prerequisite Program (PP).

For shelling mills, frequently the only CCP involves final metal detection (magnets, metal detectors). However, this must be confirmed through hazard analysis.

**DIAGRAM 2. HAZARD EVALUATION FLOW CHART**



## 2. Hazards and Hazard Management Criteria

Guidance for how to **determine whether a process step is a CCP for a significant hazard** identified during the hazard analysis is provided in the NACMCF document (NACMCF, 1998), the Codex document (CAC, 2003), and the GMA HACCP manual (Scott and Stevenson, 2006).

### 2.1 Hazards Controlled by Critical Control Points (CCPs)

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

- Acute illness/injury
- Occurrence of adverse effects within a predictable period of time following ingestion, e.g., minutes/hours/days

Therefore, if these hazards are assessed as likely to be present in the product (through raw materials, handling, etc.), then they would require strict and continuous control and are most effectively managed as CCPs.

### 2.2 Hazards Managed by Prerequisite Programs (PPs)

Potential hazards such as mycotoxins (e.g., aflatoxin), and under some circumstances pesticides, tend to be viewed as having the following characteristics:

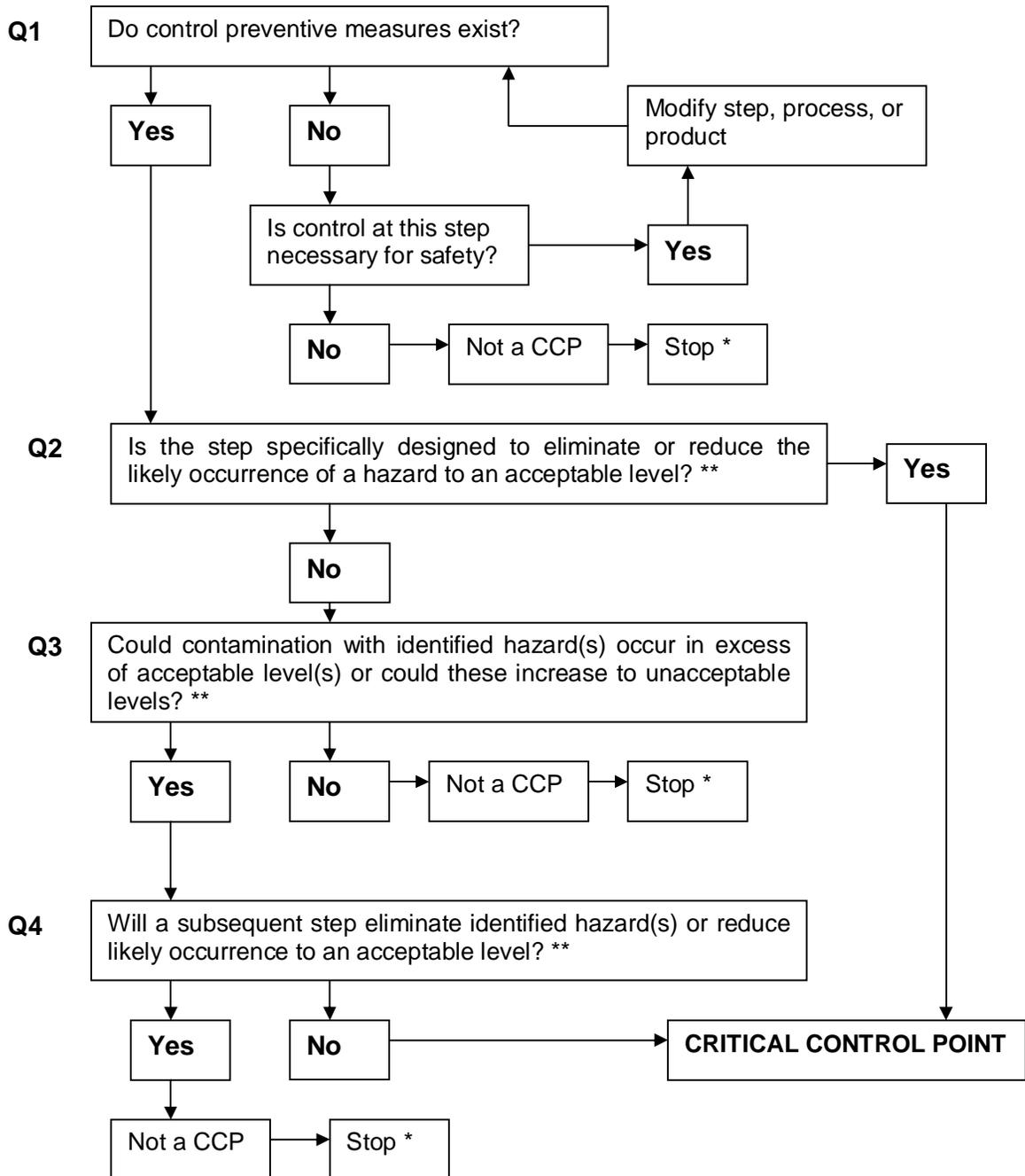
- Occurrence of illness after long term, chronic exposure (perhaps years) to the causative material
- Difficulty in attributing a particular adverse effect to a specific event due to the widespread occurrence of the causative agent in the food supply

These risks may be effectively managed by growers, using Good Agricultural Practices (GAPs), and shellers, using GMPs and prerequisite programs, prior to providing the peanuts to manufacturers to produce a ready-to-eat product. Certificates of Analysis (COAs) may be requested for aflatoxin results on incoming lots to manufacturers.

The HACCP team may use a decision tree, such as the Codex Decision Tree (Diagram 3 below) to aid in the determination of whether a particular step on the process flow diagram is a CCP.

**DIAGRAM 3. EXAMPLE OF DECISION TREE TO IDENTIFY CCPs (CODEX DECISION TREE)**

(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 CCPs of HACCP plan.

## 2.3. Examples of Hazards Addressed by CCPs vs. PPs

### Biological hazard(s)

For peanuts, the microorganism of primary focus is *Salmonella*, as a result of this organism's potential presence in raw nuts, the 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, like peanuts and peanut butter, is a concern because its mere presence in foods can cause illness. In the 2006-2007 outbreak associated with peanut butter, *Salmonella* was found at 1.5 organism per gram (estimated) in an unopened jar and a lower level was found in another recent peanut outbreak (Zink, 2008).

**Shellers who provide raw peanuts as a non-ready-to-eat ingredient do not have a CCP to eliminate *Salmonella* in their process. However, they should have PPs in place to prevent *Salmonella* growth and minimize contamination.**

The presence of *Salmonella* in peanuts **may be controlled at the manufacturer** during roasting (e.g., oil roasting, dry roasting), as well as by implementing a program to prevent post-roast recontamination prior to packaging (GMA, 2009).

Shellers who package raw peanuts for sale must include the following statement on the package:

“As with many raw agricultural food products, it is recommended that raw peanuts be cooked before consumption.”

### Chemical hazard(s)

Mycotoxins, pesticides, and food allergens are potential chemical hazards. In most cases, due to the low likelihood of occurrence and/or the nature of the hazard, they are best managed by PPs (aflatoxin, pesticide residue). However, in certain instances a CCP may be the appropriate control for a food allergen.

An Allergen Control Program should be in place if pecan contamination is likely to occur. The control steps should include eliminating the hazard prior to introduction to the peanut stream, if possible.

### Physical hazard(s)

In general, extraneous matter is defined as any object/material 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 effect; 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 cleaning, equipment calibration, preventive maintenance, employee practices.

In some cases, the characteristics (size, shape and type) of the extraneous matter may potentially cause serious harm. Typically these objects will be hard or sharp, such as glass, metal, hard plastic, ceramic. Hard or sharp foreign objects that are capable of causing injury are potential physical hazards. If the hazard analysis determines that a potential physical hazard is likely to occur, it should be controlled by a CCP.

