GUIDE FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR SPICES & SEASONINGS

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April 2023

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HACCP Guidance Glossary

CAPA	Corrective action report
CCP	Critical control points
CFR	Code of Federal Regulations
COA	Certificate of analysis
ECH	Ethylene chlorohydrin
EMP	Environmental monitoring program
EtO	Ethylene oxide
FS	Food safety
FSMA	Food Safety Modernization Act
FSP	Food safety plan
GAP	Good Agricultural Practices
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis Critical Control Point
MRP	Microbial reduction processes
PC	Preventive controls
PCHF	Preventive controls for human foods
PCQI	Preventive controls qualitied individual
PFD	Process flow diagram
PPO	Propylene oxide
RTE	Ready-to-eat
QA	Quality assurance
QC	Quality control
WOW	Hygienic Zoning and Environmental Controls

I. Introduction and History

In 2011, President Obama signed the Food Safety Modernization Act (FSMA) into law in response to a number of adverse food safety incidents. FSMA requires food facilities and importers of food to the United States to establish a food safety plan (FSP), which is based in hazard analysis and preventive controls. The law has now been fully implemented and the details of these new regulations were issued through the updated current Good Manufacucturing Practices found in 21 Code of Federal Regulations (CFR) Part 117.

The concept of preventive controls has its basis in Hazard Analysis Critical Control Point (HACCP), a longstanding and internationally adopted approach to ensure food safety. Both preventative controls and HACCP entail the identification of microbiological, chemical, and physical hazards, and the determination of appropriate controls to prevent potential food safety incidents from these hazards. However, there are nuances between the two systems. This guidance document was updated in 2023 to focus on the preventive controls requirements in the United States, while maintaining appropriate ties to HACCP which may still have relevance to the industry.

As with any program that is expected to be successful within an organization, a hazard analysis and preventive controls-based food safety plan requires the full commitment and involvement of management to provide the necessary resources, communications and backing. A culture of food safety must become part of the facility's DNA, and this is only possible with management leading the way.

Besides meeting regulatory or customer requirements, the benefits from the use of a proactive food safety program include:

- Protecting consumers and your company
- Reducing product losses
- Prioritizing/focusing resources on critical parts of the process
- Moving from a retrospective end product testing approach towards a preventive approach
- Establishing a thorough systematic food safety approach across all aspects of the supply chain
- Complimenting other quality management systems

II. Purpose and Scope

The goal of this document is to provide the spice industry with a tool to guide the development of a hazard analysis and resulting risk-based controls following FDA regulations as laid-out in 21 CFR Part 117 Subpart C - Hazard Analysis and Risk-Based Preventive Controls. This includes references to how to leverage HACCP resources within the preventive controls framerwork. Various forms with pertinent spice and seasoning examples are also provided as tools to facilitate program development. This guide applies to all ASTA member companies but especially those that fall under the U.S. FDA FSMA regulations.

III. Foundational and Supportive Food Safety Programs

Prerequisite or foundational programs should be well defined and executed in support of any successful and effective food safety system. These programs are basically elements under the overarching umbrella of Good Manufacturing Practices (GMPs) and provide a basis for operating under sanitary conditions as would be the expectation for any food company. The following are examples of typical foundational programs that should be part of your program. Although often not elevated to being critical control points in the past, based on your hazard analysis, some of these may now rise to the level of a preventive control:

- Personal Hygiene
- Hygienic Design
- Sanitation
- Allergen Management
- Hygienic Zoning and Environmental Controls (WOW)
- Preventative Maintenance
- Pest Control
- Internal Audits
- Training
- Supply Chain Program
- Chemical Storage
- Sharp Object Controls
- Warehousing and Transportation
- Traceability

IV. Food Safety Plans and HACCP Elements

21 CFR Part 117 Subpart C Section 126 provides for the regulatory requirement that all FSMA relevant facilities must have a food safety plan that is prepared or its preparation overseen by one or more preventive controls qualified individual (PCQI). A PCQI is defined in section 117.180(c) as an individual that "must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility." It is ASTA's recommendation that each facility should have at least one PCQI on staff and encourage additional staff be PCQI-trained to allow for back-up coverage.

The FSP must include the following main elements:

- Hazard analysis
- Preventive controls (PC)
    - Monitoring

    - Corrective action procedures
    - Verification activities
    - Documentation/records
- Supply-chain program
- Recall plan

One can see the similarities with the 7 principles of HACCP (National Advisory Committee on Microbiological Criteria for Foods, 1997):

1. Conduct a hazard analysis
2. Identify critical control points (CCP)
3. Establish critical limits for each CCP
4. Establish monitoring procedures
5. Establish corrective actions
6. Establish record-keeping procedures
7. Establish verification procedures

The basic difference comes in the broadening of controls requiring more rigorous management beyond just the CCPs under FSMA.

In addition, it is recommended that the FSP include other pertinent information that is useful to the overall understanding of the facility's food safety programs. These may include:

- A brief description of the company, the facility, and its history
- A facility schematic
- Organizational chart
- Composition of the food safety/HACCP team noting PCQIs and their certificates
- Product descriptions and process flow diagrams for each product type
- Allergen tables organized by ingredients, products, and lines
- Summary of foundational or prerequisite programs
- Vulnerability assessments and controls for intentional adulteration

Detailed supporting procedures and documentation would then be referenced as needed and maintained in their appropriate locations while being made readily available for inspection, review or for training purposes.

V. Food Safety Plan Development and Implementation

Developing and implementing a food safety plan can be based largely on a facility's past HACCP plan. The following outlines the basic steps and highlights key recommendations, considerations and useful resources.

1. Assemble the HACCP/Food Safety Team

A preventive controls qualified individual must lead or oversee this team and the plan development. A cross-functional team comprised of members bringing a diverse range of

pertinent expertise and experience is essential to build a well thought-out and thorough program. Besides knowledge about food safety hazards, this includes in-depth knowledge on the products, raw materials/ingredients, and processing. HACCP and/or PCQI training is recommended but not required for all team members. However, the entire team should be trained in the basic principles of food safety.

Example of HACCP/Food Safety (FS) cross-functional team members include:

- PCQI (on permanent staff preferred) or outside consultant
- Quality assurance (QA) / Quality control (QC)
- Product development
- Plant engineer
- Sanitation
- Maintenance
- Production supervisors and operators
- Warehouse
- Consumer affairs
- Plant leadership – as the plant manager is considered by the FDA to be the "agent in charge"; it is good to ensure their inclusion and engagement with the team and recommended that they attend PCQI training.

2. Describe The Product(s)

The product description summarizes product attributes and is used to help understand product specific risks and assist with recognizing relevant hazards during the hazard analysis step. There should be a product description for each unique product type. Products may be combined if they are basically the same in all aspects except maybe one or two non-critical attributes. For example, black pepper with two different particle sizes may be combined. However, black pepper that has not been treated for pathogens should not be combined with black pepper that has been treated.

The product description should include (see Annex **1** for example):

- Product name
- General description of manufacturing process
- Overview of attributes that contribute to safety and microbial stability (i.e. pH, water activity)
- Basic ingredients used without providing proprietary formulations
- Inherent product allergens or sensitizers
- How product is packaged
- Intended use
- Intended consumers
- Shelf-life if established for food safety or microbial spoilage (as opposed to a benign decline in quality attributes)
- Labeling instructions required for safety/stability

- Storage and Distribution

3. Develop and Verify Process Flow Diagram(s)

Within a spice manufacturing operation, there may be many different ways in which products are handled/processed. This could include physical cleaning, milling, blending, packing, microbial reduction, and other processes. A simple box style process flow diagram (PFD) must be developed for each product/process. Each box should represent a unique step in the process and does not need to list each piece of equipment the product passes through. For example, the PFD may list "milling" and "sifting" as process steps but does not have to call out each chute or conveyance between them as these will be a natural part of that steps' hazard assessment. This greatly minimizes the complexity of the PFD. However, caution should be taken when trying to combine processing steps. Combining processing steps is usually only recommended for post-primary packaging that present no difference in hazard analysis.

