Risk Assessment Considerations Guide

Preparing for the Food Safety Modernization Act (FSMA)
Food Safety Plan and Hazard Analysis and
Risk-Based Preventive Controls (HARPC) Development

THE AMERICAN SPICE TRADE ASSOCIATION

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Risk Identification – Introduction and Definitions

The Food Safety Modernization Act (FSMA) represents a significant shift in how the U.S. Food and Drug Administration (FDA) plans to approach food safety, with food companies tasked with greater responsibilities for prevention to ensure the safety of the food they import and produce. Under the Preventive Controls Rule, companies are required to develop and implement a Food Safety Plan. This guide focuses on a critical element of the overall food safety plan, the identification of risks.

The first step in beginning to assess and identify risks is to review **21 CFR 117.130 Hazard Analysis**:

(a) *Requirement for a hazard analysis.*

(1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control.
(2) The hazard analysis must be written regardless of its outcome.

(b) *Hazard identification.* The hazard identification must consider:

(1) Known or reasonably foreseeable hazards that include:
(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;
(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and
(iii) Physical hazards (such as stones, glass, and metal fragments); and

(2) Known or reasonably foreseeable hazards that may be present in the food for any of the following reasons:
(i) The hazard occurs naturally;
(ii) The hazard may be unintentionally introduced; or
(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c) *Hazard evaluation.*
(1)
(i) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.
(ii) The hazard evaluation required by paragraph (c)(1)(i) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

(2) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:
(i) The formulation of the food;
(ii) The condition, function, and design of the facility and equipment;
(iii) Raw materials and other ingredients;
(iv) Transportation practices;
(v) Manufacturing/processing procedures;

(vi) Packaging activities and labeling activities;
(vii) Storage and distribution;
(viii) Intended or reasonably foreseeable use;
(ix) Sanitation, including employee hygiene; and
(x) Any other relevant factors, such as the temporal (*e.g.,* weather-related) nature of some hazards (*e.g.,* levels of some natural toxins).

The CFR language is presented verbatim to clearly show how FDA has chosen to define risks, with more specific risk identification examples included in section (b) of 21 CFR 117.130. The hazard identification and analysis process is critical to understand FDA's expected standard, regardless of whether your company has already complied with a GFSI scheme or is looking at food safety for the first time.

Throughout all of the hazard evaluation components in 21 CFR 117.130c.2: i.-x., it is important to focus on risks specific to spices, spice extracts and seasonings. We have endeavored to make this guide as comprehensive as possible, however there may be additional risks that are unique to your company and your customers.

FSMA also requires all companies to have a Preventive Control Qualified Individual (PCQI) develop their Food Safety Plans and the training and/or experience of that individual is key to evaluating the hazards outlined in this guide.

Microbiological Risks

Microbiological risk, by its very definition, can be difficult to ascertain when preparing any risk assessment. The Microbiological realm is ubiquitous to any environment in low to high moisture, low to high temperatures and low to high levels of food sources. That alone makes this portion of the risk assessment difficult to measure and measure with consistency.

There are ways to identify potential risk from microbiological organisms and their effect on the supply chain. Bacteria and mold cause the most human illness through infection and toxins, making them the prominent focus of microbiological risk assessment. As FSMA is focused on organisms that are a health risk, companies throughout the supply chain, including growers, distributors, suppliers, and customers can keep a consistent focus with your company in how to approach the risk assessment. Identifying a pathogen of risk should be considered at all steps of the hazard analysis.

Viruses, parasites and other microbial types are more dependent upon water sources and human and/or animal interaction with product to determine additional risk. Risk assessments are more influenced on potential, rather than accidental contamination. Accidental contamination should be mitigated through Good Manufacturing Practices (GMPs), water quality testing and environmental monitoring, especially if your company is a manufacturer or processor of food or if there is an increased risk to factor in.

The sources of microorganisms need to be considered, including soil, water, animals and humans. All of these sources contribute to the overall risk by how often the product comes in contact with these sources at all stages of supply and manufacturing. Learn about how transient versus established microorganisms could affect your company's processes. Transient microorganisms are new to your environment and may have been brought into your environments from your supply chain, personnel and other sources. If the transient microorganisms continue to exist, they may form biofilms to protect their existence from normal sanitation practices and become established (within harborage) in your environment, increasing the risk of further product contamination.