The HACCP team can use the Hazard Evaluation Flow Chart to help determine whether or not a potential physical hazard posed by extraneous matter needs to be controlled in HACCP. The following criteria may be used to establish the CCP(s) or PP(s):

- An extraneous detection/removal device that is present on a line/process is a CCP if its primary purpose is to prevent, eliminate, or reduce to an acceptable level hazardous extraneous matter in the product and it is the last and/or most effective extraneous detection/removal device on that line/process.

Physical hazards removal/detection devices may include:

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

For example, within many shelling facilities, the HACCP team may determine that metal is likely to occur and, therefore, the final metal detectors or magnets are considered to be CCPs. In some processes, more than one detection/removal device may be designated as CCPs.

### **3.0 Critical Control Points to Eliminate Metal**

#### **3.1 Objective**

All peanut shellers receive farmer stock peanuts, which may have received “gross cleaning” at a buying point prior to receipt at the shelling mill. These farmer stock peanuts may contain dirt, sticks, stones, nut grass, field glass, field metal, pecans, bone fragments, etc. Infrequently, raw peanuts may also be contaminated with *Salmonella* or aflatoxin. At the sheller locations, the majority of these potential hazards are managed through prerequisite programs. This section focuses on CCP(s) designed to eliminate metal fragments (e.g., those that are not removed using PPs and are likely, unless controlled, to cause a significant injury).

#### **3.2 Responsibility**

All peanut shellers 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.

#### **3.3. Critical Limits**

Critical limits for metal detection, described below, and final magnets are based on data in the literature or through in-house studies. These parameters are examples only and must be validated for specific types of metal and magnets/metal detection equipment.

The scientific basis should be cited for the critical limit (e.g., regulatory guidelines, experimental studies, scientific publications). The following are examples of writing style conventions for scientific citation:

Scientific Publication

Author, Date. Title. Publication. Vol#: pages.

Regulatory Guideline

FDA (Food and Drug Administration).CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects.

<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074554.htm>

Experimental Studies

Company X, Inc. Engineering and QA Depts, (City, Country). Product Study. Engineer and/or QA representative, Last name, First Initial, year. Note book # or other identification.

The detecting limit for an end-point metal detector or magnet will depend on the type of product and the detection equipment or magnet.

**For metal detectors**, 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:

- 1.5mm for ferrous
- 2.0mm for non-ferrous (brass)
- 2.5mm for stainless steel (316 grade)
- At no time should they be larger than 7mm (0.28 in) for all metals

The FDA Health Hazard Evaluation Board “found that foreign objects that are less than 7mm, maximum dimension, rarely cause trauma or serious injury except in special risk groups such as infants, surgery patients, and the elderly.”

(<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074554.htm>)

The reject mechanism should direct product rejects from the process flow automatically into an identified area, bin or container. An action level should be defined on the basis of historical trend analysis. If this action level is exceeded, then all diverted rejected product should be evaluated to determine the cause for rejection. Where no action level is defined, 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. 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.

### 3.4 Monitoring Activity/Frequency

**Examples of monitoring procedures** for metal detection are provided below.

- Visual observation to ensure detector is working properly and product is passing through the detector should be taken at 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, above (refer to SOP# xx)
- Monitoring is generally performed by an equipment/line operator or QA technician

### 3.5 Corrective Action Activity

In the event that a deviation is noted, the sheller should have documented corrective actions in place to manage product hold and disposition, equipment repair, calibration and verification and/or line clean-up, inspection and restart, depending upon the reason for the deviation. In the event that a deviation is noted during or after operations, all product since the last documented time that there was no deviation should be placed on hold pending product review and determination of product disposition. In cases where deviations from critical limits are detected during a review of records, after peanuts are shelled and packaged (bagged or cased), all affected product should be placed on hold and the designated management personnel notified to determine disposition. Hold/ Release documentation should be available.

**For example, corrective action for deviations to critical limits** at the metal detector may include repair or re-calibration of metal detector or repair or replacement of reject mechanism. In addition, product run since the last acceptable checks on critical limits should 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 peanuts and further cleaning or controlled disposal or crushing (for peanut oil) of rejected peanuts.

### 3.6 CCP Verification Activities

Verification activities should be performed for each CCP to verify that the CCP critical limits are within control. These activities should be performed at a frequency sufficient to demonstrate control.

Functionality verification for electronic detection and rejection devices should take place during production with the normal product flow. Minimum frequency for system verification should occur at the following times:

- 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 changeover
- Following any repairs, maintenance or adjustments

- On a regular basis as determined by the site (recommended minimum every 4 hours, length of time based on acceptable risk/value of held product and process capability experience or studies)

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, each test piece (ferrous, non-ferrous and 316 non-magnetic stainless steel) should be passed through the detection device and detected and rejected, as defined by the particular facility's food safety program. Consideration should be given to using a combination of leading edge and trailing edge passes where possible. 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.

**Examples of verification** activities include:

- Designated 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 once/shift
- Management reviews and signs metal detector records daily
- HACCP team performs HACCP system audit annually, reviewing procedures and paperwork for compliance and effectiveness
- Annual metal detector calibration per manufacturer's recommendation

### **3.7 Monitoring, Corrective Action and Verification Responsibility**

Trained employees should be designated for monitoring and initiating corrective actions, and for CCP verification. It may be beneficial to involve members of the HACCP team in corrective actions should a deviation to a critical limit occur, and in CCP verification as appropriate.

### **3.8 Record Location**

All records should have a designated, secure location. Examples of records include: metal detector calibration logs, metal detector verification records, hold and release records, corrective action records, traceability records.

## **4. HACCP Plan Administration**

A completed HACCP plan should contain the following components:

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

Forms are acceptable if they follow NACMCF and/or Codex principles and guidelines. Example forms can be found in Appendix 3 (p. 98 above). Format of the forms is optional as long as the appropriate content is present. Retention time for HACCP records should be at least as long as the shelf-life of finished product, or as designated in company policies, FDA regulations, customer requirements or other appropriate regulatory standards.

## **5. HACCP System Validation Procedures**

HACCP plan validation ensures that all hazards have been identified, every hazard is being effectively controlled to the degree necessary, and only appropriate hazards are controlled within the HACCP system. HACCP system validation involves the collection and evaluation of scientific, historical and technical information to assess whether the HACCP plan, when properly implemented, efficiently identifies and controls all food safety hazards and emerging issues associated with the product or process.

The CCP for metal detection must be validated and the validation (both supplier/industry studies and in-plant studies) should be performed by qualified personnel.

### **5.1 When to Validate a HACCP Plan**

- New plans or significantly changed existing plans
- Whenever there is a systematic or recurring product safety issue, or industry recall of similar product
- Existing plans (no changes), on a schedule determined by the supplier that is no longer than two years or per regulatory requirement

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

- Review product information, including raw ingredient specification, product description, and packaging material documented in the hazard analysis
- Review the process flowchart to ascertain that appropriate equipment and current process steps are included

### **5.3 Evaluate the product (category) safety history**

- Review CCP deviation records
- Review test results from sample monitoring (e.g., physical, analytical and/or microbiological, if applicable)
- Review industry recalls/withdrawals for the product category
- Determine if there are any new or emerging hazards
- Review regulatory agency recommendations
- Review customer and consumer complaints related to food safety

### **5.4 Evaluate new developments**

- New product consumption or storage methods
  - Use as an ingredient by consumer
  - New customer (manufacturer) uses or processing methods
  - Retail methods or labeling changes
- Technological advances
- Equipment supplier recommendations
- Changes in suppliers

### **5.5 Use the information gathered when creating the plan (refer to Sections 1.1 – 3.5)**

Review CCP documentation for each CCP to determine:

- Are all hazards that need to be addressed in HACCP addressed?
  - The Hazard Evaluation Flow Chart may be used (refer to Section 1.4)
- If addressed by CCP, is the CCP the right one?
  - The modified Codex Decision Tree may be used (refer to Section 2)
- 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?