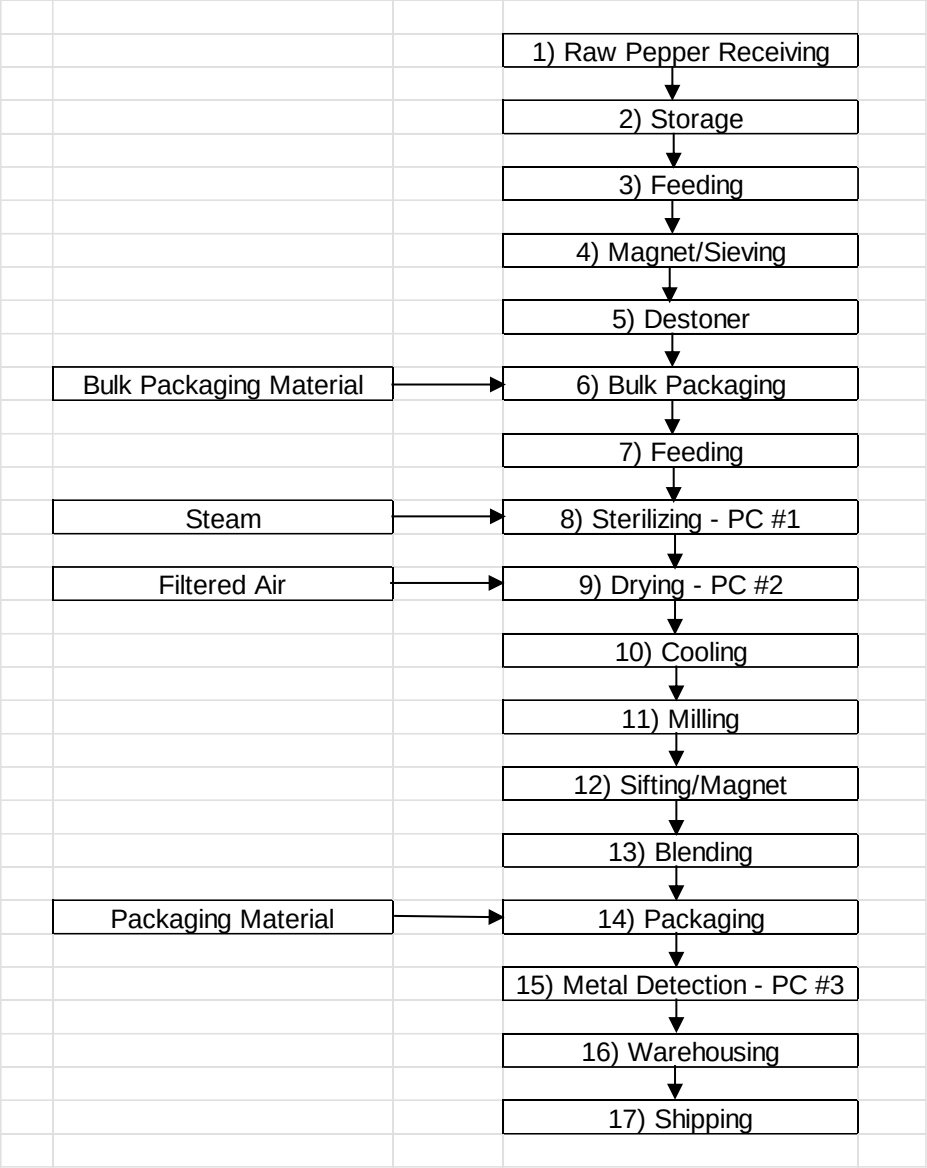
Note: There may be times where equipment call-outs can be useful in the PFD, especially when you have similar lines but they differ in a specific unit of operation, e.g. a different manufacturer or model.

The PFD must include inputs (i.e. ingredients, process aids, gases, packaging) and outputs and where they enter or leave the process. The diagram must also include any rework or work in progress streams. Proprietary processing details should not be included in these flow diagrams. Again, products can be combined on a PFD if common processing steps are experienced with only subtle/minor differences on the same process line. However, it is best to have a different flow diagram for each processing line even if they appear identical since line changes may have been or could be made to one and not the other. This will help ensure a full and proper assessment.

It is important that the HACCP/FS team walk the process to verify that the PFD is true and accurate. This walk-through can also be used as part of the line hazard assessment (as discussed in ASTA's 2017 "Risk Assessment Considerations Guide"). Talking to the operators provides additional insight related to the line operation, equipment and/or procedural challenges. The PFD should be adjusted as needed per the team's findings. The team should also establish a change management procedure to ensure notification if any line changes are made that could affect the hazard analysis.

It is advised to give each process step a sequential number which would then be referenced in the hazard analysis to ensure all steps have been assessed. Additional designations may be used to help distinguish between various PFDs/process lines. For example, "M" has been used as a prefix to show that it is from the milling operation, and "S" has been used to show that it is from the seasoning PFD. This technique can be repeated for all applicable processes operated by the company. Upon completion of the hazard analysis and risk-based controls determination, the appropriate PC and/or CCP designation should also be referenced on the PFDs. Figure 1. provides an example flow diagram. Document version tracking should also be used.

Figure 1. Spice milling HACCP process flow diagram



4. Conduct Hazard Analysis

The hazard analysis is the backbone of the food safety plan. Conducting a proper hazard analysis requires the HACCP/FS team to utilize the product description, the process flow diagram, line risk assessments, along with their experience and expertise and available resources and reference materials to identify all potential hazards that are reasonably likely to occur. This includes analyzing each process input and each process step to determine if a hazard can be introduced, increased or controlled.

The significance of each identified hazard is then assessed using a severity and likelihood matrix with justifications for the risk rankings. Similar to the Codex HACCP decision tree (Annex 3), the matrix is then used to help determine which hazards require a preventive control. Once it is

determined which hazards require a preventive control, the next step is to identify the appropriate control(s) for each hazard requiring a preventive control. For ingredients, the hazard analysis should note if hazards requiring a preventive control are to be controlled by the supplier or by the receiving facility. If controlled by the supplier, the Supply Chain Program is used to verify that the control was applied.

Per FDA's Preventive Controls for Human Foods Draft Guidance (2018), the hazard analysis must be thoroughly documented and facilitated by using a well laid-out template to organize and communicate the assessment. Things to consider when identifying potential hazards include:

- Raw materials and ingredients used
- Intrinsic characteristics of the product at different stages of the process and in its final form.
- Processing step risk factors (e.g. human error, cross contamination, cross contact, etc.)
- Employee hygiene practices
- Microbial load during storage, and before and after processing steps
- Facility design and hygienic zoning
- Equipment hygienic design and risks
- Packaging, including integrity, labeling
- Storage and distribution
- Consumer use and potential abuse

Hazards Types, Sources, and Controls

There are three primary types of hazards to consider when conducting a hazard analysis – biological, chemical and physical. There are numerous potential hazards within each group, including but not limited to the following:

Chemical Hazards (sources):

- Pesticide residues, fertilizers, antibiotics, other agricultural chemicals (raw materials/ingredients)
- Heavy metals i.e., lead, arsenic, mercury and cadmium (raw materials/ingredients)
- Cleaning chemicals (sanitation, improper storage)
- Mycotoxins i.e., aflatoxin and ochratoxin A (raw materials/ingredients)
- Facility pest control chemicals (misuse, improper storage)
- Unapproved or undeclared food additives i.e., some food colors (raw materials/ingredients)
- Allergenic materials i.e., the nine major food allergens in the U.S. (raw materials/ingredients, inadequate separation, mixed product)
- Radiological contamination (raw materials/ingredients; ground water)

Physical Hazards (sources):

- Glass (equipment; light fixtures)

- Hard plastics and ceramics (equipment)
- Metal (raw materials/ingredients, equipment)
- Stones (raw materials)
- Wood (pallets; raw materials)
- Natural food components i.e., seeds, shells (raw materials)

Biological Hazards (sources):

- Infectious pathogens i.e., *Salmonella,* pathogenic *E. coli* and *Listeria monocytogenes* (raw materials/ingredients, cross contamination process environment, inadequate sanitation, inadequate processing, poor personal hygiene)
- Toxin producing pathogens (sporeformers and non-sporeformers) i.e., *Bacillus cereus, Clostridium perfringens, and Staphylococcus aureus* (raw materials/ingredients, time/temp abuse, poor personal hygiene)

A good starting reference for a list of hazards to be considered is found in FDA's Preventive Controls for Human Foods Draft Guidance, Appendix 1: Potential Hazards for Foods and Processes (PCHF). The appendix is especially useful for assessing raw materials and ingredients. Not every product type can be found in the appendix; and there may be hazards noted that are not relevant to your product or hazards not listed that are relevant. This is where the cross-functional expertise of the team is critical to make appropriate assessments and decisions. Industry news plus regulatory alerts and web sites can also provide insights into potential hazards for a given ingredient, product, or process that may need to be considered.

Hazard analysis worksheets can be developed to create a checklist of all potential resources to be used when assessing each ingredient or process step and drive team discussions. This can then be used as a reference for future assessments by documenting past logic. Hazards deemed reasonably likely to occur can then be moved to the food safety plan's hazard analysis tables. The FDA's PCHF draft guidance also includes tools such the allergen assessment tables organized by ingredients, products/labels, and process lines (see Annex 2 for examples). These can further aid the thoroughness of the allergen hazard analyses.

ASTA's 2017 "Risk Assessment Considerations Guide" provides one roadmap for conducting hazard assessments. The focus is on hazards or contaminants that can cause harm if consumed and those that are heavily regulated and would be considered adulterants. Including "hazards" that are based on consumer satisfaction or quality/specifications as opposed to a true safety concern can dilute the food safety effort and lead to an excessively busy food safety plan.