Consider your microbial controls and ask these questions about your company's current state:

- What kind of controls does your company have in place to deal with the pathogens coming from the field or supply chain?
- Do your suppliers have adequate Good Agricultural Practices (GAPs) and/or GMPs?
- Are you using a validated microbial pathogen reduction process?
- What steps is your company taking to minimize microbiological contamination, post-processing?
- How is your company controlling accidental versus potential contamination?
- How does your company deal with transient versus established microorganisms?
- Does your company already have these existing programs?
    - Sanitation
    - Environmental Monitoring
    - Good Manufacturing Practices
        - Handwashing
        - Employee health policy
        - Trash and waste removal
        - Storage best practices
        - Maintenance on equipment best practices
        - Pest control
        - Hygienic zoning

All of these questions contribute to determining microbial risk factors that can help identify gaps, mitigation strategies and improvement opportunities both initially and as your company continues to implement FSMA.

Physical Risks

Physical risks must be considered across the supply chain and in your company's manufacturing operation. Physical risks are present at all stages from farm to table, and risk identification for physical risks can be fairly simple.

The most important risk to consider is how foreign material is controlled at all levels of manufacturing from receiving to distribution. Most common foreign material control programs use GMPs or GAPs to mitigate physical risks that include:

- Wood
- Ceramics
- Plastic
- Metal
- Stone
- Glass
- Filth (pest, dirt and pest droppings)
- Paint
- String, fibers, soft plastics
- Maintenance grease/lube

Chemical Risks

Chemical risks can be assessed and broken down into several categories:

- Unapproved food or color additives
- Mycotoxins
- Pesticides
- Pest control chemicals
- Fertilizers
- Illegal dyes
- Heavy metals
- Allergens
- Chemical sensitizers
- Sanitation chemicals
- Radiological – potential isotopes found in ingredients or raw agricultural products

The addition of radiological hazards to the chemical hazard and risk profiles poses other considerations for ingredient and product risks from countries that may have suffered nuclear fallout. Risk profiles for your company may indicate that the nuclear fallout may have affected the soil and/or the water supply. These then must be considered in your company's ingredient and product assessments.

There are a range of questions to be asked to help your company navigate chemical risks:

- Do your raw agricultural commodity suppliers utilize GAPs or audit their suppliers to see if they do?
- Do you import ingredients or RACs from a known nuclear fallout country?
- Does your company have adequate testing resources to ensure chemical risks from allergens, pesticides, mycotoxins and/or heavy metals are captured?
- Does your company use FDA-approved cleaners, sanitizers and/or boiler chemicals?

- Are your company's sanitation chemicals stored securely and access limited?
- Has your company identified any allergens, used or stored, and minimized allergen cross-contact potential?
- Does your company have an adequate plan to minimize allergen cross-contact on equipment and in processes?
- Does your company follow proper, applicable labeling laws and procedures that include allergens?

Resources to utilize in your risk assessment considerations:

American Spice Trade Association (ASTA) – www.astaspice.org

- Clean, Safe Spices, Guidance Document http://www.astaspice.org/food-safety/clean-safe-spices-guidance-document/
- Good Manufacturing Practices Guide for Spices http://www.astaspice.org/food-safety/good-manufacturing-practice-gmp-guidelines-for-spices/
- HACCP Guide for Seasonings and Spices http://www.astaspice.org/food-safety/haccp-guide-to-spices-and-seasonings/
- Good Agricultural Practices for Spices http://www.astaspice.org/food-safety/good-agricultural-practices-guide-gap-guide/
- ASTA FSMA Decision Tree http://www.astaspice.org/government-relations-advocacy/complying-with-u-s-policy-regulations/asta-fsma-decision-tree/

Food and Drug Administration (FDA) – www.fda.gov

- FSMA 21 part 117 (GMPs) – https://www.federalregister.gov/articles/2015/09/17/2015-21920/current-good-manufacturing-practice-hazard-analysis-and-risk-based-preventive-controls-for-human#h-426
- Bad Bug Book – http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/

Farm and Field Risk Awareness

Farm and field risk awareness can be complicated to manage and assess without first knowing the full chain of supply from your company back to the farm of origin. Once your company establishes the supply chain through the distributor, supplier and farm connections, this ASTA Risk Assessment Considerations Guide can help your company align the farms and fields to minimize and assess risk and enhance food safety. This alignment is done through General Agricultural Practices (GAP). GAPs are developed specifically to assist in prevention of food safety and quality issues at the farm and next level processing/distribution of farm grown spices.

The original Good Agricultural Practices Guide was developed as a joint project by members of the International Organization of Spice Trade Associations (IOSTA). The ASTA Guide is based on that document, updated in 2016 to reflect U.S. regulations and issues specific to exporting to the U.S. The GAP Guide is available on the ASTA website at http://www.astaspice.org/food-safety/good-agricultural-practices-guide-gap-guide/.

