GOOD MANUFACTURING PRACTICES (GMP)

GUIDE FOR SPICES

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I. Introduction

Spices are dried plant products used to enhance the flavor of foods. Their safety and wholesomeness are of utmost importance to the spice industry, food industry customers, consumers, and regulators. As with any agricultural product, safety, quality, and consistency of a spice product can be impacted by one or all of the many steps it undergoes between the farm and table. The American Spice Trade Association (ASTA) has sponsored many programs to assist its members in assuring that spices are safe and meet regulatory requirements. Globally, there are numerous regulations, guidelines, standards, and specifications providing a framework and guardrails for the safe and hygienic production of foods including spices, including the current Good Manufacturing Practices (GMPs) published by the U.S. Food and Drug Administration (FDA) under 21 Code of Federal Regulations Part 117, which was updated as part of the FDA Food Safety Modernization Act (FSMA). This ASTA guidance document is designed to complement this regulation as well as build upon proven spice industry practices.

II. Purpose and Scope

The goal of this document is to provide the spice industry with a tool to highlight and focus on GMPs critical for the safe production of spices. This guidance is heavily based upon the U.S. GMPs; however, the food safety and hygiene principles apply globally. For U.S. processors and importers, it is also important to understand the definition of adulteration as laid out in the Federal Food, Drug, and Cosmetic Act to aid compliance. As provided by 21 USC § 342, a food may be deemed adulterated for reasons that include if it:

- Has been manufactured under such conditions that it is unfit for food; or
- Has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

Although each section focuses on a particular area or process within the manufacturing environment, the specifics should not obscure the core principles on which GMPs are based. These core principles are:

- Hygienic facility design
- Hygienic equipment design
- Thorough documentation that includes procedures, forms, and manuals
- Process validation where required
- Preventive and/or prescriptive maintenance program
- Corrective and preventive actions
- Quality assurance (QA)/quality control (QC) verification testing
- Inventory control or product positive release programs
- Traceability
- Management of incidents and product recall
- Employee training and qualifications
- Sanitation programs
- Waste and by-product management
- Pest control
- Chemical and physical product contamination control

- Dispatch and transport
- Allergen management
- Product packaging and labeling
- Personal hygiene
- Internal audits for hygiene, food safety, and quality

Members of the spice trade are encouraged to use this document together with the regulations and other references to develop and implement programs that assure the spices they sell meet the highest internal, regulatory, and consumer standards. As such, ASTA recommends that all members, their suppliers, and employees adhere to the following GMPs relevant to their operations as part of their overall food safety program. Please share this guidance document as appropriate.

III. Hygienic Design Standards

Hygienic design and construction of food processing facilities are essential for producing safe and wholesome food.

Grounds

A. The grounds around the facility shall be properly designed, landscaped, and maintained to minimize the presence of contaminants that could find passage into the facility.

    1. Avoid or closely control areas that can become pest harborage sites (e.g., overgrown groundcover, plants that attract birds, and equipment storage areas). For example, no uncovered or unsealed pipes or other equipment should be present.

    2. Ensure that grounds, driveways, parking lots, and dock areas are properly sloped for drainage and maintained to avoid standing water and collection points.

    3. Use dust control methods where dirt roads are in use near manufacturing areas.

    4. Provide transition areas with appropriate hygienic measures (e.g., floor mats, brushes, alcohol sprays, sanitizer granules) at all entry points to minimize tracking contaminants into the facility.

B. Assess the impact of surrounding properties (that may be under separate ownership) on potential contaminants and address as appropriate.

Facility

A. General

    1. Floors, walls, and ceilings of a food manufacturing facility shall be designed and constructed so that it can be adequately cleaned and maintained.

2. Give consideration to overhead pipes and structures to minimize the risk of drippage, condensation, or fall-out that could contaminate the product stream.

3. Ensure facility buildings and structures are of suitable size, construction, and design to provide adequate, unobstructed space to facilitate maintenance and sanitary operations for food manufacturing purposes and to minimize risk of cross contamination or allergen cross contact.