**5.6 Use appropriate members of the HACCP team to determine if the HACCP plan needs to be changed.**

- Documentation of the validation process can be done using a validation check list (see example below from NCIMS) to identify new food safety information.
- New information, if identified, should be evaluated by the HACCP team and documented.
- If needed, the plant HACCP coordinator should update the HACCP plan, as determined by the HACCP team.

NOTE: It should be noted that whenever there are changes to product, package or process, as appropriate, the HACCP team should be convened to review the effect on the existing HACCP plan. The review during validation is intended only to verify that all changes made since the last validation are reflected in the hazard analysis and, as needed, in the HACCP plan itself.

Example from the HACCP program developed by the NCIMS: HACCP Validation Checklist

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

**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; processing methods or systems, including computers and their software; packaging; product distribution systems; or the intended use or intended customers (manufacturers) or consumers of the shelled product and rate or type of customer or 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"/>			
Raw material / Packaging changed?	<input type="checkbox"/>	<input type="checkbox"/>			
Any new product consumption, manufacturing 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"/>			
Shelled 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 consumer health 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 customer or 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"/>			

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# **Good Agricultural Practices Manual**

**Guidelines for**

# **California Pistachio Growers**

**2009 Edition**

**California Pistachio Research Board**



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## INTRODUCTION

The California pistachio industry first developed a Good Agricultural Practices (GAPs) manual in 2000. Most of the guidance was adapted from the United States Food and Drug Administration's Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables because that was one of the few available references for food safety guidelines. Virtually all references were concerned with meat, eggs, and fresh fruit and vegetables. At that time, there had been no reports of microbial contamination in tree nuts and, due to their low moisture content, tree nuts were thought to be largely immune from microbial food safety concerns. However, human illnesses were traced to Salmonella contaminated almonds, first in Canada in 2001 and again in 2004 in the US. The pistachio industry considered microbial contamination highly unlikely due to its growing and harvesting practices and the common practice of roasting. Despite these mitigating factors, salmonella was detected in pistachios in 2009 and, although no illnesses were conclusively linked to pistachios, over 16 million pounds of pistachios were ultimately recalled. This event has forced a fundamental reassessment of food safety in the pistachio industry from the farm through the processing of pistachios for sale as a ready-to-eat food. This will include the revised GAPs contained in this manual prepared by the California Pistachio Research Board. The CPRB has also prepared a Pistachio Producer Self Audit to help the pistachio producer identify and mitigate potential food safety risks during pistachio production.

The pistachio industry has historically focused on fungal contaminants, the associated mycotoxins, and chronic food safety risks. These revised GAPs will retain the earlier sections on aflatoxin risk while adding greater emphasis on managing the more acute microbial contamination risks.

Food safety risks in minimally processed dry products like almonds, pistachios, and peanuts are different from high moisture foods. Yet, there are still many similarities among crop production practices in different commodities and, thus, these guidelines incorporate aspects of microbial control found to be practicable and valuable in other crops.

A brief description of the California pistachio industry follows. This description is intended to describe the environmental conditions under which pistachios are grown, the horticultural techniques used to raise a pistachio crop through harvest, and to allow the reader a better understanding of potential sources of food contaminants in the field.

## THE CALIFORNIA PISTACHIO INDUSTRY

Pistachios have been grown in California at least since the turn of the 20<sup>th</sup> century but the pistachio industry really began in the late 1960s when an appropriate variety (Kerman), a suitable pollinator (Peters) and good rootstock (*Pistacia atlantica* and *P. integerrima*) all came together. The industry has grown from the first commercial harvest in 1976 of 1.5 million pounds from 4500 acres to the 2007 production of 416 million pounds from 103,000 acres. Planting of new orchards has continued and in 2009 there are 112,000 bearing acres and 80,000 nonbearing acres which will gradually come into bearing over the next 5 years.

The California pistachio industry is located primarily in the southern San Joaquin Valley. Merced, Madera, Fresno, Kings, Tulare and Kern counties accounted for 97% of the production in 2006-2008. Most of the remaining production occurs in the Sacramento Valley. The growing season is typically hot and dry; daytime temperatures commonly exceed 100 degrees F. and rainfall between May and October is virtually absent. The city of Fresno is centrally located and the average daily high in July is 98F and the 30 year average for July precipitation is trace. Due to the lack of precipitation, all pistachios are irrigated. The most common irrigation method uses micro-irrigation technology including drip and micro-sprinklers; this is used on about 97% of the pistachio acreage. Of the remaining 3%, some are flood irrigated and small amount are irrigated using solid-set low angle sprinklers to prevent irrigation water from contacting nuts and foliage.

Pistachio trees typically bloom in mid April. There are both male and female trees, planted in a ratio of about 1 male per 24 females. The pollen is airborne and the female flowers do not require insects for pollination. Flowers and nuts are borne in clusters. A mature nut consists of a fleshy hull surrounding the nut shell, which in turn encloses the nutmeat. Following pollination the hull increases in size from smaller than a BB to its maximum size of about 1 cm in diameter by 1.5 cm in length by early June. The nut shell then begins to differentiate and harden until it is completely sized and hardened by early July. Only after the shell has hardened does the nutmeat begin to grow. As the nutmeat grows, it fills the shell and, by virtue of its growth exceeding the shell size, cracks the shell open. This creates the naturally opened nuts characteristic of pistachios. With rare exceptions, the hull remains intact during this entire process, protecting the nutmeat from insects and pathogens. The rare exceptions are nuts commonly called "early splits" where the hull and shell both split along the same suture, exposing the nutmeat. These nuts commonly become infested with navel orangeworm and can be infected with *Aspergillus* fungi, a fungus that can produce a mycotoxin called aflatoxin. The early split process begins in early August and continues until harvest. The earlier the hull splits, the more likely infestation and contamination becomes. The shells on early split nuts are, however, frequently stained and discolored. This allows them to be removed with great success during post harvest processing.

Harvest normally begins in early September and may continue through late October. California pistachios are mechanically harvested. The tree is vigorously shaken and the falling nuts are collected on canvas-covered catch frames. Due to the vigor of the shaking, nuts sometimes fly beyond the frames; these nuts are not recovered and nuts that fall to the ground are left. The frames are angled such that the nuts fall onto a conveyor which transports them to harvest bins or trailers. Harvest workers do not handle the nuts during this entire process. The nuts are transported in bottom dump trailers to the processing facility where they are dehulled and dried. When harvested, the nuts are commonly about 30% moisture. The harvest process through preliminary drying to about 9-10% moisture takes less than 24 hours and commonly less than 16 hours. Final drying to about 5-7% moisture takes place in silos and may take an additional 2-3 days. At this point, the pistachios are a stable raw agricultural commodity.

Creating a ready-to-eat food from the raw commodity requires additional activities which are the subject of a companion guide to these GAPs, Good Processing Practices for Pistachios.

## SOURCES OF POTENTIAL FOOD BORNE PATHOGENS IN THE PISTACHIO ORCHARD ENVIRONMENT

Our understanding of the origins and persistence of microbes in the agricultural environment that ultimately may contaminate food has changed considerably over the past decade. Organisms such as *Salmonella* and *E. coli* are normally inhabitants/pathogens of animal gastrointestinal systems and were thought to be poorly adapted for survival in agricultural field environments. However, the almond experience with *Salmonella* has indicated that these organisms can survive in the orchard environment for years, not the weeks or months previously thought. Combine the greater environmental persistence with data that suggests the minimum number of bacteria necessary to cause human disease is much closer to 1 than 100 and it is easy to see how what was previously a negligible issue has assumed much greater importance. In the following discussion, *Salmonella* will be referred to frequently but the comments pertain to microbial pathogens in general.