Supplier Risks

It is critical that your suppliers understand your company's vision for food safety and meet the food safety standards you establish. This section provides guidance and a sample of key questions to ask when evaluating suppliers and to determine if they are adequately addressing potential risks to support the safe production of your raw materials. Open-ended questions will provide more details on their programs and procedures. Creating and maintaining a vendor approval program will help monitor risks on an on-going basis beyond the initial assessment. Companies often receive materials through a global supply chain. It is important to confirm different country or region specific regulations and requirements and whether they meet your specific country/region requirements as well. The FSMA Foreign Supplier Verification Program (FSVP) requires that importers perform certain risk-based activities to verify that food imported into the U. S. has been produced in a manner that meets U.S. safety standards.

Farm/Growing Region

Suppliers who provide raw agricultural commodities need to ensure risks are addressed during growing and harvesting. These first steps are critical to control to reduce hazards further downstream. Suppliers must understand and manage risk back to the farm. Some questions to consider:

- How does the supplier control material adulteration or fraud?
- How does the supplier control/monitor heavy metals?
- How does the supplier prevent cross contamination between their crops?
- What pesticides are used and how does the supplier control usage?
- How does the supplier ensure a safe water supply for use on the raw commodities?

Inbound receipt

The first point to control risk from entering a facility is at receipt. An adequate receiving process will control materials as they come in and prevent entry of non-conforming materials. Proper storage is also important in controlling material integrity. Some questions to consider:

- Does the supplier have an inspection program to ensure vehicles are received in sanitary condition?
- How does the supplier confirm the received materials meet specification?
- What controls exist for the receipt of bulk raw materials?
- How does the supplier ensure temperature sensitive materials are received and stored appropriately?
- How does the supplier control the separation of food, packaging and non-food related materials into the facility?

Cleaning and Sanitation

Cleaning programs ensure the facility and equipment is maintained to sanitary standards. Cleaning programs help control microbial growth, pest activity, and prevent allergen contamination. Questions to consider:

- Is there a master sanitation schedule to address cleaning frequency for all areas of the production facility or warehouse facility? Is schedule being followed?
- Are Sanitation Standard Operation Procedures (SSOPs) created for all areas of the facility and equipment?
- Does processing equipment meet a sanitary design standard; can equipment be cleaned effectively?
- Are the cleaning chemicals appropriate for use in the production facility? Are safety Data Sheets (SDS) sheets available?
- Are cleaning chemicals and supply are adequately stored/controlled to prevent contamination of food or packaging?
- Does the supplier use any Clean-in-Place (CIP) processes for cleaning/sanitation? How is the CIP process monitored?
- Does the supplier have Pre-op documentation to confirm lines/areas are ready for production after cleaning or Preventive Maintenance (PM) work?

Pest Control

Adequate pest control programs can support other prerequisites in preventing rodent, insect or other activity within and around the facility. Mismanagement of the program can lead to pest infestation in the facility and products. Some questions to consider:

- Is pest control managed internally or from a 3rd party pest control service?
- Is the program up-to-date with maps, inspections and treatments?
- If a 3rd party service is used:
    - Are the pest control operators licensed?
    - What is the level of frequency of service?
    - How are chemicals, treatments and bait controlled?

Allergen Controls

Allergen controls are necessary to prevent cross contamination in receiving, storage and through production. Questions to consider:

- Has the supplier identified what allergens are used in their facility?
- What controls exist during the receiving process?
- How are materials with allergens controlled in storage?
- Does the facility have separation controls in the warehouse or segregated production lines?
- Is there a cleaning changeover program when producing products with allergens to products without allergens?

Microbiological controls

Suppliers must have programs in place to address biological hazards in their facility. Control of microorganisms, particularly pathogens is critical to produce food safe product. Some questions to consider:

- Does the supplier produce Ready-to-Eat (RTE) or Non-RTE products? If both, what controls are used to prevent contamination between RTE and Non-RTE lines, materials or products?
- Are any materials or products subject to a validated pathogen reduction process? Where these processes exist:
    - Are there designated areas/barriers between pre- and post-treatment?
    - Is there control of pre- and post-treatments areas?
    - Is the pathogen reduction process validated?
    - Are there designated equipment/lines?
    - Are there special Personal Protective Equipment (PPE) requirements?
    - Is the pathogen reduction process acceptable for your use (e.g. Ethylene Oxide)?
- Are there any finished product testing programs? Is there a positive release system?
- Is there an environmental monitoring program? What are the target organisms?
- How are product or environmental samples pulled and maintained?
    - Is sample size appropriate based on lethality step or intended use?
    - Are samples tested internally or sent to 3rd party lab?
    - If on-site lab is used, what controls exist to prevent contamination from the lab?