For each input (raw material/ingredient) and process step, determine which hazards are reasonably likely to be introduced by some vector and, if uncontrolled, would present a risk to the consumer. At a minimum the following vectors should be considered: all employees and service providers (operators, maintenance technicians, pest control, contractors), visitors, air flow, water flow, mobile equipment, tools, cleaning practices, sampling techniques, recycled packaging and other materials, waste disposal, reworked material, and non-conforming products. There may be other vectors applicable to your operation. If product is exposed to the processing environment post- or with no microbiological treatment, the hazard of cross-contamination from

environmental pathogens shall be included in the hazard analysis. Consideration should be given to whether each process step can increase a hazard (e.g. growth of toxin producing pathogens) or reduce/remove a hazard (e.g. microbial inactivation step or metal detection systems). For the former, a preventive control may be needed. For the latter, that step may be a preventive control and/or CCP.

The following section provides additional considerations for each of the three hazard types.

a. Chemical Hazards

Chemical hazards may be naturally occurring, unintentionally introduced, or intentionally introduced for economic gain.

Naturally occurring hazards are normally introduced via ingredients or raw materials. Examples include mycotoxins (i.e. aflatoxin and ochratoxin A) and inherent allergens (e.g. sesame in sesame seeds). As some of these hazards are difficult to recondition/eliminate, it is essential to minimize their presence in the raw materials. Mitigation strategies often include the use of suitable controls in the growing and drying area. The International Organization for Spice Trade Associations (IOSTA)'s "Good Agricultural Practices (GAPs) Guide" (2020) covers these points and is available from the ASTA Website.

Unintentionally added chemical hazards could occur in ingredients (e.g., unapproved additives or colors such as Red No. 4), from misformulation (e.g., excessive addition of sulfites or undeclared Yellow No. 5), during production (e.g., agricultural chemicals), or processing (e.g., acrylamide formation during thermal processes or contamination from chemicals used in the facility). Chemicals used in the manufacturing process for a specific process, such as preservatives, flavor enhancers, meat tenderizers, colors and antioxidants also have the potential to cause harm if misused. Some examples of the unintentional chemical hazards occurring during production include sanitizers, lubricants, pest control chemicals, cleaning chemicals, laboratory chemicals, and water treatment additives, all of which have the potential to be carried over into the product and must be rigorously controlled. While most of these chemicals do not pose a health hazard when used properly, some are capable of causing serious health problems if used incorrectly. The impact of the presence or excessive levels of these chemicals can range from consumer complaints and product adulteration per regulations to more serious adverse health reactions such as throat burning, gastrointestinal issues or potentially life-threatening hypersensitivity reactions.

Furthermore, chemicals added intentionally for economic gain may also present hazards that must be considered. These are often ingredients or fraudulent substitutes (e.g., non-spice plant material in saffron) that are cheaper than the material being marketed, additives to make a product look higher quality (e.g., lead containing dyes in cumin and lead chromate in turmeric), or substances added to bulk-up or influence a value-adding parameter (e.g., melamine in dairy powder). Industry news, fraud databases (such as FoodChain ID), and regulatory actions are good resources for potential reports of fraud.

While most incidents of food fraud are not hazardous, there may be incidents that can cause serious health issues (e.g., heavy metals, melamine, etc.). The ASTA "Identification and Prevention of Adulteration Guidance Document" (2016) is a valuable resource on key strategies to prevent fraud in the spice sector.

In the U.S., many chemicals found in food processing, both added and naturally occurring, are regulated by FDA, USDA, or EPA. For example, FDA has numerous lists of food additives in 21 Code of Federal Regulations. In addition, FDA has a list of substances that are specifically prohibited in foods, 21 CFR 189. In some cases, if the substance is necessary in the production of a food product or cannot be avoided by good manufacturing practices, the FDA has established tolerance limits, such as 20 ppb for aflatoxins. Further, the EPA regulates and determines the tolerances or exemptions from tolerances for pesticide residues on raw agricultural commodities in 40 CFR 180.

Examples of common chemical hazards for spices include:

- **Undeclared allergens**, which are one of the leading causes of food recalls, have the potential to cause serious reactions for consumers with food allergies. Allergens may be naturally occurring within a raw material or unintentionally added via cross contact in the manufacturing process or during harvesting, storage or transport. For raw materials, consideration should be given to the growing environment. Allergenic materials may be grown next to the spice crop and/or share harvesting, storage, or transport equipment where comingling may occur and lead to the adventitious presence of an unidentified/unlabeled allergen. One example is peanut and garlic, which may be grown on the same fields. Companies should conduct risk assessments and implement allergen controls to mitigate agricultural cross-contact and proper allergen handling to prevent cross-contact (sanitation and practices) and/or mislabeling in the facility. Additional information on food allergens can be found in "FAQs for the American Spice Trade Association (ASTA) on the Potential Risks Related to Allergens in Spices" (May 2021).

- **Heavy metals** such as lead, mercury, arsenic, and cadmium, which may be present in spices, normally at low levels, have the potential to impair cognitive development (i.e., lead) or lead to cancer or other diseases (i.e., arsenic) at high levels. These chemicals may be present within the growing environment or enter the food stream through leaching from equipment or utensils (i.e., from lead solder) or illegal dyes. Being aware of regional risks factors based on past regulatory actions can help identify potential for contamination. Supply chain controls and verification through testing are key strategies to control heavy metals. ASTA has published industry guidance levels on heavy metals in spices, as well as an FAQ document and spice safety fact sheet (ASTA, 2022a, 2022b, 2022c) on its website under "Heavy Metals".

- **Mycotoxins**, which are produced by the growth of certain molds on raw agricultural products in the field or during storage, may be teratogenic, mutagenic, or carcinogenic at high levels. Production of mycotoxins is of increased concern in times of drought, flooding, and insect damage. Low levels of mycotoxins are sometimes

found in spices. In particular, low levels may be present in capsicums, turmeric, ginger, nutmeg and black pepper. Control measures include prevention via GAPs, foundational supply chain programs, or through product testing/rejection upon arrival. More information on mycotoxin control can be found in the Codex Alimentarius Committee's "Code of Practice for the Prevention and Reduction of Mycotoxins in Spices", CXC 78-2017, adopted in 2017.

- **Pesticides** include insecticides, fungicides, herbicides, and rodenticides that may be used in growing and storing spices, as well as microbiological reduction treatment methods, which may leave residues. In general, low levels of pesticide residues are not considered to pose a health hazard. However, foods containing residues exceeding tolerances set by the EPA, or for which no tolerance is set, are considered adulterated and are required to be considered as a part of a company's hazard analysis. Companies should conduct risk assessments based on their specific supply chains to determine if pesticides are a hazard requiring preventive control. Controls may include supplier verification of good agricultural practices that are verified through testing. Integrated pest management programs shall include safe usage and storage of pest control chemicals. Additionally, ethylene oxide and propylene oxide are important treatment methods to control pathogens in spices that are regulated as pesticides. Additional information on the use of these methods is available in ASTA's "Clean, Safe, Spices Guidance Document" (2017) and "Ethylene Oxide White Paper" (2023).

In conclusion, key controls to mitigate risks from chemical hazards include:

- GAPs
- Supply chain program with certificate of analysis (COA) verification where appropriate
- Allergen control program including accurate allergen labeling, product/packaging verification, effective sanitations and preventing cross contact
- Chemical storage/inventory control

b. Physical Hazards

For the spice and seasoning industries, a major objective is to remove physical hazards that may be associated with raw materials. This is true for any industry that deals with field or comparable materials. Physical hazards can result in personal injuries, such as a cut from glass or metal shaving to the throat or intestines. Broken teeth and choking hazards are another key concern for larger physical hazards that breach the controls for some whole products. Physical hazards may be introduced through raw materials (e.g. stones, buckshot, wood splinters), ingredients (e.g. metal), equipment (e.g. metal or hard plastics, preventative maintenance failures, poor design), or from the process environment (e.g. loose materials, inadequate infrastructure maintenance).

The ASTA Cleanliness Specifications list extraneous/foreign matter that is considered to be a physical hazard. The list includes, but is not limited to: stones, dirt, wire, string,

stems, sticks, nontoxic foreign seeds, excreta, manure and other animal contamination. FSPs normally focus on physical hazards that are more likely to cause injury as requiring preventive versus those less likely (i.e. string, dirt) and controlled by foundational controls.

Unlike the severity rankings for most biological and chemical hazards which are fairly constant, the physical characteristics of foreign objects can have a significant impact on their severity or harm to a consumer. These risk factors are size, hardness, sharpness, and shape. The type of food and target consumer involved may also impact the severity/risk, making the product description an important assessment tool. FDA's Compliance Policy Guide Section 555.425, "Foods – Adulteration Involving Hard or Sharp Foreign Objects" (1999) classifies a product that is ready-to-eat as being adulterated if it contains a hard or sharp foreign object greater than 7mm in length and less than 25mm in length. FDA has also noted that if the target consumers for a food material are for infants or the elderly, objects between 2mm and 7mm can be viewed as a hazard in such a situation. It should be noted, however, that glass of any particle size is a hazard. Other hard or sharp objects found in product at less than 7mm may trigger the need for a risk assessment and root cause analysis by the company.