*Salmonella* bacteria have wide host ranges (they infect many different animal species) and infections do not always cause observable disease. One study estimates that one in five Germans are symptomless carriers of *Salmonella*! Because they have wide host ranges and animals defecate, *Salmonella* should be considered ubiquitous. However, if the number of *Salmonella* increases, the risk of contamination increases. Thus, we should be aware of what conditions may increase the populations of potential food borne pathogens in the orchard.

Contamination of pistachios by human pathogens in the orchard has never been demonstrated but, as a result of the recent *Salmonella* contamination, we recognize that it might occur. Given the lack of detection, any discussion of potential sources is theoretical and relies on guesswork and the experience of other commodities.

The use of the orchard site prior to development as a pistachio orchard may influence the initial level of potential pathogens. If the orchard site was “virgin” ground prior to its development as an orchard, the potential pathogen level is generally considered low. If however, the land was previously used for a confined animal feeding operation, the risk could be considerably higher. If the land was reclaimed for agricultural use by application of animal waste or municipal biosolids, the risk could also be greater but this may also be dependent on the condition of the applied wastes. It is important to remember that this is not a quantitative measure but something each grower should be aware of when assessing total risk.

Adjacent land uses may also be important. Potential pathogens may be airborne in dust, domestic animals may stray into the orchard and defecate, there may be pathogen-contaminated runoff from adjacent animal operations – again, nothing quantitative but these factors can contribute to total risk.

Water sources should be considered as possible sources of food borne pathogens. Surface waters may contain animal fecal matter and wells can become contaminated with bacteria.

Wild animals as well as domestic animals have been identified as a source of pathogens in some disease outbreaks.

In many cases, the most significant source of foodborne pathogens may be animal wastes, particularly manures, that have been added to improve soil texture as well as for nutrients. The “quality” of these amendments varies widely and, while our concern is primarily food safety, animal manure-based soil amendments are not currently regulated for food safety but nutrient content.

There is little human contact with pistachios prior to and during harvest due to the mechanized nature of pistachio cultivation and harvesting. However, field workers must be provided with adequate sanitary facilities to insure that human waste does not enter the orchard.

Many of the potential sources of food-borne pathogens would increase the population numbers on the orchard floor. Because pistachios are harvested using shakers equipped with catchframes and pistachios are not gleaned from the orchard floor, there is no contact between pistachios and the potentially pathogen-laden soil. Nevertheless, pathogens may be “aerosolized” by various orchard activities including pest scouting, cultivation, spraying, and harvest and be deposited on the pistachios. Thus, it is important to consider all the activities in an orchard that could potentially contribute to pathogen contamination of pistachios.

## RANCH HISTORY AND ADJACENT LAND USES

As mentioned earlier, land use prior to orchard establishment and use patterns of adjacent lands can have food safety impact. Whenever possible, historical and adjacent land uses should be considered when choosing an orchard site. Pistachio orchards are long-lived and adjacent land uses will certainly change during the productive life of the orchard. The grower may have little control over the changing land use but awareness of potential problems may help determine if mitigation is needed and what control options are most feasible.

### PRE-ESTABLISHMENT CONSIDERATIONS

Many potential human pathogens are associated with animal manure and feces. Consequently, prior use of the orchard site for a confined animal feeding operation (feedlot, dairy, poultry farm, etc), pasture, or for other animal husbandry purposes may create food safety concerns. Similarly, reclamation of marginal lands for agricultural purposes by application of manures and municipal biosolid waste may also create concerns. These concerns are, to a significant extent, mitigated by the 6-7 years of orchard establishment before the first commercial harvest.

Mine tailings and industrial wastes frequently contain high concentrations of heavy metals such as lead, mercury, and arsenic. Waste sites tend not to be a concern in the pistachio production areas and, because these pollutants are not usually mobile in plants, they are a greater concern for root crops than tree nuts. Indeed, in some locations root crops have become contaminated with arsenic due to the use of arsenic-based insecticides nearly 30 years earlier. Regardless, surface contamination of pistachios would likely be removed with the pistachio hull in the dehulling process but, depending on the particular circumstances, other mitigation measures may be needed.

Prior use of a particular site as a landfill may lead to bacterial food safety concerns and may have broader ecological concerns, especially if agronomic practices breach the landfill containment structures. In the pistachio producing areas of California, landfill sites are well documented and make unlikely orchard sites.

Agriculture in the San Joaquin and Sacramento Valleys of California dates back to the Gold Rush days of the 1850s but many early agricultural enterprises were primarily ranching and small grain production. Intensive agriculture is a more recent occurrence, frequently dating back 75 or fewer years. Nevertheless, compiling an accurate history of prior uses of any particular piece of land may be difficult due to the lack of records from earlier enterprises. Fortunately, the more recent the enterprise, the more effect it is likely to have on current food safety concerns. Thus, it is not necessary to document all land uses over the last century but it is valuable to determine the land uses prior to establishment as a pistachio orchard.

The geography of the orchard site should be considered as well. Precipitation in the pistachio producing areas tends to be low, especially during the growing season, but storm runoff can become concentrated and flooding may occur. Water drainage patterns should be determined.

### POST-ESTABLISHMENT CONSIDERATIONS

The productive life of a pistachio orchard is not known. While orchards have been removed due to conversion to other uses (primarily housing), we are not aware of any orchard that

has been removed due to declining production as a result of age. Many people estimate that the productive life is over 70 years. Because pistachios are one of the most long-lived perennial crops, adjacent land uses are certain to change during the life of the orchard.

Pre-existing situations have likely been addressed in the years since orchard establishment. Because food-borne pathogens can enter the orchard through wind-borne dust, storm runoff, animals, etc., it is important to consider these potential pathogen sources as adjacent land uses change. Some sources may be outside the pistachio growers control while mitigation may be possible with others. Pathogens and pollutants are frequently spread by water. Runoff from heavy rains may impact orchards adversely, particularly if confined animal operations have been established since orchard establishment. Diversion berms, runoff control structures, and vegetation buffers may help prevent polluted water from contaminating the orchard. Potential hazards may not be apparent and maps are a valuable tool to help identify and prioritize risks. Maps should be prepared for each pistachio orchard, indicating adjacent land uses, prevailing wind direction, topography indicating storm runoff flows, and adjacent riparian zones and wildlife habitat. How far the map should extend from the orchard is difficult to say because the mechanisms of microbial “transferrance” from one location to another are not known. In pesticide reports, growers are commonly asked about adjacent uses and are expected to know if their pesticide use creates a potential concern. Growers could use the same standard for identifying food safety risks as well as mark their map to show how distant hazards without all intervening uses.

It may seem that advice growers receive is sometimes at cross purposes, particularly with regard to wildlife. On one hand, growers are encouraged to set aside land for wildlife and to create wildlife habitat on their ranches with corridors that encourage animals to move between different areas. On the other hand, growers are warned of the food safety risks associated with animal ingress into their orchard and are told to prevent animal ingress. Similarly, diversified agriculture is encouraged under sustainability advice but the conflict it creates within food safety is rarely mentioned. Regardless, it is not the purpose of these GAPs to resolve these conflicts and we recognize that a sustainable agricultural production system must first and foremost be safe.

## **IMPLICATIONS**

While we do not anticipate a food safety incident that would necessitate tracing product back to individual (or a subset of) growers, we cannot see the future. If such an incident were to occur, the investigative authorities, be they federal or state, would ask for a ranch history and a map of adjacent land uses. It may seem daunting to develop these but a good faith effort should be made to document history and land uses. It may not all come together in one year but it would be entirely appropriate to set some benchmarks for document development and append these to your history and land use map. It creates a goal and, hopefully, due diligence on the part of the pistachio producer.