HARPC/HACCP/Food Safety Plans

HARPC, HACCP (GFSI required), or Food Safety plans are critical to ensure your suppliers are addressing risk to prevent potential hazards in their process. These plans are built on the established pre-requisite programs that must also be in place to ensure the plan is effective. Some questions to consider:

- Does the supplier have the pre-requisite programs needed to support a HACCP or food safety plan?
- Does the supplier have a documented HACCP or Food Safety Plan? Is there evidence of compliance?
- Does the supplier have a document flow chart associated with each line/product group?
- Does the supplier clarify their Control Points (CPs), Critical Control Points (CCPs), Prerequisite Programs (PRPs), or Operating or Operational Prerequisite Programs (OPRPs)? What are the controls?
- Does the supplier have HACCP/Food Safety plan training records for all employees?

Process Control

A supplier's process control programs ensure the process meets established expectations. Lack of control can lead to mis-formulations, product contamination or mis-labeled product. It is

critical that your suppliers have adequate process controls to address food safety risks. Some questions to consider:

- How does the supplier confirm correct ingredients are used in production?
- How does the supplier confirm correct weight of ingredients used in production?
- How does the supplier confirm packaging material and labels have the correct information?
- How does the supplier confirm the correct packaging material and labels are used in production?
- How does the supplier manage product claims (e.g. Non-GMO, Gluten Free, Organic)?
- What type of tamper evidence does the supplier use to confirm finished product integrity?
- How does the supplier confirm weight of in-process or finished good products?
- How does the supplier manage non-conforming product to ensure no inadvertent use or shipment?
- How does the supplier manage material or product rework?
- How does the supplier ensure traceability of materials, in-process and finished goods to their customer?
- Where are the open product zones that could lead to introduction of foreign material?
- What preventative controls exist around open product zones?
- What type of foreign material detection controls are used in process?
- Does the supplier have a detection equipment calibration program?

Shipping/Transportation

Shipment of goods is the last point where the supplier has control of their materials or products. All goods need to be shipped in a sanitary and secure manner. Questions to consider:

- Does the supplier have a vehicle inspection procedure for out-bound loads?
- How does the supplier ensure that each load is secure?
- Does the supplier provide a Certificate of Analysis (COA) with each load to show conformance to specification?
- How does the supplier control and ensure proper temperatures are maintained through the entire shipment process?

Processing Risk Evaluation and Outsourced Processing Risks

Your company's manufacturing processes and processing of your products, whether in-house or outsourced, needs to be evaluated in a risk assessment. This processing risk evaluation takes a complete look at the risks presented from current processes used and also from co-manufacturing or co-packaging with other companies. Most of this evaluation can be done directly through using the ASTA HACCP Guide for Spices and Seasonings available on the ASTA website at http://www.astaspice.org/food-safety/haccp-guide-to-spices-and-seasonings/.

By following this guide and creating a HACCP plan, and/or a HARPC plan for FDA audits, your company can utilize the risks presented from the evaluation to consider in your company's overall risk assessment. Conversely, this risk assessment guide can help to identify risks to be considered in your company's HACCP or HARPC plan. The risk assessment can also help your company prepare standards, monitoring, validation and verification for your company's co-manufacturing and co-packing suppliers to further assure no additional risks are presented or have to be dealt with in your company's HACCP or HARPC plan(s).

You can ask the following questions about the product/process in general:

- Are any returned/reworked products used as ingredients? If so, could they cause a hazard?
- Are preservatives or additives used in the product formulation to kill or inhibit the growth of microorganisms?
- Does the amount and type of acid ingredients, and the resulting product pH, affect the growth/survival of microorganisms?
- Does the water activity of the finished product affect microbial growth?
- Should refrigeration be maintained for products during transit or in storage?
- Are any chemical or physical hazards associated with any packaging materials?

For Co-Packers and Co-Manufacturers:

- Are potential hazards known from any ingredients or primary packaging directly supplied by a contracted customer?
- Are HACCP/HARPC plan(s) available from the Co-Packer and/or Co-Manufacturer to show they have a Quality Management System and hazard control in place?

Fully describe the hazards identified and assess the significance of the hazard based on available scientific and technical literature. This information can be obtained through public libraries, universities, trade associations, in-plant expertise, and/or extension services. This will help you assess the risk, severity, and significance of the hazards identified.