In addition to foundational GMPs, key controls to mitigate risks from physical hazards include:

- Supply chain programs
- Removal devices i.e., sifters, screeners, magnets, bottle washers
- Glass and brittle plastics programs
- Preventative maintenance programs
- Sanitation with re-operational line inspections for verification
- Detection devices i.e., metal detectors and x-ray systems

Detailed information on recommended equipment for removing the physical impurities from raw spices can be found in the ASTA publication "Principles of Physical Cleaning of Spices" (2014). The guide provides information by spice on recommended equipment, as well as the general functionality of the equipment.

c. Biological Hazards

One of the greatest risks for illness from food comes from microbiological hazards. The severity of illness can range from short, self-resolving intestinal discomfort to severe symptoms requiring hospitalization or even death. Understanding the microbiological hazards presented by each raw material and ingredient is a critical part of the hazard analysis.

Due to the environment in which they are grown, spices often harbor large numbers of bacteria and fungi, which may include pathogens. Although a number of microorganisms are killed during the drying of spices and herbs, many bacteria and molds survive. Drying must be carried out in a hygienic manner that ensures thorough uniform drying and

prevents re-contamination during the drying process. Guidance on drying techniques can be obtained from the IOSTA Good Agricultural Practice guide that is available from the ASTA website. As undesirable organisms may still remain, the ones of public health significance (pathogens) are the focus of the FSP.

There are numerous resources for information on the various pathogens, their pathogenesis, potential sources, growth characteristics, and controls, these include: FDA's Bad Bug Book, the CDC website, and ICMSF Microorganisms in Foods 5 Characteristics of Microbial Pathogens. The FDA's 2013/2017 "Risk Profile: Pathogens and Filth in Spices" is also a useful reference for ASTA members.

Microbiological hazards can be divided into two major categories for hazard analysis purposes: infectious pathogens and toxin producing pathogens. These two categories of microbiological hazards often require different control measures.

Infectious food borne pathogens include bacteria, parasites, and viruses. However, for spices and seasonings, bacterial pathogens, particularly *Salmonella*, pose the most likely threat and are the focus of this discussion. Once ingested, infectious pathogens invade intestinal tissue and/or take up residence resulting in illness from the body's immune response or cellular damage. The infectious dose (the number of cells that need to be ingested to cause illness) varies by organism. However, it is important to note that some pathogens, i.e. *Salmonella*, may only require a few cells to cause illness.

Growth of some infectious pathogens (i.e. *Salmonella*) in food is NOT required for illness to be possible. If these pathogens can simply survive in the food, they are a risk. This is reinforced by the fact that several low water activity foods that cannot support growth have been vehicles in serious outbreaks. A summary of outbreaks and recalls associated with spices is includes in ASTA's "Microbiology of Spices White Paper" (2021). The focus of controlling infectious pathogens is to prevent entry and inactivate them if presumed present. Entry may come from raw materials or cross contamination via insanitary processing environments; so controls mainly involve supply chain program and environmental controls (i.e. employee practices, sanitation, and hygienic zoning). For inherent pathogens that may be associated with incoming raw materials, a validated inactivation, or kill step to a 5-log reduction would be the desired control. Inactivation steps include: thermal (i.e., steam), fumigation, or irradiation and are further discussed in the following section, "Microbial Reduction Processes".

On the other hand, toxin producing bacterial pathogens must grow to high numbers in a food to where enough toxin can be generated to cause illness. Some of these toxins may be heat stable and survive thermal treatments. For example, if *Staphylococcus aureus* is allowed to grow to levels of >100,000-1,000,000 cells per gram of food, it can produce a heat stable toxin. Even if the food is cooked to kill the organism, the toxin would remain and potentially cause illness once ingested. The key to control is preventing growth whether by intrinsic (i.e., pH or water activity) or extrinsic (i.e., holding temperature) factors.

Toxin producing pathogens include both sporeformers (i.e., *Bacillus cereu*s and *Clostridium botulinum*) and non-sporeformers (*S. aureus*). Bacterial spores are significantly more resistant to heat, radiation, chemicals and other environmental stress factors. This is important to consider if a sporicidal inactivation step is required per your hazard analysis. Preventive controls designed to inactivate vegetative bacterial cells may not be adequate for inactivating spores.

Since the majority of spices and seasonings are low water activity, infectious pathogens are the most likely hazards requiring preventive controls. However, if the spices are exposed to excess moisture or they are incorporated into a higher water activity food or beverage products that are capable of supporting bacterial growth such as processed meats or dairy products, then the potential impact of toxin producing pathogens must be taken into consideration.

Several methods for controlling microorganisms in spices during growing, planting, harvesting, storage, and export are outlined in the ASTA publication "Clean, Safe Spices Guidance Document" (2017). Key pathogen controls include:

- Supply chain programs with COA verification per microbiological specification
- Master sanitation schedule and environmental controls (including hygienic zoning, minimizing the presence of water, and employee practices) to prevent cross contamination with environmental monitoring program (EMP) verification
- Process line sanitation
- Validated pathogen inactivation steps
- Product design – intrinsic/extrinsic factors
- Packaging integrity
- Preventative maintenance program

Given their importance, microbial reduction processes and protecting ready-to-eat (RTE) product from cross-contact are explained in more detail below.

<u>Microbial Reduction Processes</u>

A variety of microbial reduction processes (MRPs) are employed within the spice industry to ensure the safety of spices. It is important for companies relying on MRPs to validate each process using representative products to which it will be applied. Validation should focus on the critical process parameters used to deliver the target log reduction, as outlined in ASTA's "Validation of Microbial Reduction Processes for Spices" (2013), "Guidance on Science-Based Groupings to Optimize Validation of Spice Process Controls" (2022), and ASTA's webinar series on validation of microbial reduction processes (2017). The validation must be completed in order to have documented proof that the process is reliable as designed. Additional resources on validation are included on the ASTA website, including an ASTA webinar series on validation of microbial reduction processes.

Following is an overview of the three most widely used MRPs in the spice industry. While the focus is on these three, it is understood that alternate treatment technologies are available on the market. Alternative treatments may offer advantages; however, most also have significant drawbacks and must be critically assessed and validated.

Ethylene oxide (EtO)/propylene oxide (PPO) fumigation

Fumigation is a process that entails the use of a gas, such as EtO or PPO, to achieve an effective microbial kill without the use of high temperatures. It is currently permitted in the U.S., although proposed air emissions standards and an updated proposed interim decision on EtO use as a pesticide were published in April, 2023, which may affect its usage in the U.S. (EPA, 2023a, 2023b). Use of the gas as a fumigant is banned in the EU and a number of other countries. Ethylene chlorohydrin (ECH) is a potential residue of EtO application in spices. EPA has set EtO residue limits of 7 ppm on spices and 7 ppm on dried vegetables, as well as ECH tolerances of 940 ppm on spices and 940 ppm on dried vegetables. ETO is not permitted to be used on basil. Proper fumigation relies upon several factors including product density, package permeability, product stacking configuration, gas concentration, chamber pressure, temperature, and off gassing time that must be validated and controlled. Additional information is available in ASTA's "Clean, Safe, Spices Guide" (2017) and on ASTA's webpage under "Processing Treatments".

Steam and/or dry heat

Treatment with high-temperature steam is a safe and efficient process for reducing microbial loads. It is particularly useful for whole spices and is effective for some herb products. This treatment leaves no regulated residues and is considered a natural and environmentally friendly treatment. However, the control of water activity (drying) after treatment is essential to prevent microbial growth/spoilage or quality issues. Furthermore, steam has quality parameters drawbacks as it reduces flavor, aroma, and color. Critical parameters to be validated and controlled are temperature, exposure time, density, and water activity.

Irradiation

Irradiation is a simple, safe, and efficient way to reduce microorganisms in almost all spices. Irradiation allows the processing of spices in the final packaging, which eliminates the problem of recontamination during re-packaging. At low doses, there is minimal product temperature increase, there is no significant impact to product quality. The critical parameters to be validated and controlled are product palletizing configuration, density, and exposure time. Irradiation, however, adds another risk to the process that is known as a radiological hazard. The initial validation of the irradiation treatment should include any testing required for free radicals or supporting scientific data to ensure safe levels.

Regulations around irradiation of foods vary considerably between countries. In the U.S., CFR 21 Part 179 notes that for microbial disinfection of spices that are used to impart flavor and for turmeric and paprika when used as color additives, the maximum dose of irradiation is not to exceed 30 kGy (3 Mrad). Directly treated materials must bear the "radura" logo along with either the statement "Treated with radiation" or the statement "Treated by irradiation".

Protecting RTE Product from Environmental Cross Contamination

As previously discussed, the hazard of cross contamination from environmental pathogens shall be considered when RTE product is exposed to the processing environment and almost always requires preventive controls. These controls include foundational GMPs, sanitation, and other programs intended to control environmental pathogens such as hygienic zoning and minimizing the presence of water that can promote microbial growth. Verification includes environmental monitoring for pathogens. Please refer to ASTA's 2019 "Guidance on Environmental Monitoring Programs" for details related to this verification activity.