## WATER USAGE

Water use in pistachio production may involve several field operations but especially includes irrigation and the application of pesticides and fertilizers. There is no use of water in field harvest operations but water is used during the hulling/drying process. Water use in these off-farm harvest operations will be covered in a later section. Regardless, water can be a direct source of microbial contamination and it can spread a localized contamination source. Its potential as a direct source of contamination is related to the source and its quality.

## AGRICULTURAL WATER SOURCES

Growers obtain irrigation water from a variety of sources including wells located on the ranch, surface waters delivered through streams, ditches, canals, and reservoirs and, less frequently, from municipal wells and recycled water from other agricultural and municipal sources. A single orchard frequently uses water from more than one source. The potential for pathogen contamination varies with the source, as does the susceptibility of irrigation water to on-farm contamination. Regardless of the water source, growers should limit the exposure of the nut to irrigation water. It has been thought that the hull would protect the nut meat from contamination but this is untested and bacteria may be carried by the hull into later processing steps. For this reason, limiting contact is the most prudent course of action.

Municipal water is not widely used for irrigation. Potable municipal supplies have few food safety concerns but the irrigation system should be inspected for potential contamination sites. Pumps, holding tanks, canals, and reservoirs should be closely examined to ensure that animals do not have access to these areas and the water is not subject to animal fecal contamination.

Well water may be obtained from deep wells or from relatively shallow wells. The potential for water contamination may vary with the sources and are influenced by surface activities. Growers should have their water checked periodically for chemical and microbial contaminants. Chemical contaminants such as nitrates may indicate excess fertilizer is leaching into the water supply and the amounts applied to the crop should be accounted for in a nitrogen nutrition budget. Pesticide residues in the water may indicate that chemicals are leaching around well heads and casings into the supply and microbial contaminants may indicate that animal access to the well should be restricted. The California Department of Water Resources has indicated that it will be inspecting well heads to insure that the well is situated correctly to reduce the risk of flow into the well. Examining the well and correcting discrepancies prior to inspection is prudent. Regardless, pesticides and foliar fertilizer sprays should be prepared in an area removed from the well and the well should be equipped with anti-siphon devices to eliminate siphoning as a means of well contamination.

Growers should assess the potential for contamination of surface water when these waters are used for irrigation. Surface waters may be subject to intermittent, temporary contamination from upstream livestock operations, either from unrestricted access to the water by livestock, discharge of waste into the water, or by polluted runoff from heavy rainfall.

Recycled water from municipal sewage treatment facilities should be carefully examined to insure its suitability for irrigation. Growers should require proof from the supplier that the water does not contain potential pathogens as well as proof of a routine and credible testing program.

## **NON IRRIGATION WATER USES**

Water is commonly used in pesticide and fertilizer applications. Spray water will of course come in contact with the pistachio nuts and that is intended for efficient pest control. Growers should assess the quality of water used in these applications and whenever feasible use potable water for these purposes. The quality requirements for potable water may not be feasible under field conditions, especially in some areas of the San Joaquin Valley prone to arsenic levels above the new EPA tolerances. However, our focus has been on microbial contaminants and verifying that spray water meets microbial contaminant tolerances is prudent.

## **TESTING AND TREATING WATER FOR MICROBIAL CONTAMINATION**

Pistachio growers routinely treat water to insure it's suitability for use in micro-irrigation systems. This may not be treatment for microbial contamination but water seldom arrives at the ranch in condition to be used directly and treating water to insure its suitability is an accepted concept. For food safety reasons, the concept is being expanded to include microbial contamination.

A decade ago, there was no scientifically valid water quality testing program for microbial contamination of agricultural waters. That is still true today because little is known about the transference mechanisms from water to the crop in the field. Thus, we cannot say whether a particular level of microbes in the water creates a food safety risk and testing may not be useful for all growers. However, we would not normally expect to see microbial contamination in deep wells. Finding microbial contaminants in well water obligates the grower to find the avenue of contamination and close it as well as to treat the well water to eliminate the contamination that is present. There are a number of guides for treating wells for microbial contamination and methods from North Dakota State and Oregon State Universities are posted on line.

When should testing and treatment be done? Clearly, wells are used for irrigation and testing should be done before water is needed for irrigation. It may also be appropriate to test when the well is at the greatest risk for contamination, particularly during the rainy season when contaminants can be leached into the well through cracked casing and improperly positioned well heads. This also allows time for appropriate corrective action before irrigation demands arrive. Checking the water quality at the end of the growing season would allow the maximum time for correcting the problem. Water quality frequently encompasses many materials. In the case of food safety, treating the well to insure that the water meets potable standards with respect to microbial contaminants should be adequate.

## **IMPLICATIONS**

As with Ranch History and Adjacent Land Use, documentation is critical. Water sources were noted on the ranch map created earlier and growers should conduct at least annual testing of each water source. Results should be documented for each individual source as well as whether corrective actions were needed and when they were undertaken.

## FERTILIZER, MANURE, AND MUNICIPAL BIOSOLIDS

Adequate plant nutrition is essential for commercial pistachio production. Nutritional programs commonly use commercially prepared inorganic fertilizers applied to the soil by broadcast or through the irrigation system or by foliar sprays. Properly treated manure (animal excrement and/or plant remains) or biosolids (treated sewage plant waste, primarily human excrement) can also be effective and safe fertilizers. In addition, soil organic matter is critical to soil health, nutrient availability, and water penetration; manures can be effective sources of organic soil amendments. However, untreated or improperly treated manure or biosolids may contain pathogens that could contaminate pistachios and pose food safety concerns. Application of fertilizers, manures, biosolids, and soil amendments are subject to a number of different regulatory schemes. Fertilizer and manure nutrient contents should be documented. Biosolids must be tested for pathogens and treated to reduce or eliminate them but manures from animal feces do not. Pistachio processors may have additional requirements or exclusions for biosolids, manures, and fertilizers. Growers need to follow good agricultural practices for handling manure and biosolids to minimize microbial hazards.

Regardless of the reason for application, growers should prepare a fertilizer “budget” based on expected plant nutritional needs for each growing season and insure that their fertilizer and manure applications are within plant needs. Excessive application of nutrients is uneconomical, can lead to lush growth that is more susceptible to disease and pests, and can cause ground and surface water pollution. Due to water pollution, the State of California is considering how to regulate application of manures. Additionally, with the current concern about greenhouse gases and global warming, growers should be aware that nitrogen application can lead to nitrous oxide emissions. Nitrous oxide has 300 times the potential of carbon dioxide as a greenhouse gas and also contributes to ozone pollution.

### MICROBIAL HAZARDS

Manure and feces are significant sources of human pathogens. *E. coli* 0157:H7 originates primarily from feces of cattle, sheep, deer, and wild pigs. Other pathogens originating from human or animal feces include *Salmonella*, *Cryptosporidium*, *Shigella*, and hepatitis B. The orchard environment selects against many potential pathogens but others may persist for extended time periods. Thus, manure and biosolids must be closely managed to limit potential pathogen contamination and reduce the risk of pathogen persistence and proliferation in the orchard.

Growers should also be aware that human or animal fecal matter may be unwittingly introduced into the growing area. Potential sources include use of improperly treated manure, livestock or poultry operations, nearby manure or biosolids use, and high concentrations of wildlife in the orchard.

Following GAPs may reduce the potential for microbial contamination. These practices focus on reducing pathogen introduction into the orchard as well as measures to reduce the potential movement of pathogens onto pistachios.