Review and evaluate the actual operating practices in your manufacturing flows. After describing the hazards you've identified with each step, you should:

- Observe the actual operation in your establishment and be sure that it is the usual process or practice.
- Observe employee practices where raw or contaminated product could cross-contaminate workers' hands, gloves or equipment used for finished/post-process products.
- Observe product handling following any microbiological reduction process for potential cross contamination. This includes studying traffic patterns of raw ingredients, finished products and employees within the establishment. Hygienic Zoning is a good plan to create, implement and follow for product handling.
- Review any past incidents of physical, biological, or chemical contamination that have occurred to determine the frequency, significance, and nature of the occurrence(s).

Packaging Risks

Food packaging was not typically considered as a major risk due to the low water activity of the packaging material. However, that changed as food safety related packaging issues emerged, and packaging is now given the same hazard assessment as food. It is now a requirement by GFSI schemes and global food safety standards that packaging is to be evaluated in the HACCP plans. All packaging suppliers must also undergo an approval process like that for raw material/ and ingredient suppliers.

The following criteria need to be considered for the approval of packaging manufacturers:

- Allergen contamination
- Foreign body risks
- Microbiological contamination
- Chemical contamination
- Full traceability

The following issues are critical for consideration of packaging to ensure product safety:

- Purchase of packaging which use staples or other foreign-body hazards as part of the packaging materials shall be avoided.
- Food grade certificates shall be available.
- Foreign body contamination originating with the packaging container, e.g. jars, cans, shall be assessed.
- Manufacturing company of packaging shall have a glass and brittle plastic policy other than the product to prevent possible contamination.
- Chemical contamination risks shall be taken into account (e.g. taint, odor, allergen, component transfer from inks and glues).
- Potential problems arising from the use of recycled materials need to be analyzed.
- The potential for unintended migration of substances from the packaging material into food must be noted.
- Packaging materials shall be stored away from food ingredients.
- Pests are usually an issue that are transported with packaging materials. It is important for the supplier to have a proper and effective pest control management.
- If wooden pallets are used for the transfer of packaging materials, they shall be in good condition, dry, clean, and free from damage and contamination.
- When purchasing primary packaging (food contact), the supplier shall be made aware of any particular characteristics of the food, e.g. high fat content, which may affect packaging suitability.
- Liners and bags for use in direct contact with ingredients shall be colored and resistant to tearing to prevent possible contamination.
- When packing raw materials, many suppliers use jute bags. These shall also be of good material, and splits/strips shall be avoided.

Food Fraud Risk

Economically Motivated Adulteration and Unintentional/Cross-contamination

The risk management assessment needs to consider Economically Motivated Adulteration (EMA). There should be a system in place to monitor changing variables that can have an influence on the ever changing risks that can contribute to EMA.

This list of examples is not exhaustive, however, it provides examples of when EMA has been a problem for the spice industry in the past:

- Raw material prices have increased significantly making them prone to bulking with cheaper materials.
- Buyers may push for cheaper prices of raw material or raw spice, putting pressure on the industry to get "creative" in offering low price "solutions"
- Source country has had a natural disaster (e.g. adverse weather, political unrest, earthquake, nuclear catastrophe) which could have an effect on the product availability or availability for the usual production cost.
- There has been a crop failure which may not only drive up prices, but could also introduce alternative materials to help extend the crop to meet world demand.
- The product has an unusual appearance, which could indicate the inclusion of a color or the treatment with an oil or chemical to boost the appearance.

Risks should be considered for unintentional adulteration as well, provided that the prerequisite or preventive control programs are in place to minimize:

- Allergen cross-contact
- Employees working in raw processing areas (low risk) versus finished goods areas (high risk) and minimizing movement of pedestrian flows from low risk to high risk areas
- Foreign material movement from low risk to high risk areas

Some ways to help minimize the risk or programs to develop are:

- Sanitation programs to ensure equipment is clean
- Master Sanitation Schedules (MSS) as a part of sanitation frequency based on risk
- Hygienic Zoning of Processing Areas – Process Mapping and traffic patterns

Information on adulteration is detailed on the ASTA website at http://www.astaspice.org/food-safety/adulteration-and-food-fraud/. Identification and Prevention of Adulteration Guidance is now available to assist companies in understanding the motivation behind adulteration and the potential vulnerabilities in the supply chain where adulteration can occur. This document is also available on the ASTA website at http://www.astaspice.org/food-safety/identification-prevention-adulteration-guidance-document/.

Post-Processing Storage/Distribution Risks

Supply chains in the spice industry are often complex and products are typically shipped long distances. This makes mapping the distribution network and maintaining a handle on traceability more essential for retailers and manufacturers.