Simply stated, the main goals of hygienic zoning are to establish barriers, practices, and levels of hygiene needed to minimize the introduction and spread of environmental pathogens within the manufacturing facility. The stringency of these hygienic controls would increase as the level of risk to the product stream increases. A cross functional team should be used to map out the various hygienic zones in the facility and assess factors such as potential vector patterns (see Figure 2) and product stream risks.

As noted in ASTA's 2023 "Good Manufacturing Practices (GMP) – Guide for Spices", Hygienic zones may be characterized in various ways. However, the food industry often recognizes the following designations:

"High Hygiene" or "Primary Pathogen Control Areas (PPCA)" or "Ready To Eat (RTE) Areas" where there is exposed RTE product (e.g. post-kill step). Examples include treated spice milling, sifting, or packaging rooms. For such areas, more stringent sanitation requirements and environmental controls should be applied. The PPCA can be further elevated to a Sensitive/High Hygiene designation for areas producing food for sensitive populations such as infants, and foods dedicated to clinical settings.

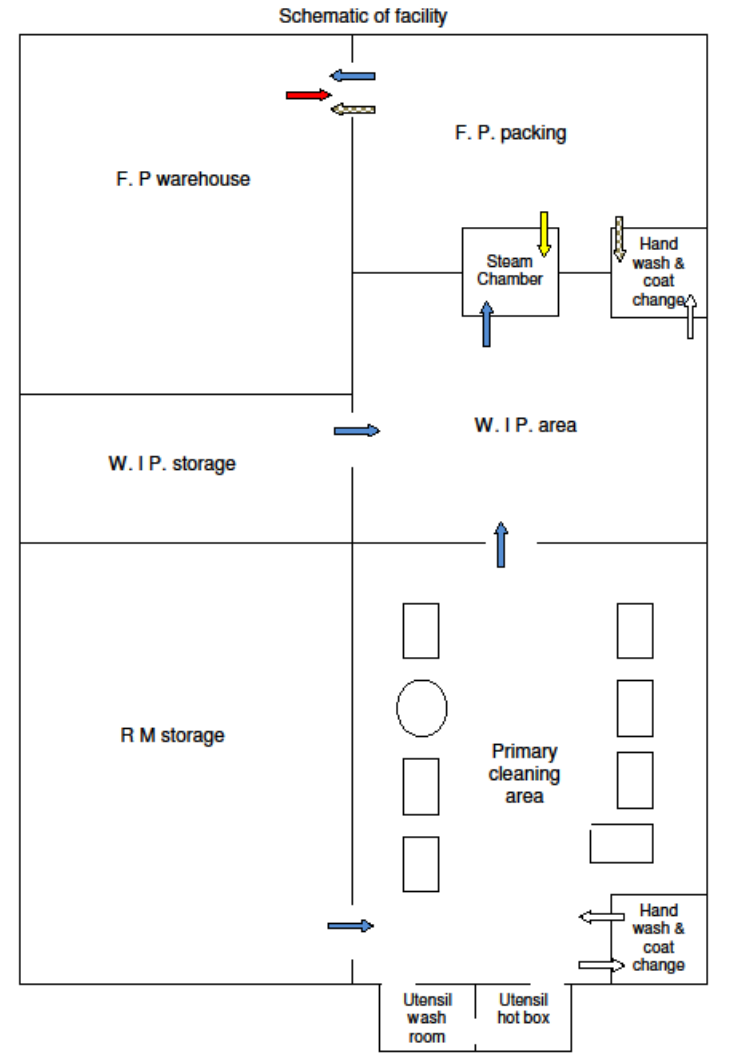
"Medium Hygiene" or "Basic GMP" or "Non-RTE (NRTE) Areas" include raw material storage and pre-kill step processing, sealed ingredient storage, and finished product warehouses. These must be kept clean to meet basic GMP requirements. Separation of these areas from the PPCA (e.g. isolation of raw ingredient handling and separate tools) is necessary to prevent cross contamination.

"Lower Hygiene" or "Non-Manufacturing Areas" or "Non-Product Areas" include offices, employee welfare areas (i.e., cafeterias and locker rooms), and usually

maintenance rooms. These areas should meet basic sanitation requirements but are not required to meet GMPs.

From here “Transition Areas” are established and visually designated for pathways or entries from a less stringent hygienic area to more stringent area. For example, from a non-manufacturing area (locker rooms, cafeteria, etc.) to Basic GMP or PPCA, or from Basic GMP to the PPCA. Hygienic steps are required in these areas (i.e., hand washing, footwear treatments, etc.).

Figure 2. Schematic of facility noting potential vector flows from the various areas.



Vectors – Product waste, packaging waste, Contractors, Water, Air, Operators, Lab staff, visitors / auditors, recycled packaging, product flow, allergens, common process equipment, cleaning techniques, etc.

Vectors of cross-contamination

Companies must undergo an evaluation of their processing facility to identify which zones are high risk for potential contamination of an RTE product. When carrying out the study, it is important to ensure that all potential vectors of cross-contamination are considered. A few examples are given below:

- People
- Tools
- Air and water flow
- Equipment
- Recycled packaging
- Pest control contractor
- Waste disposal
- Engineering / electrical contractors
- Process flow
- Storage bins / hoppers
- Product flow
- Laboratory sampling
- Cleaning activity

All of these vectors have the potential to carry contamination from one area within the facility to another and there may be additional factors that are applicable to your operation. To identify the potential for cross-contamination, it is recommended that a site plan is produced which clearly identifies all possible transfers between hygienic zones with discussions around mitigations.

Assess Risk to Determine If Hazard Requires PC

Once a hazard has been identified as reasonably likely to occur and must be included in the hazard analysis for an ingredient or at a processing step, the overall risk is to be assessed to understand its significance and whether it should require a preventive control. To assist in this assessment, the severity of the hazard is considered along with the likelihood or probability of occurrence in the absence of preventive controls.

For example, the severity of a medium sized shard of glass being in a product is much higher than the severity associated with a very small piece of soft plastic; the presence of *C. botulinum* toxin would be significantly more severe than the presence of *S, aureus* toxin; and the presence of an undeclared peanut allergen would be more severe than presence of a low level of a banned pesticide.

ASTA recommends that the team conducting the hazard analysis first consider what they all understand as an adverse health affect, so that each team member is working to the same objective. Companies may choose to establish default severity rankings for various hazards to facilitate the assessment, such as:

- Susceptibility of intended consumer (e.g., infants, elderly, immunocompromised)
- Magnitude and duration of illness or injury
- Impact of secondary problems.

Estimating the likelihood of the hazard occurring can vary between companies, facilities or even the individual process lines. As noted in the FDA PCHF draft guidance, the likelihood of occurrence can be influenced by several factors:

- Frequency of association of hazard with the food, supplier or manufacturing facility
- Effectiveness of supplier or facility foundational programs such as CGMPs
- Method of preparation; specific line risks
- Conditions during transportation
- Expected storage conditions
- Likely preparation and handling steps before consumption

Outbreaks, recalls, scientific literature, facility experience and historical data can assist in likelihood determinations.

The team's hazard analysis discussions should take the above into consideration and conclusions summarized and documented. Many companies use either a scoring system or a 3 x 3 matrix of low, medium, and high to characterize and rank risks. An example of a 3 x 3 matrix is shared below. Either system should be well defined to minimize subjectivity and each score or rating must then be justified and documented within the hazard analysis. More significant hazard risks would likely require a preventive control.

Figure 3. Example of hazard analysis.

Likelihood / Severity	1 - Probability of occurring is low; not known to occur except on rare occasions (low)	2 - Probability of occurring is medium; known to occur at a low but occasional frequency (med)	3 - Probability of occurring is high; known to occur frequently or assume constant presence (high)
3 - Serious to permanent health issues (high)	**3**	**6**	**9**
2 - Moderate illness or injury, but recoverable, no long-term health issues (med)	**2**	**4**	**6**
1 - Minor health issues, no need for medical attention (low)	**1**	**2**	**3**

1-2 = Preventive Control not necessary
3-4 = Preventive Control to be considered
6-9 = Preventive Control likely required

In the above example, the outcome of the severity / likelihood review will guide the HACCP/FS team to evaluate the significance of the control(s) required. “Low” severity/likelihood risks (green shaded cells) will probably be controlled by foundational control programs. “Medium” severity/likelihood risks (yellow shaded cells) may require a preventive control and should be appropriately discussed. “High” severity/likelihood risks (red shaded cells) will likely require a preventive control. This is a similar approach to determining what is considered a CCP under a HACCP plan using the Codex CCP decision tree (see Annex 3). Furthermore, Annex 4 includes a Sample Hazard Analysis, as a Hazard Analysis example that demonstrates how to use the above Likelihood/Severity Matrix to determine and document the control that will be used for the hazard types present in your process steps.