### MEASURES TO REDUCE PATHOGEN INTRODUCTION INTO THE ORCHARD

Pathogens may be introduced into the orchard through water, runoff, and air pollution or through animal and human manure and feces. In previous sections, we discussed risks associated with water and adjacent land uses and the importance of assessing and documenting these risks. In this section, only manure and feces will be discussed.

A variety of treatments may be used to reduce pathogens in manure, biosolids and other organic materials. The treatments may be performed by the grower using material produced on the farm or by a third party (supplier). Treatment choices will depend on the needs and resources of the grower or the supplier. In general, treatments are either passive or active.

### **Passive Treatments**

Passive treatments generally rely on environmental factors such as temperature and moisture fluctuations along with time to reduce pathogen populations. Holding times will vary depending on regional and seasonal climatic variations and the type and source of material. Growers relying on passive treatment must ensure that manures are well aged and decomposed before applying to the orchard; this will reduce the risk of manure application but not as much as properly performed active treatments.

### **Active Treatments**

Pasteurization, aerobic and anaerobic digestion, and heat drying are examples of active treatments used to reduce pathogen populations in raw manure and biosolids. Composting, a controlled and monitored process, is probably the most widely used active treatment.

Composting should not be confused with passive treatments. The United States Composting Council under a grant provided by the EPA has established a manual of test methods for evaluating composts as well as a Seal of Testing Approval for composts that meet the testing standards. The USCC has an informative web page at [www.compostingcouncil.org](http://www.compostingcouncil.org).

## **ACTIONS TO REDUCE MICROBIAL HAZARDS FROM MANURE**

- Apply only actively treated certified manures whenever possible
  - Obtain records and analyses from the supplier on treatment parameters, nutrient and pathogen tests, treatment dates, and other analytical tests
- If composting is performed on the farm:
  - Actively monitor the process to ensure that all materials receive adequate treatment
  - Consider barriers to secure storage and treatment areas
  - Segregate composting from orchard equipment and/or develop standard operating protocols for cleaning equipment. Document cleaning!
  - Limit traffic patterns that could carry raw manure into the orchard.
- The quality of treated materials will vary. Maximize the amount of time between application of material to the orchard and harvest, paying particular attention to quality. Target preharvest intervals for application of manure for registered organic producers range from 120 days for crops that have soil contact to 90 days for crops that do not have soil contact.

- Incorporate the manure/compost into the soil as soon after application as possible and within the above PHI.
- As harvest approaches, avoid field activities that would potentially deposit microbe-laden dust on the pistachios.

Dairy lagoon waste should never be applied to pistachio orchards. In addition to the food safety concerns, the salt content and other organic matter in the liquid waste adversely affects soil and tree health.

## **BIOSOLID APPLICATION TO AGRICULTURAL LANDS**

Biosolids are organic wastes from municipal sewage plants. Before the invention of the Fritz-Haber process of converting nitrogen gas into nitrogen fertilizer, human waste was widely used as a fertilizer and remains in use in many countries. Biosolids are regulated by the EPA under 40 CFR 503 and their application to agricultural lands is controversial. Biosolids are classified by the level of active treatment they have undergone and analytical records of their composition must be provided to the landowner when they are applied. These records must be maintained for several years after application. The microbiological impact of biosolids, especially those not thoroughly treated, are obvious but the heavy metal and salt levels present in biosolids is often not appreciated or understood. Soils treated with biosolids will require extensive leaching to remove the salts before planting – the salts may contaminate ground or surface waters and growers should consult with appropriate authorities to determine if this could affect the legality of the biosolids application.

The phytotoxic salt levels preclude application of biosolids to existing orchards and biosolids can only be considered before planting. Even so, anyone thinking of remediating marginal lands with biosolid applications should consult pistachio processors to insure that there will be a market for their product when the trees are ready for harvest.

## **IMPLICATIONS**

Growers must have documentation for materials applied to their orchards. Application of biosolids requires documentation and certificates of analysis. Nutrient content of the applied manure should be documented. While there are currently no restrictions on soil amendments, it would be prudent to keep the same records as required for other applications. These include the supplier of the material, the nature of the material, relevant test data, dates of active/passive treatments, date of application to the orchard, date of other activities done to incorporate the material, and expected/actual dates of harvest (preharvest interval).

## PESTS AND PESTICIDE USE

Pesticides include fungicides, insecticides, acaricides, and herbicides. Pesticides must be registered with both the EPA and the California Department of Pesticide Regulation (CDPR) and have a current label with pistachios listed as a site of application for legal use of the pesticide in a pistachio orchard. Pesticides may be registered under different sections of federal law; these registration sections are commonly called Section 3 (full registration), Section 18 (emergency registration) and Section 24c (special local needs). Regardless, the pesticide must be registered in California for pistachios to allow legal use.

California has among the most restrictive pesticide laws in the world and California farmers are obligated to follow these laws. Not only are the registration requirements frequently more limiting, but pesticides must be formulated to limit the emissions of volatile organic compounds (VOCs) and growers must report pesticide applications to their county agricultural commissioner's office. The county in turn reports these applications to CDPR who publishes summary statistics of pesticide use in the state and county by chemical and/or crop. These reports are available on the CDPR website as Pesticide Use Reports. Thus, we can determine which pesticides are being used and to what extent and can track use of different chemicals over the years. We know, for example, that Guthion (active ingredient – azinphos methyl) use declined well in advance of its registration loss and that use of phosmet is declining. The use of reduced risk insecticides has increased significantly.

CDPR also has a Pesticide Information Portal (PIP) where the public can request information about pesticide applications. For example, it is possible to determine the calendar date(s) of specific pesticides on pistachios down to township/range/section (TRS) or to determine which pesticides were sprayed on a particular crop at a particular TRS.

Pesticides can impact food safety in any of three ways: residues of unregistered materials, residues above the legal tolerance, and microbial contamination of spray water. Unregistered materials may occur on pistachios due to chemical drift from adjacent lands, soil contamination by unregistered persistent pesticides, mistaken application or by purposeful application of an unregistered material. There is little a grower can do about drift from adjacent farms. A significant amount of pesticide applied in the orchard ends up on the soil and movement of pesticide from contaminated soil to the pistachio fruit, while possible, is unlikely. Mistaken application (wrong orchard, wrong crop) and purposeful application cannot be separated except in those cases where the pesticide has an activity spectrum not needed on the crop. Regardless, the crop may be considered adulterated if residues are found in violation of legal tolerances.

The development process of pesticide labels should preclude above tolerance residues when the pesticide is legally applied. However, if the sprayer has not been accurately calibrated and the pesticide is being used at high rates, over application could result. It is important to accurately calibrate sprayers.

The quality of spray water can vary and pesticide applicators should monitor the source and quality of the water used for pesticide application. If possible, potable water from municipal sources should be used but this is frequently not feasible. While potable water standards limit a number of compounds that do not have food safety impacts as spray water, water quality should be tested to insure that the water meets potable microbiological standards.

## PEST MANAGEMENT DECISIONS

The pistachio grower must make pest management decisions based on a wide variety of inputs and expected outcomes. The inputs may range from qualitative to quantitative and the outcome may not be easily measured, depending on the pest.

Integrated Pest Management (IPM) is a pest management philosophy that combines pest population levels, the presence and numbers of pest parasites and predators, predicted economic losses if left uncontrolled, and the cost of control to determine whether control is justified and environmentally sound. Decisions based on IPM are thought to be better based than older control methods based on calendar dates. Because parasites and predators frequently attack insects and mites while they are virtually unknown for pathogens, IPM has historically been more associated with insect and mite control.

Pathogens frequently respond fairly specifically to environmental conditions and an accumulation of weather conditions (temperature, humidity, and/or precipitation) is commonly used to prescribe fungicide applications. The fungicide prescription may be for a single application or can call for repeated applications on a set schedule.