In practice the typical distribution network consists of a number of fixed locations (storage facilities) with the distribution between locations carried out either by a company's own transportation or very often by subcontracted vehicles. Distributors range from major distribution groups to single driver operator businesses.

It is essential to determine the risks and threats associated with the storage and distribution to complete the overall process of hazard analyses in the food chain.

Prerequisites to assess associated with storage and distribution include:

- Condition and maintenance of buildings, equipment and transport vehicles as appropriate
- Documented practices for the safe handling, storage and transport of products
- Procedures for handling damages, waste product and returns
- Pest control procedures
- Sanitation procedures (cleaning and disinfection)
- Maintenance of the cold chain (not applicable to ambient stable products)
- Personal hygiene (limited applicability to pre-packed food products or consumer products)
- Training.

The scope shall (*) cover:

- The types of products stored or distributed and any particular specified storage or handling conditions; for example, temperature control, maximum stacking height, conditions of light
- The product flow from receipt, storage and dispatch transport to the recipient of the product. This shall include any cross-docking or intermediate storage steps that may be used in the distribution and any returns activities.

(*) "shall" is the terminology used in most GFSI standards and shows that it is a requirement. The term "may" is used when it is a recommendation and not a requirement

Potential hazards associated with each step include:

- Microbiological growth resulting from temperature abuse of products that require temperature control
- Physical contamination, e.g. glass contamination from broken lights, wood splinters from pallets.
- Chemical contamination, e.g. product tainting spillage, cleaning chemicals
- Physical damage, e.g. breakage, puncturing of packaging, water damage
- Allergens via cross-contamination

A likelihood/severity analysis indicated in the HACCP sample plans shall be performed for each potential hazard.

Location Standards and GMPs

The following are critical for the safe storage and distribution of products:

- Walls, floors, ceilings and pipe work shall be clean and maintained in good condition
- Floors shall be impervious and maintained in good repair.
- Drainage shall be adequate.
- All water supplies used for cleaning shall be potable.
- Adequate lighting to be provided for effective inspection of product and cleaning. Lights shall be shatterproof.
- If glass windows are present, they shall be protected against breakage.
- Proper pest-control shall be carried out.
- All doors shall be close fitting and proofed against pest entry.
- External storage shall be minimized and products protected from contamination and deterioration.
- Site security shall be taken into account and necessary precautions taken.
- Adequate segregation is important to effectively isolate the products to minimize the risk of cross-contamination.
- Battery charging areas shall be well ventilated.
- Cleaning chemicals shall be stored in a secure location.
- Cleaning facilities shall be separated from product handling and storage.
- Where products are subject to weather damage, vehicles shall be loaded and unloaded in covered bays.
- Suitable hand-wash facilities shall be provided and easily accessible to staff.
- Facilities shall be provided for the safe storage of personal items so such items are not taken into storage areas.
- Where products are repacked onto pallets for storage or further distribution, packing configuration shall prevent the risk of damage. Band wrapping is recommended.
- Products shall be stored off the floor either on pallets or racking.
- If wood pallets are used, slip-sheets shall be used prior to loading.
- Environmental monitoring shall be done based on risk.
- If temperature control is required, an automatic alarm system shall be used.

- All spillages and breakages that pose risk to the product shall be recorded.
- Where allergens are stored or transported, risk of cross-contamination shall be assessed. Dedicated storage areas are recommended for allergens.
- Staff shall be adequately trained and competencies tested. They shall be made aware of the hygiene standards that include the clothes, jewelry, smoking, eating, drinking, hand-cleaning, and reporting of sickness.

The Role of Vehicles and Loading Docks in the Safe Transport and Distribution of Products
The following shall be taken into account:

- The area for loading/unloading shall be kept clean and in suitable condition to prevent rain damage.
- Load support, load lock strips and fastenings shall be in good condition, as well as rear door shutter and tall lifts if used.
- Access to all vehicles shall be restricted to authorized staff.
- Procedures for vehicle security shall be documented and understood by the drivers.
- Where vehicle load areas are fully enclosed, doors shall be locked when not loading/unloading. Where seals are used, these shall be checked for integrity before unloading.
- Vehicle maintenance shall be in place to prevent breakdown. In case of a breakdown or accident, procedures shall ensure that product safety and quality is maintained. This will include: clear instructions and emergency contact numbers for the drivers; instructions on how to preserve any specific temperature or other controls specific to the load, and checks required to be made on the load before commencing.
- For temperature-controlled vehicles, the temperature range shall be specified and automatic temperature and time-recording equipment shall be used to monitor and record the data.