5. Establishing Preventive Controls

In discussing preventive controls, it is useful to capture specific definitions and language from the FDA’s “Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry”. There are four main types of preventive controls:

- Supply-chain controls
- Allergen controls
- Sanitation controls
- Process controls

Process controls in the spice industry would include process steps such as:

- Metal detection
- X-ray scanning

- Microbial reduction processes

Establishing these controls involves the validation, verification activities, corrective actions, verification activities, and documentation. Two exceptions are the supply chain program that does not require validation, monitoring, verification and reanalysis; and the recall plan that is exempt from these requirements.

Annex 5 provides examples of forms that can be used to properly document a Preventive Control to be included in the FSP.

Validation

Per the FDA PCHF draft guidance, "Validation" is defined as "Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards."

In an FSP, individual preventive controls may require validation while others may not. The FDA does not require validation for allergen controls, sanitation controls, the recall plan or the supply-chain program. However, for a process step deemed to be a preventive control, a validation to show effectiveness under the given operating control parameters would be required. Evidence can be obtained through the use of relevant scientific data/studies found in literature or through design and execution of challenge studies. Once validated, you must ensure that the process parameters noted under the preventive control limits are within the parameters that were validated in order to be compliant.

ASTA has a variety of resources available on validation on its "Microbial Safety" webpage, including "ASTA White Paper on Process Validation" (2013), "Guidance on Science-Based Groupings to Optimize Validation of Spice Process Controls" (2022), and a validation of process controls webinar series.

Monitoring activities

Per the FDA PCHF draft guidance, "Monitor" is defined as "To conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended." Preventive controls and/or CCPs must have written procedures detailing:

- What must be measured/monitored;
- How it is to be measured/monitored;
- Who is responsible for performing these tasks; and
- The frequency at which it is to be conducted.

These key points are then summarized on the preventive control table. The supportive, detailed procedures should be maintained for reference and used for employee training with sign-offs.

The PCHF goes on to say, “What you monitor should be directly related to control of the hazard. For example, for process controls you would monitor parameters to ensure the minimum/maximum values are met. For other preventive controls, you could monitor that the activity has been conducted consistent with a defined procedure. The frequency of monitoring depends upon the circumstances. Continuous monitoring is always desirable, and in some cases necessary. In other cases, it may not be necessary or practical. You should monitor often enough that the normal variability in the values you are measuring can be determined and a deviation from normal will be detected.” Monitoring documentation includes continuous monitoring such as temperature monitoring circular charts or digital recordings to spot check records and exception reports.

Corrective action procedures

Per the FDA PCHF draft guidance, “Corrective Action” is defined as **“**An action to identify and correct a problem that occurred during the production of food, including actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).”

Preventive control/CCP procedures must include actions to be taken in the event control limits are not met per monitoring, control is compromised in some way, or verification results are non-compliant. These predetermined corrective actions help to avoid confusion and allow more rapid response minimizing the risk of more product being put at risk. The corrective actions should state procedures to restore process control and determine the safe disposition of the affected product.

Effective corrective action plans will correct and eliminate the cause of the non-compliance to assure that the PC/CCP is brought quickly back under control, segregate, assess and determine the disposition of the non-compliant product, and include preventative action steps where appropriate to avoid reoccurrence.

When a deviation occurs, identify non-conforming product. The following steps that may be used for determining product disposition and developing a corrective action plan.

- Determine if the product presents a safety hazard based on expert evaluation and/or physical, chemical or microbiological test results.
- If no hazard exists based on the evaluations, the product may be released.
- If a potential hazard exists determine if the product can be reworked/reprocessed using a validated process; diverted for a safe use; or must be destroyed.

It is critical to document and capture the deviation event and corrective actions taken. The corrective action report (or CAPA report) should contain the following at minimum:

- Product identification (e.g. product description, amount of product on hold, location)
- Description of the deviation
- Root cause investigation findings where appropriate
- Corrective action taken with dates, including final disposition of the affected product

- Name of the individual responsible for taking the corrective action
- Any test or verification results
- Certificates of destruction in the event product must be destroyed
- Appropriate management sign-offs

Part of the corrective action discussion must also look at trends/reoccurrences and the need to reassess the FSP. A critical excerpt from the FDA PCHF draft guidance notes, "When critical limit deviations frequently reoccur, the process and the Food Safety Plan may need reanalysis and modification. A formal process may be needed to manage major changes that need to be implemented. This may include reissuing forms, retraining employees, phasing in changes, managing label information, informing suppliers, and other tasks, depending on the nature of the change."

Verification Activities

Per the FDA PCHF draft guidance, "Verification" is defined as **"**The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan." Verification activities must be overseen and periodically reviewed by a PCQI. Note all supportive documentation/reports in the PC summary table. Verification activities may include:

- Making sure calibration activities were conducted per procedure and conduct accuracy checks.
- Product testing for pathogens, appropriate indicator organisms, or other appropriate hazards
- Environmental monitoring results and trending data
- Review of PC monitoring records for completeness and compliance
- Review of corrective action records for appropriateness of responses
- Conducting spot audits

Records

"If it wasn't documented, it didn't happen." This age old maxim cannot be understated when you are discussing records to support your food safety programs. Records are critical to demonstrate program compliance. A well thought out recordkeeping system should be established with document version and tracking mechanisms built-in as well as a record retention policy. 21 CFR Part 117 Subpart F provides requirements for FSP records including retention requirements.

It is also helpful to ensure the record/document titles are consistent within the FS/HACCP Plan to properly reference them. There may be multiple records associated with a PC/CCP. Examples include:

- Monitoring records i.e. temperature charts
- Documented corrective actions/CAPA
- Verification activities

- Calibrations
- Product testing
- Supply chain documentation
- Training documents

At minimum, the PCQI should review records within a week of completion and take actions as appropriate if deviations from procedures or errors are noted. Critical process records may need to be reviewed daily especially if required for product release.

VI. FSP Review/Reassessment/Re-evaluation

As with many policies and programs, the food safety plan must be reviewed and updated periodically and as needed to remain effective and relevant. The FDA calls for an FSP to be reanalyzed at least every 3 years. As previously noted, repeated PC parameter deviations are one situation for FSP reassessment. Additional situations/events may include:

- Change in raw materials or the supplier of raw materials
- Change in ingredients/recipe
- Change in processing conditions, process flow or equipment
- Change in packaging, storage and distribution conditions
- Change in consumer use
- Emergence of a new risk (e.g. adulteration of an ingredient)
- Recall of a similar or related raw material, ingredient or product
- Updated company policy(ies) or regulations
- New process or change in process conditions
- Customer complaints
- Internal or third-party audit findings
- Regulatory inspection findings
- Addition or change in a raw material, ingredients or supplier
- Specification or product design changes that affect risk assessments
- Emergence of a new risk (e.g. known adulteration of an ingredient)
- New scientific information on a hazard associated with an ingredient or product type

VII. Conclusion

This guidance document outlines the preventive controls requirements in the U.S., while maintaining ties to HACCP plan which may still have relevance to the industry. As emphasized in this document, hazard analysis and preventive controls-based food safety plans require the commitment and involvement of management to provide necessary resources, communications, and backing. A culture of food safety must become part of the facility's DNA, and this is only possible with management leading the way.

VIII. Definition of Terms

Term	Definition
CONTROL MEASURES	Those actions and/or activities that are required to eliminate hazards or reduce their occurrence to an acceptable level.
CORRECTIVE ACTION	The action to be taken when results of monitoring the PC/CCP indicate a trend towards loss of control.
CRITICAL CONTROL POINT (CCP)	A step which, if controlled, will eliminate or reduce a hazard to an acceptable level.
CRITICAL LIMIT	A maximum and/or minimum value of controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard.
DEVIATION	Failure to meet a critical limit.
DEVIATION REPORT	Record of non-conformance to critical process limits with reference to any product involved in the deviation. May include but is not limited to: date, description of deviation, reason for hold, number of containers held, hold date, product code/identification, product disposition, and responsible individuals.
FACILITY PLAN	A detailed plan of the facility showing all departments, entrances, walls, exits etc. this schematic is often used to show all movement of people, products, equipment etc. giving the ability to look for potential vectors of cross-contamination.
FOOD SAFETY PLAN	PCHF "The primary documents in a preventive controls food safety system that provides a systematic approach to the identification of food safety hazards that must be controlled to prevent or minimize the likelihood of foodborne illness or injury. It contains a collection of written documents that describes activities that ensure the safety of food during manufacturing, processing, packing, and holding."
HACCP PLAN	The written document based on seven principles of HACCP which defines the procedures to be followed.
FSP/HACCP TEAM	A multidisciplinary group of individuals that undertakes a HACCP study.
HAZARD	A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
HAZARD ANALYSIS	Process of collecting and evaluating information on potential food hazards to decide which are significant and must be addressed in the HACCP plan.
LIKELIHOOD	Probability that a hazard will occur in the absence of preventive controls.