The sensitivity of weeds to herbicides may vary with the age of the weed as well as the specific herbicide. Because some weeds may be insensitive to common herbicides, cultivation is also used to control weed infestations. Disking is commonly used but repeated disking can damage surface roots, increase susceptibility to pathogens such as *Verticillium* fungi, accelerate the loss of soil organic matter, and lead to soil compaction. Consequently, a mixture of herbicides and cultivation is used to control weeds.

## IMPLICATIONS

Pesticides are seemingly essential to pistachio production, from weed control for efficient water and fertilizer use to fungicides for maintaining tree health and insecticides for protecting the nuts from pests. Pesticides must be used responsibly to insure food safety and this includes using registered materials in a legal manner and using the appropriate technologies (sprayer calibration and water testing). Like so many other activities in farming today, documentation is essential. This includes reporting pesticide use to CDPR and maintaining your own records of applications as well as maintaining records of sprayer maintenance and calibration and water testing and treatment.

## AFLATOXIN AND NAVEL ORANGEWORM CONTROL

Aflatoxin is a potent carcinogen produced by the fungi *Aspergillus flavus* and *A. parasiticus*. These fungi and aflatoxin have been found in a wide variety of foods and agricultural commodities including tree nuts, peanuts, figs, corn, cottonseed meal, rice, and spices. When fed a diet contaminated with aflatoxin, poultry and other animals develop liver disorders and die of acute poisoning. In humans, aflatoxin consumption is rarely acutely toxic and it acts more as a chronic toxin. Thus, it is associated with liver cancer, especially in the presence of other predisposing factors including alcohol and tobacco use as well as hepatitis. Aflatoxin contamination in food and animal feed is tightly regulated in the United States and in many other countries. The United States has an action level (maximum allowable concentration) of 20 ppb for human food and the State of California extends that tolerance to pet and animal food. The federal marketing order for pistachios currently regulates domestic shipments of pistachios at 15 ppb, the European Union at 4 ppb and the international tolerance as set by the Codex Alimentarius Commission is 10 ppb.

Aflatoxin was discovered in the late 1960s and the potential for aflatoxin contamination in pistachios was recognized internationally in the early 1970s. Aflatoxin contamination was the subject of a report to the California Pistachio Commission in 1979 and, since then, the pistachio industry has conducted extensive research on aflatoxin contamination. Results have been published in the annual CPC reports.

*Aspergillus* is a weak pathogen and cannot normally infect hull tissue. As long as the hull is intact, the nutmeat within is safe from *Aspergillus* infection. *Aspergillus* consequently relies on indirect methods to gain access to the nutmeat, particularly early splits and navel orangeworm (NOW, *Amyelois transitella*). Nuts damaged by early splits and NOW account for over 90% of the aflatoxin present in the pistachio crop at the time of harvest. Growers should consider practices that reduce the amount of *Aspergillus flavus* inoculum in the orchard, increase hull integrity, and control NOW populations in the orchard. Together, these practices will lower the risk of aflatoxin contamination.

### REDUCTION OF INOCULUM

*Aspergillus flavus* overwinters as a spore in relatively small numbers in the orchard. As the weather warms, spores germinate and colonize organic matter on the orchard floor. Measurable increases in spore numbers become detectable in late June or early July. It is thought that spores are moved from the orchard floor into the canopy and into split nuts by wind and orchard traffic, particularly traffic that raises dust. Incorporation of organic material into the soil may influence *Aspergillus* population increases and limiting orchard activities that raise dust may also reduce colonization of nuts. (Limiting dust-raising activities is also recommended to reduce the movement of bacteria from the orchard floor to the nuts).

The industry is currently conducting field evaluations of nontoxigenic *Aspergillus flavus* to determine if it can displace isolates that produce aflatoxin and thus limit the potential of aflatoxin contamination. Nuts could become infected with *Aspergillus* but the nontoxigenic *Aspergillus* would not be able to produce aflatoxin.

### INCREASING HULL INTEGRITY

Hull integrity can be breached by early splitting and by the natural senescence that occurs as the crop matures. The exact causes of early splits are not known but some cultural practices have been associated with increased incidence. In particular, water stress has

been shown to increase the incidence of early splitting. In drought years or when water is difficult to access due to political considerations, some growers have sought to conserve by practicing “deficit irrigation”. This practice is also implemented when growers attempt to overcome a history of low splitting percentages. Regardless of the reason, early split incidence also increases and with it, increased navel orangeworm incidence and increased aflatoxin contamination.

Diseases, particularly *Alternaria* blight, and inadequate nutrition can hasten hull senescence and degradation.

Pistachio growers are paid more for split nuts than nonsplits and many growers believe that the splitting percentage increases the longer the nuts stay on the tree. There is no data to support this belief during the time the hull has reached physiological maturity and if it happens, it is not likely to be significant. Delaying harvest may thus slightly increase the splitting percentage but the splitting percentage increases very slowly while hull degradation increases relatively rapidly. Consequently, the increased number of clean split nuts may be decreased by increased staining and increased insect damage and the increase in economic return may be largely illusory. In addition, the grower may lose significant crop due to nut dehiscence in wind storms Especially from the viewpoint of food safety but also from product quality, a delayed harvest has more downside potential than upside. Growers are urged to harvest earlier rather than later, with the realization that due to limited harvest equipment and hulling capacity, early harvest is not possible for all.

Growers with large acreages are urged to consider split harvest where a light shake is done to remove the earliest maturing nuts and a second shake is done to remove the later maturing crop.

## **CONTROLLING NAVEL ORANGEWORM POPULATIONS**

Navel orangeworm (NOW) is a difficult pest to control, in part because monitoring the populations is difficult and in part because the NOW larva is protected by the nut from contact insecticides. NOW can overwinter in the orchard in mummy nuts, both on the ground and in the tree. NOW in tree mummies have higher survival rates than those on the ground and whenever possible, nuts remaining on the tree after harvest should be knocked to the ground. Disking the ground mummies to bury them or mowing them to destroy them after removing as many nuts as possible from the berm by blowing or raking will also decrease NOW survival.

NOW populations can increase dramatically when the pest has access to current season nuts. Pesticide applications should be considered in consultation with your Farm Advisor or pest consultant. In general, pesticides need to be applied in a protectant manner because these pesticides are not systemic and once the worm is in the nut, pesticides cannot reach it. Fortunately, many of the pesticides currently registered for pistachios and navel orangeworm are fairly persistent (up to 3 weeks) and sprays do not need to be made on a shorter rotation.

As important as NOW is in the pistachio aflatoxin paradigm, there is little data to support an aggressive control program. Many growers practice sanitation (removal from the tree) with some disking combined with early harvest and experience few if any NOW problems.

Current research hopes to develop a pheromone technique for monitoring NOW populations as well as for disrupting mate location and breeding.

## **IMPLICATIONS**

NOW and aflatoxin are problems that originate in the field and have little or no opportunity to increase after pistachios are delivered to the handler. It is incumbent on the grower to understand and control these problems. Growers should review their cultural practices to help maintain hull integrity and consider various means to reduce NOW infestation.

## HARVEST SANITATION

Pistachios are harvested fresh and must be “processed” rapidly, generally within 24 hours, before natural chemical processes and the release of tannins from the fleshy hull results in shell staining that preclude their sale as an inshell product.

Pistachio harvest is not precisely defined but, for these purposes, will be considered as the activities preparing field equipment (shakers, bulk loaders, forklifts, etc) for use, field preparation activities to allow equipment safe and efficient operation, shaking the pistachios from the tree and transport to the hulling and drying facility, and the hulling and drying operations necessary to create a stable raw agricultural commodity. Thus, harvest activities are both on-farm and off-farm; many of on-farm activities are commonly under the control of the grower while the off-farm activities are commonly under the control of the pistachio processor. All these activities can have significant impacts on potential microbial contamination.