Other equipment in the storage areas that may have an effect on food safety include:

- Roll cages, pallet lifts, forklift trucks shall be maintained in good condition
- If racks are present in the warehouse, they shall be adequately maintained and inspected for damage and cleanliness.
- All diesel-powered handling equipment shall incorporate an exhaust filter system to prevent contamination to the products.
- Condition of wooden pallets shall be checked regularly to prevent the risk of contamination.
- Knives and other tools shall be controlled. Snap-off blades are forbidden.

Waste as a contamination factor in storage areas

- Accumulation of waste shall be prevented.
- External waste shall be emptied regularly and top closed.

Validation/Verification Activities of Risk Assessments

Validation and verification activities of your company's risk assessments provide feedback to evaluate how well your company's assessment of risk/hazard lines up to the expected standards.

Definitions:
Validation – the process to prove that the risk assessment and risk management work as intended, on an ongoing basis and provide feedback to your company's development of the hazard analysis per FSMA 21 CFR 117.130 by identifying any initial gaps in the assessments.

Verification – the process to prove that the risk assessment and risk management is still working as intended and provide feedback to your company's compliance with the hazard analysis per FSMA 21 CFR 117.130 by identifying any continuous improvement needed for your company's assessments or gaps that may have occurred as a result of changes in risks through suppliers, processes or regulations.

Validation and Verification are a good steps to ensure your company has considered all risks outlined in this guidance and can ensure they are covered in your company's Food Safety Plan.

Validation

Validation helps ensure the risks identified have been thoroughly examined for the hazards that can be controlled, utilizing customer, company, or supplier control. Scientific studies and data generation help to provide justification to the level of risk your company can handle and what your company may require from its suppliers and its customers. The justification of standards of whether or not to do a validation should also be proven by scientific studies and/or historically generated data.

Verification

Verification within the Food Safety Plan is mandated in 21 CFR 117.126 *Food Safety Plan* but is different from the verification for risk assessments and risk management.

Verification for risk assessments means that your company is constantly and consistently reviewing risks identified through the hazard analysis and other risks that may come from within the company as the company deals with process changes, new formulations, new suppliers, new risks identified from suppliers, new risks with supplier or own recalls, and many other possibilities outlined in this guidance.

Verification of risks also helps your company to ensure compliance and puts your company's resources to best use. Risk assessments can help determine the frequency of verification to help align your company's internal audits. Self-audits or internal audits can help to continue verification, not just for your risk assessments but also for your Food Safety Plan.
Internal audits are a good continuous improvement tool that provide instant feedback on a regular basis and keep your company prepared for FSMA compliance.