4. Ceilings and walls should be constructed of smooth, non-porous, and easily cleanable material.

5. Construct floors that are smooth and easy to clean. Floors should be sloped toward drains and away from walls and other equipment junctions.

6. Building doors for both personnel and forklifts should be effectively protected with air curtains or by other effective means to preclude pests and contaminates. All outside opening doors should be self-closing, tight fitting, and maintained in good repair.

7. Seal all openings in ceilings and walls where pipes or equipment pass.

8. Install hygienic drains with appropriate S or P traps to prevent back-flow and easily cleanable strainers and drain covers.

9. Wherever possible, any horizontal surface should be angled for easy cleaning and to avoid creating collection points.

10. The facility roof should be easily accessible to maintenance, security, and inspectors but not for non-authorized personnel.

11. Provide adequate lighting using shatter-resistant light bulbs and easily cleanable fixtures in employee welfare areas and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned. Skylights and windows shall also be shatter resistant. 21 CFR § 117.20(b)(5).

B. Designing for Hygienic Zoning

1. Facility construction and layout should be such that exposed product is adequately separated and protected from any operations that could cause contamination.

2. The facility should be mapped to denote areas of differing risk and hygienic requirements to allow design of optimal traffic flows, air handling systems, drain locations and flow. This would also include locating transition areas for hygienic action steps (e.g., handwashing, shoe sanitizing, smock changes) required for movement between zones of differing

hygienic levels.

2.1 Hygienic zones may be characterized in various ways. However, the food industry often recognizes the following designations:

i) "High Hygiene" or "Primary Pathogen Control Areas" or "Ready To Eat (RTE) Areas" – where there is exposed RTE product (post-kill step).

a. Examples include treated spice milling, sifting, or packaging rooms.

ii) "Medium Hygiene" or "Basic GMP" or "Non-RTE (NRTE) Areas."

a. Examples include raw material storage and processing (pre-kill step), sealed ingredient storage, and finished product warehouse.

iii) "Lower Hygiene" or "Non-Manufacturing Areas" or "Non-Product Areas."

a. Examples include maintenance shops and employee welfare areas.

3. During design, appropriate physical and/or spatial separation should be provided between NRTE and RTE ingredients and products. This would include air pressure differentials from high to low hygiene areas.

4. Ventilation

4.1 All ventilation systems shall be cleanable, properly functioning, and designed to prevent product contamination from condensation, mold, bacteria, insects, dust, odors, steam, or noxious fumes.

4.2 Locate and operate fans and other air-blowing equipment in a manner that minimizes risk to the product stream. 21 CFR § 117.20(b)(6). For example, motor fans should be mounted to blow air away from the product zone where possible. Floor fans should have filters on back grille to minimize foreign matter risks.

4.3 Provide adequate ventilation and air movement to minimize the formation of condensation in high humidity areas.

4.4 Ventilation fans in walls should be screened so that there is no insect ingress when fans are turned off.

4.5 Ventilation fans in roofs should be protected to prevent rain access and should not be located above any open processing or storage areas. If this is unavoidable, catch trays should be located below the vents and designed for easy access, cleaning and inspection.

4.6 All toilet facilities, locker rooms, labs, and chemical storage areas should be mechanically ventilated to the outside.

4.7 The processing facility should be under positive air pressure to prevent dust, flying insect entry, and cross-contamination from unfiltered air.

4.8 Screen and filter all incoming air for processing areas; air filters should be routinely inspected and replaced or cleaned. Use appropriate Minimum Efficiency Reporting Value (MERV) rated filters for the areas being serviced based on product risk. For example, processing rooms with exposed product may need higher MERV rated filters than might be used in a warehouse setting where the product is in its final packaging.