### ON FARM ACTIVITIES

Most growers do not own their harvest machinery and instead use the services of custom harvesters. Regardless, the orchard floor must be prepared for harvest. Harvest equipment is large and heavy and irrigation system leaks that create soft and muddy spots in the equipment drive lanes should be repaired. Low branches that would impede equipment need to be removed or propped out of the path. Dips in the drive lanes should be leveled. All these activities will lead to an increase in worker activity in the field and sanitation and hygiene should be a special concern. Areas designated for off-loading bulk harvesters or bins into trucks should be cleaned and leveled.

Equipment under the control of the grower should be cleaned and, if harvesting involves bins, bins should be cleaned and stored to protect from animal infestations and contamination with animal feces. Harvest bins are precisely that – bins used for harvest and not transport of chemicals, fertilizers, toxic substances, or even hulled and dried pistachios. Equipment cleaning in the field is problematic – rarely is there access to high pressure washes and steam cleaning. If washing is done, be sure that waste water does not drain into the orchard or into the well head area.

Removal of pistachios by shaking is done with equipment equipped with catch frames that prevent the pistachios from falling to the ground. Nevertheless, some pistachios do fall on the ground because they fall outside the catch frame, the catch frame has coverage gaps (especially around the tree trunk), or in transferring the pistachios from bins and bulk loaders into transport trailers. It is generally not cost efficient to rake or glean these pistachios. Contact with the ground may also contaminate the nuts with bacteria present in the soil or with manure/compost/animal feces that are present on the soil. In effect, contact with the ground has made the soil a food contact surface if these nuts are gleaned. It borders on the ridiculous to carefully control field activities to reduce potentially microbe laden dust contaminating the nuts on the tree and then turn around and throw a shovel full of dirt (and nuts) into the bin or bulk loader while gleaning the fallen or spilled pistachios.

### TRANSPORT TO HULLING MACHINERY

Pistachios are transported from the orchard to the hullers in tractor-trailer rigs. Each trailer contains up to about 60,000 pounds of fresh in-hull pistachios. In the early years of the industry, there was some experimentation with different types of trailers and trailer walls and the current arrangement grew out of these experiments.

Transport time to the huller varies with the huller and orchard locations. Almost all California hullers are located in the southern San Joaquin Valley and over 90% of the production is within a two-hour transport time of these hullers. The remaining production is no more than 6 hours from the huller.

As mentioned earlier, pistachios must be hulled and dried within about 24 hours of shaking to prevent shell staining and degradation of other quality parameters. It is incumbent on the grower to insure that the trucks can be loaded promptly and within a narrow timeframe so the first harvested pistachios do not exceed the 24 hour hulling “window”.

## **OFF FARM HARVEST SANITATION**

It is not the intention of the GAP manual to cover the steps from handler receipt of raw pistachios to storage. Some steps however, particularly flotation tanks, wash lines, and dryers have microbiological implications.

Pistachios are dehulled in various types of machines and immediately after hulling, are put in flotation tanks. These tanks separate nuts which have less than about 50% nut meats (immature nuts, insect damaged nuts, and blanks) from those that have greater amounts of nut meat. Those nuts with less than 50% meat tend to float while the others sink. The floaters are removed and handled separately from the sinkers. Anytime water is involved, the risk for bacterial contamination and proliferation is increased. This risk may be mitigated by adding various antimicrobial chemicals to the flotation tank water, monitoring the activity of the chemicals, and changing the water. The most commonly used chemical is hypochlorous acid (bleach) and to maintain suitable activity, the tank pH must be monitored to insure that it remains below pH 7 and preferably below pH 6. The antimicrobial activity of bleach can also be compromised if organic material levels of the water become too great. Research is currently being conducted in a number of commodities on other chemicals that may be more robust.

Sinkers are conveyed to dryers and, during the conveying, are washed with water sprays to remove any organic matter that may have adhered to the nut. While not currently practiced, the rinse line offers an additional step where an antimicrobial can be used to reduce microbial contamination.

At harvest, fresh pistachios are approximately 30% moisture. To create a stable agricultural commodity, the nuts must be dried to 7% moisture or less. At these low moisture levels, fungi and bacteria may survive but they do not proliferate. Fresh pistachios are dried in commercial dryers supplemented by natural gas or propane fired heaters. The drying process takes 6-8 hours and reduces the moisture to about 9%. The temperature profiles within the dryers have not been measured and their utility as a control step for reducing microbial contamination requires additional research. Preliminary research measuring total aerobic bacteria indicated that microbial contamination is reduced by about 100-fold during drying. Additional drying with forced ambient air supplemented as needed with natural or propane gas-fired heaters is done in the silo to reduce the moisture levels to 7% or less.

## **IMPLICATIONS**

Pistachios must be removed from the tree, transported, hulled, and dried in an efficient and timely manner to maintain or improve their quality and microbiological safety. While much of the harvest process is not controlled by the grower, the grower can facilitate harvest by ensuring that the orchard and loading areas have been adequately prepared.

## **SANITATION AND HYGIENE**

Good sanitation and hygiene practices are essential at every link of the food production chain to reduce the risk of food contamination. Workers can transmit many food-borne illnesses if they do not know and follow good hygienic principles. The risk of transmission of potential pathogens in the orchard by direct contact is low because there is limited or no human contact but poor sanitation practices can put the crop at risk. While pistachio processors use a variety of techniques to reduce the risk of contamination, this should not be regarded as a license to ignore basic hygienic principles. Indeed, the techniques used by processors presupposes due diligence on the part of the grower.

### **LEGAL REQUIREMENTS**

The United States Code of Federal Regulations Title 21, Section 110.10 prescribes hygienic practices in food processing. While these are not legal requirements in the orchard, growers should consider the standards in an overall hygiene and sanitation program. There are established health standards in the Occupational Safety and Health Act that growers are required to follow.

### **WORKER TRAINING**

Growers should be aware of the signs and symptoms of illnesses, especially those of infectious diseases that could contaminate food. When there is a question whether conditions exist that could compromise food safety, the worker should be reassigned to a job without potential food contact. Sometimes, simply covering a lesion may be adequate.

A personal hygiene training program should be considered. Good hygiene protects the worker from illness as well as reduces the potential for contamination. The importance of handwashing and handwashing technique should be stressed and employees should be encouraged to use the toilet facilities rather than relieving themselves in the orchard. Regardless, a training program need not be limited to sanitation but could also include proper use of protective clothing required during and following some pesticide applications. Regardless, the content of the program and a roster of the attendees should be documented.

### **TOILET FACILITIES**

Training is inadequate if toilet facilities are not close enough to the work site or are not maintained in a condition that would encourage their use. Toilet facilities should be clean and well supplied as well as have handwashing provisions. A maintenance log should be kept to provide documentation of adequate toilet facilities. If a farm labor contractor is used and the contractor provides a portable latrine for worker use, it is still incumbent on the grower to insure that the facilities are adequate. After all, it is the grower who bears the risks associated with poor field hygiene! Regardless of who supplies the latrine, a plan for proper disposal of waste should be in place and contingency plans for containment and cleanup of leakage and spill should be made. Contamination of the orchard with human waste should be avoided. California agricultural field sanitation regulations are located in the California Code of Regulations, Title 8, Section 3457.

While farm labor contractors frequently provide portable latrines, growers should not neglect sanitary facilities for harvest crews. The duration of harvest is short but the effects of poor sanitation may linger for years.

## **IMPLICATIONS**

As described earlier, humans in the orchard can be a significant source of potential food-borne pathogens. Because direct supervision of orchard workers is problematic, the grower should encourage good sanitation and hygiene by developing training materials and providing adequate facilities. The grower should demonstrate due diligence through documentation of training and facility maintenance.