Risk Assessment Flowchart and Roadmap

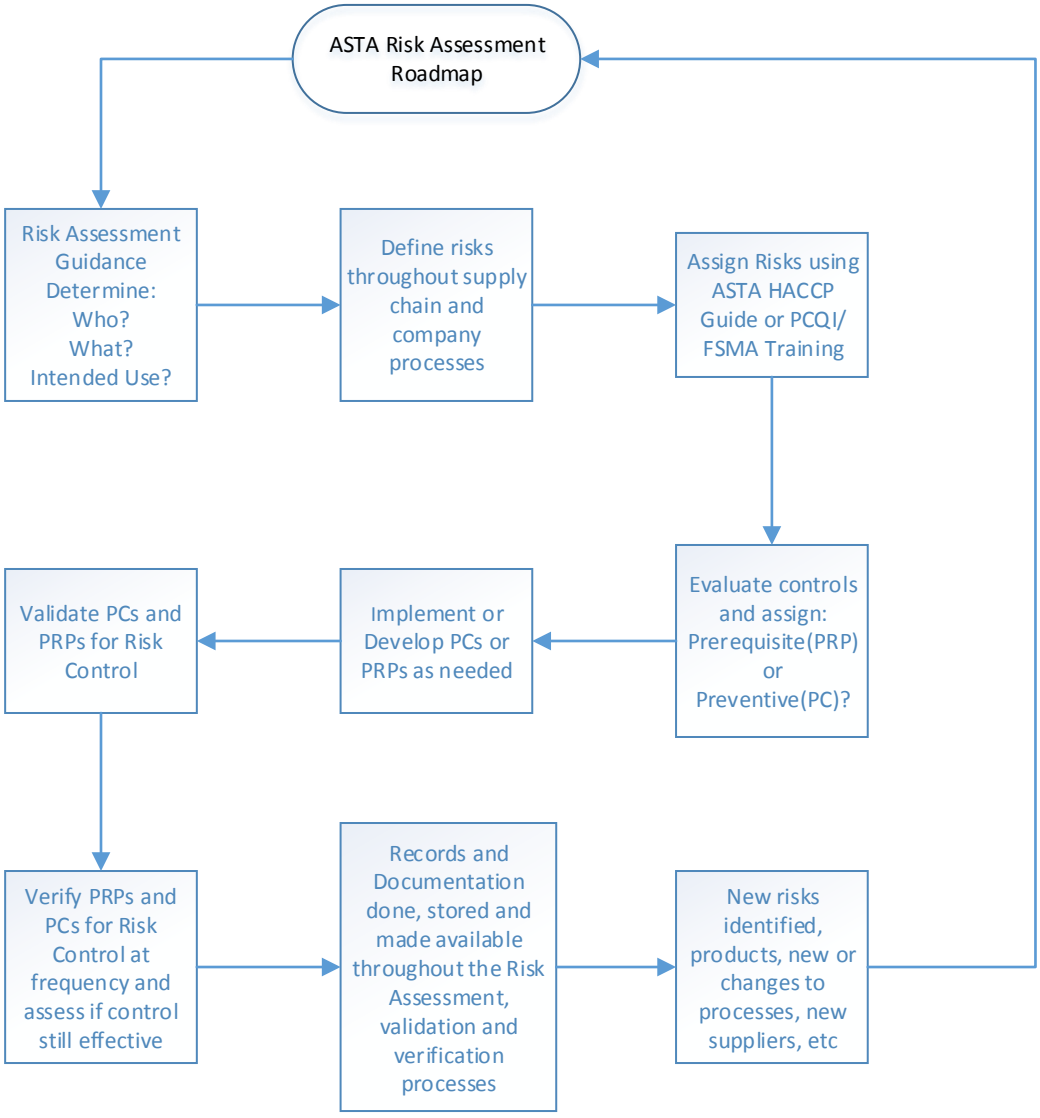
This section of the guide aims to provide a general roadmap to assist with your company's journey of risk assessment considerations. It is always helpful to set a map or an outline for how to reach the destination: Prepared risk assessments for your HACCP/HARPC/GFSI hazard analysis and food safety plans.

This roadmap intends to serve three scenarios for companies

- new to FSMA or HACCP/HARPC hazard analysis work;
- introducing new equipment to their processes or new processes; of
- introducing new suppliers to their supply chain and supplier quality programs.

In other instances, your company may benefit from a fresh look at this guidance and practical application where risk assessment considerations are needed. The roadmap is first presented in written format:

1. Using this Guide, determine three things:
    a. **Who?** Who needs appropriate training (PCQI or Practitioner) to assess risk?
    b. **What?** What risk levels or priorities need to be assessed depending on your products?
    c. **Intended Use?** What is the intended use of your products used in the supply chain or for consumer use (Ready-to-Eat)?
2. Define risks
    a. Identify the risks throughout the supply chain and in your company's processes
3. Assign risk – low, medium or high
    a. Use the ASTA HACCP Guide or,
    b. Use the HARPC and PCQI training
4. Evaluate controls for the risks identified and assigned
    a. What policies and procedures are in place to control the assigned risk?
    b. Are the current standards and controls adequate?
    c. Will your company consider this risk a CCP as a risk needing a Preventive Control (PC) or Prerequisite Program (PRP)?
5. Implement or develop Preventive Controls or Prerequisite Programs as needed
6. Validate PC/PRP for risk control
    a. Do the policies and/or procedures work?
    b. Document validation performed
    c. Will PRPs or preventive controls need a revalidation? If so, at what frequency?
7. Verify Controls
    a. Verify records of controls and preventive controls
    b. Were the risks reassessed at a determined frequency?
    c. Do the policies and/or procedures still work? Are they still effective?
8. Records and Documentation throughout
    a. Document risk assessments and compile validations
    b. Records made available for audit by internal, customer, regulatory or third-party
    c. Records kept a minimum of two (2) years


ASTA Risk Assessment Roadmap
Risk Assessment Guidance Determine: Who? What? Intended Use?
Define risks throughout supply chain and company processes
Assign Risks using ASTA HACCP Guide or PCQI/ FSMA Training
Evaluate controls and assign: Prerequisite(PRP) or Preventive(PC)?
Implement or Develop PCs or PRPs as needed
Validate PCs and PRPs for Risk Control
Verify PRPs and PCs for Risk Control at frequency and assess if control still effective
Records and Documentation done, stored and made available throughout the Risk Assessment, validation and verification processes
New risks identified, products, new or changes to processes, new suppliers, etc