MONITORING	A planned sequence of observations or measurements of a CCP target level and tolerance. These are designed to produce an accurate record and to provide evidence for future use in verification that the CCP is under control.
PREREQUISITE PROGRAMS	Procedures and/or programs that provide the basic environmental and operating conditions necessary for the production of safe, wholesome food.
PREVENTIVE CONTROL	PCHF "Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packaging, or holding at the time of the analysis."
PREVENTIVE CONTROLS QUALIFIED INDIVIDUAL (PCQI):	PCHF "A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system."
PROCESS FLOW DIAGRAM	A process flow diagram that shows every activity that is associated with the processing and storage of the product or process in question, including all inputs and outputs from the process.
RISK	An estimate of the probability of a hazard occurring. Probability determined by using severity and likelihood of occurrence.
ROOT CAUSE	"A factor that caused a nonconformance and should be permanently eliminated through process improvement. The root cause is the core issue—the highest-level cause—that sets in motion the entire cause-and-effect reaction that ultimately leads to the problem(s)." – ASQ "An initiating cause of a chain of events which leads to an outcome or effect of interest." - Wiktionary
SEVERITY	The seriousness of the effects (i.e. illness or injury) of a hazard on a consumer.
VALIDATION	Activities focused on collecting and evaluating scientific and technical information to determine if the overall HACCP plan, when properly implemented, will be effective in controlling hazards.
VECTORS	A item, whether it be people, product, air or water flow, tools and equipment, engineering activity etc. that has

	the ability to transfer a contaminant from one area to another.
VERIFICATION	Activities, other than monitoring, that determine whether the HACCP plan is working properly, i.e. equipment calibration, records review, micro testing, or application of test pieces.

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    Useful sections are:
    Chapter 10 - raw meat and poultry, pp. 176-193
    Chapter 11 - roast beef, pp. 234-238
    Chapter 11 - canned ham, pp. 238-242

17. International Commission on Microbiological Specification for Foods. *Microorganisms in Foods 4. Application of Hazard Analysis and Critical Control Point (HACCP). Systems to Ensure Microbiological Safety and Quality.* Blackwell Scientific Publications, Boston, 1989.

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    Useful section:
    Chapter 4-microbiological hazards, pp. 72-103

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    Useful sections:

        Chapter 11- forms for hazard analysis, CCPs, critical limits, HACCP master sheet, example HACCP for breaded chicken.

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X. Expert Authorities on Food Safety

Federal Government Agencies

FDA Center for Food Safety and Applied Nutrition - http://vm.cfsan.fda.gov/list.html

- National Food Safety Initiative
- 1997 Food Code
- The Bad Bug Book - https://www.fda.gov/media/83271/download
- FDA Defect Action Levels - http://www.cfsan.fda.gov/~dms/dalbook.html

UDSA Food Safety and Inspection Service - http://www.fsis.usda.gov/

- Consumer food safety publications
- FSIS/CDC/FDA Sentinel Site Study (FoodNet) information and data
- Generic HACCP models

USDA/FDA Foodborne Illness Education Information Center - http://www.nal.usda.gov/fnic/foodborne/foodborn.htm

- Links to other food safety sites
- Food safety and HACCP Training materials
- Foodsafe- an interactive electronic discussion group intended as a communication tool to link professionals interested in food safety issues.

Centers For Disease Control and Prevention - http://www.cdc.gov/

- Morbidity and Mortality Weekly Report- case histories of food and waterborne outbreaks

- Web site provides information on Food Irradiation, Food Safety and Food-Related Diseases
- Foodborne Germas and Illness - https://www.cdc.gov/foodsafety/foodborne-germs.html

US Environmental Protection Agency - http://www.epa.gov/

- Pesticides
- Water quality
- ETO limits

Academia

Department of Food Microbiology and Toxicology, University of Wisconsin - Madison

- Food Research Institute

Iowa State University Extension Food Safety Project -
http://www.extension.iastate.edu/foodsafety/

FDA Food Safety Plan Builder
https://www.fda.gov/food/food-safety-modernization-act-fsma/food-safety-plan-builder

Food Chain ID – food fraud database
https://www.foodchainid.com/

XI. Annexes

Annex 1	Product Description Form & Example
Annex 2	Allergen Ingredient Analysis Worksheets
Annex 3	Codex HACCP CCP Decision Tree
Annex 4	Hazard Analysis Template & Example
Annex 5	Controls Worksheets & Examples

Annex 1. Product Description Form & Example

FORM 2-A PRODUCT DESCRIPTION

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Product Name(s)	
Product Description, including Important Food Safety Characteristics	
Ingredients	
Packaging Used	
Intended Use	
Intended Consumers	
Shelf Life	
Labeling Instructions related to Safety	
Storage and Distribution	

Approved: (signature or initials) _____

Date: _____

Example – Completed Form 2-A

Product Description – EXAMPLE ONLY	
Product Name(s)	Ground black pepper
Product/process Description, including Important Food Safety Characteristics	Untreated black peppercorns received, cleaned, steam treated, milled, sifted, and packaged.
	Stream treated; low water activity (<0.4) provides microbial stability.
Ingredients	Black peppercorns
Allergens	None; and produced on dedicated line
Packaging Used	Plastic jars with tamper seal and plastic cap
Intended Use	Ready to eat
Intended Consumers	General population
Shelf Life	24 months based on quality attributes only
Labeling Instructions	No special instructions required
Storage & Distribution	Ambient

Annex 2. Allergen Ingredient Analysis Worksheets

FORM 2-E FOOD ALLERGEN INGREDIENT ANALYSIS

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Food Allergens in Ingredient Formulation or in Precautionary Labeling

Raw Material Name	Supplier	Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	Food Allergens in Precautionary Labeling

The above form is taken from FDA's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry (2016). Since its publication, sesame has been recognized as the ninth major food allergen in the U.S.

Example – Completed Form 2-E (Including Sesame)

Raw Material Name	Supplier	Egg	Milk	Soy	Wheat	Tree Nut (add market name)	Peanut	Sesame	Fish (add market name)	Shellfish (add market name)	Allergens in Precautionary Labeling (as declared on material packaging or technical data sheet)
Skim Milk Powder	Company A		X								None
Cinnamon Bark	Company B										None
Almond Flour	Company C					X - Almond					Made on shared equipment that also processes pecans

FORM 2-F FOOD ALLERGEN LABEL VERIFICATION LIST

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Product	Allergen Statement
	Contains:
	Contains:
	Contains:
	Contains:

Example – Completed Form 2-F

Product Allergen Label Verification List – FOR EXAMPLE ONLY	
Product	**Allergen Statement**
Fictitious Cinnamon Almond and Milk Seasoning Blend	Contains: Milk, Almond May contain pecan.
Ground Cinnamon	Contains: N/A

FORM 2-G PRODUCTION LINE FOOD ALLERGEN ASSESSMENT

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Product Name	Production Line	Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)

The above form is taken from FDA's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry (2016). Since its publication, sesame has been recognized as the ninth major food allergen in the U.S.

Example – Completed Form 2-G (Including Sesame)

Product Name	**Production Line**	**Egg**	**Milk**	**Soy**	**Wheat**	**Tree Nut (add market name)**	**Peanut**	**Sesame**	**Fish (add market name)**	**Shellfish (add market name)**
Fictitious Cinnamon Almond and Milk Seasoning Blend	Blender A		X			X- almond; may contain pecans				
Ground Cinnamon	Mill #7									

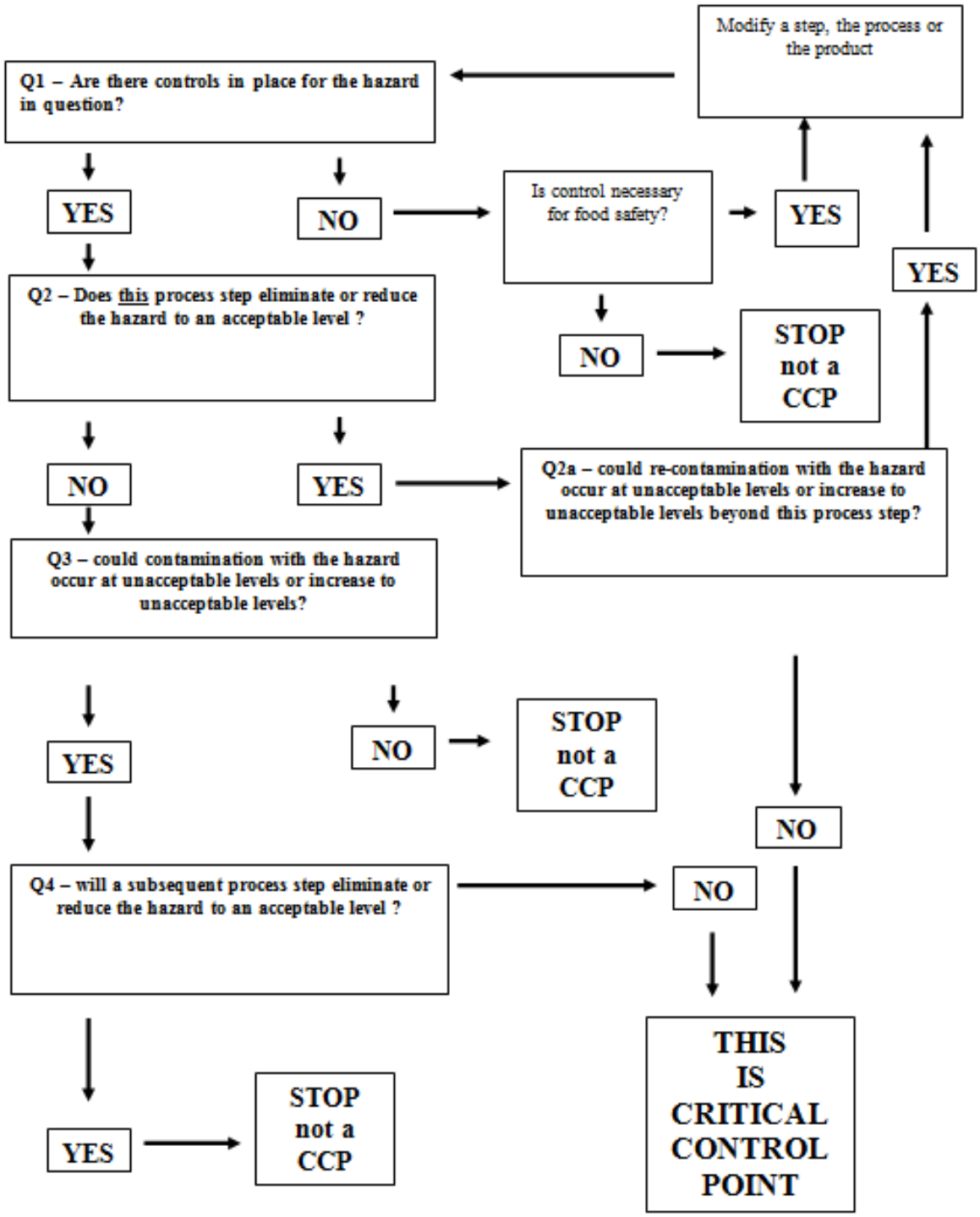
FORM 2-H FOOD ALLERGEN CONTROLS

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Allergen Control Step	Hazard(s)	Criterion	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records

Annex 3. Codex HACCP CCP Decision Tree



Annex 4. Hazard Analysis Template & Example

FORM 2-B HAZARD ANALYSIS*

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step B = biological C = chemical, including radiological P = physical	(3) Are any potential food safety hazards requiring preventive control? (Yes/No)	(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supplier, other preventive control*	(6) Is the preventive control applied at this step? (Yes/No)

* The current FSPCA form includes some additional features, such as a separate column for "Yes" and "No" responses and a separate row at each step for biological, chemical, and physical hazards (labeled B, C, and P, respectively).

Example – Completed Form 2-B (Next Page)

Hazard Analysis – FOR EXAMPLE ONLY

Ingredient (only group like ingredients that have the exact same hazards)	**Type of Hazard**	Food safety **hazard** that may be introduced by this material	**Severity**	**Likelihood**	**Resulting Risk Level**	Does this hazard **require a preventive control**? (Yes/No) If yes, is the control with supplier or receiving plant?	**Justification** for this decision	What **preventive control measures** and/or CCPs can be applied to significantly minimize or prevent the food safety hazard?
Skim Milk Powder	B							
	C							
	P							
Untreated black peppercorns	B	Infectious pathogens i.e., *Salmonella* potential to be associated with untreated material	High 3	Medium 2	6	Yes; receiving plant	Potential to occur based on industry recalls, FDA retail surveys and import alerts	Steam treatment inactivation step
	C	Pesticides	Low 1	Low 1	1	No	Unlikely to occur due to GAP practices and periodic surveillance by approved suppliers	N/A
	P	Foreign matter i.e., metal, stones	Medium 2	Low 1	2	No	Unlikely to occur based on approved supplier controls of cleaning and metal detection. Subsequent process step of metal detection along with in-line magnets and sifter at receiving plant also help to minimize risk.	

Processing Step (include step # from flow diagram)	**Type of Hazard**	Food safety **hazard** that may be introduced, controlled, or enhanced at this step	**Severity**	**Likelihood**	**Resulting Risk Level** (S^L)	Does this hazard **require a preventive control**? (Yes/No)	**Justification** for this decision	What **preventive control measures** and/or CCPs can be applied to significantly minimize or prevent the food safety hazard?	Is the preventive control **applied at this step**? (Yes/No)
#2 Stream Treatment	B	Infectious pathogens i.e., *Salmonella* potential to be associated with untreated material	High 3	Medium 2	6	Yes	Potential to occur based on industry recalls, FDA retail surveys and import alerts	Steam treatment is process preventive control/CCP	Yes
	C	None							
	P	None							
#4 Milling	B	Infectious pathogens i.e., *Salmonella* potential from environmental cross contamination since produce is exposed to processing environment	High 3	Medium 2	6	Yes	Potential to occur on industry events, untreated material handling within the facility, and past plant EMP findings	Sanitation with EMP verification	Yes
	C	None							
	P	Metal, potential from equipment	Medium 2	Medium 2	4	Yes	Has been known to occur on occasion based on plant experience	Metal detection (supplemented with in line magnets and sifter)	No
#7 Metal Detection	B	None							
	C	None							
	P	Metal, protection from equipment	Medium 2	Medium 2	4	Yes	Has been known to occur on occasion based on plant experience	Metal detection	Yes

Box 2-3. Example Hazard Analysis Work Sheet (Also see Form 2-B, Appendix 2)[2]

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step B = biological C = chemical, including radiological P = physical	(3) Are any potential food safety hazards requiring preventive control? (Yes/No)	(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supplier, other preventive control*	(6) Is the preventive control applied at this step? (Yes/No)

Annex 5. Controls Worksheets & Examples

Appendix 6-A: Summary Process Control Table for Baking; Cookie Processor A

FORM 2-C (Modified)[12] PROCESS CONTROLS

PAGE _____

PRODUCTS: Cookies baked in batches on trays in ovens and packaged by wrapping the cookies by twos in plastic
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

PROCESS CONTROL STEP: Baking
HAZARD(S): *Salmonella*

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[13]
Minimum oven temperature of 350°F (177°C) (operating limit is 352°F (178°C))	Temperature of oven	• Recording thermometer in oven • Manual check of recording chart and mark the recording with the batch number • Record temperature on baking record sheet	Continuous recording during each batch; manual check before putting cookies in oven	Baker	If oven was not at least 350°F (177°C): • Cookies will be diverted to cattle feed; and • Employees will be retrained on the importance of ensuring that the oven temperature has reached the set point.	• Annual calibration of thermometer • Records review by PCQI within one week of record creation (baking sheets, temperature recording chart, calibration logs) • Review of corrective action records within one week of a deviation	• Baking record sheets • Temperature recording charts • Calibration records • Corrective action records

FORM 2-C PROCESS CONTROLS

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Process Control Step	Hazard(s)	Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records

Example – Completed Form 2-C (Next Page)

Preventive Control Summary Sheet – FOR EXAMPLE ONLY
Product(s):
Process Line(s):
Plant Name:
Address:
Issue Date:
Supersedes:

Process / Step	Hazard(s) Controlled	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
#1 Steam Treatment	Infectious pathogens	Minimum xx°C for xx seconds (as determined by thermal process validation study)	Feed rate, auger rate, and fluid bed temperature	In-line recorder and thermocouples	Continuous	Line operator	If any critical limit is not met, place all produce on hold that may have been made outside critical limits. Regain control limits prior to making acceptable product. Reprocess on hold product as directed by QA. Conduct root cause investigation as appropriate.	Review process logs prior to product disposition. Weekly dwell time checks. Quarterly thermocouple calibration. Finished product microbiological testing.	Electronic Process Logs; Dwell Time Checks Log Sheet; Calibration Logs; Process Validation Study as reference
#3 Metal Detection	Metal	All product passed through working metal detector set to detect minimum sizes of Ferrous 1.0mm; Non-ferrous 1.5mm; and Stainless 2.0mm	Metal detector working and rejects test pieces	Check metal detector operating and run test pieces through aperture per SOP	Every 4 hours	Line operator	If metal detector not operating or any test piece is not rejected, place all product on hold since last good check. QA to determine action steps and disposition. Conduct root cause analysis.	Review metal detector log sheets. Quarterly metal detector calibration.	Metal Detector Log Sheet; Metal Detector Calibration Logs; Preventive Maintenance Records

FORM 2-D SANITATION CONTROLS

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Location	
Purpose	
Frequency	
Who	
Procedure	
Monitoring	
Corrections (Corrective actions where necessary)	
Records	

Verification: (signature or initials)_____

Date: _____

Form 2-I: Supply-chain-applied Preventive Controls Program

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Determination of Verification Procedures

Ingredient:

Hazards requiring a supply-chain-applied control	
Preventive controls applied by the supplier	
Verification activities	
Verification procedures	
Records	

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

Ingredient (requiring supply-chain-applied control)	**Approved Supplier**	**Hazard(s) requiring supply-chain-applied control**	**Date of Approval**	**Verification method**	**Verification records**

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

[Document procedures used for receiving ingredients requiring a supply-chain-applied control.]