5. Warehouse/Storage

5.1 Provide protective coverings for dock doors and bulk unloading areas.

5.2 Dock doors should seal tight to dock plates. Install brushes around dock doors and plates to prevent pest entry.

5.3 Provide adequate spacing and racking to allow safe segregation of “QA hold”, potential non-conforming materials, and allergens from non or differing allergens. Design to optimize “first in, first out” procedures.

5.4 Provide interior perimeter space of at least 18 inches (often painted white) on which materials are not allowed to be positioned to facilitate cleaning, inspection, and pest control.

6. Employee Welfare

6.1 Each facility shall be equipped with adequate toilet and handwashing facilities which are convenient, easily cleanable, and maintained. Handwashing stations shall have running water at a suitable temperature.

6.2 Provide adequate and convenient hand washing and hand sanitizing stations in locker rooms, toilet facilities, entrances to work areas, high hygienic workstation areas, and at transition areas between lower to higher hygienic zones (e.g., when moving from raw to RTE areas).

6.3 Hand washing facilities should include:

i) A sufficient number of sinks/basins to accommodate personnel without delay, especially during shift changes.

ii) Liquid, non-scented soap dispensers and optional hand sanitizer dispensers.

iii) Warm water source – water temperature should be comfortable (not too cold not too hot) to encourage proper washing and rinsing time.

iv) Hands-free tap (e.g., knee- or elbow-operated) where possible.

v) Single-use paper towels or other drying devices, not cloth rolls.

vi) A foot-operated waste bin where paper towels are used.

6.4 Construct toilet doors to be self-closing and not open into food processing, except where alternate means have been taken to protect against contamination (e.g., double doors/vestibules, positive air-flow systems) .

6.5 Where deemed necessary through the hygienic zoning or allergen control assessments, provide separate employee facilities or amenities between NRTE and RTE or nut allergen versus non-nut process operators.

7. Plumbing/Sewage/Waste

7.1 The water supply shall be adequate for the operations intended and shall be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials shall be safe and of adequate sanitary quality (i.e., meets potable water standards). Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required. 21 CFR § 117.37(a).

7.2 Ensure all plumbing conforms to applicable sanitary codes. Plumbing shall be of adequate size and able to:

i) Carry adequate quantities of water to required locations throughout the facility.

ii) Properly convey sewage and liquid disposable waste from the facility.

iii) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge

water or other liquid waste on the floor.

iv) Prevent backflow from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water for food or food manufacturing. 21 CFR § 117.37(b).

7.3 Sewage shall be disposed of into an adequate sewerage system or other adequate means. 21 CFR § 117.37(c).

7.4 Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, water supplies, and ground surfaces. 21 CFR § 117.37(f).

Equipment

A. General

1. All equipment and utensils used in manufacturing, processing, packing, or holding food shall be so designed and of such material and workmanship as to be adequately cleanable and maintained to protect against allergen cross-contact and contamination, including lubricants, fuel, metal fragments, contaminated water. 21 CFR § 117.40(a)(2).

2. Equipment surfaces (especially the food-contact surfaces) shall be smooth and non-porous and manufactured with smooth seams and continuous welds to facilitate effective cleaning and minimize microbial growth niches.

3. The equipment shall be made of non-toxic materials that are compatible with the environment, products, cleaning methods and chemicals to avoid corrosion, leaching, and foreign matter risks. Stainless steel is the preferred material for food contact surfaces.

4. Product zones should be free of recesses, dead ends, projections, ledges, sharp corners, pipe threading, and similar areas that will contribute to product accumulation or impede effective sanitation.

5. Equipment shall be designed, constructed, and spaced to allow for proper cleaning, sanitization, and inspection. Consideration should be given to the impact of activities, such as sanitation or dusting on risk to or from adjacent lines.

6. Equipment should be designed or located to preclude condensate or to divert condensate away from product and product contact surfaces and directly to drain whenever possible.

7. Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food shall be so constructed that it can be kept in a clean and sanitary condition. 21 CFR § 117.40(c).

B. Specifics

1. Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition. Hygienic access points or means for easy disassembly should be provided. 21 CFR § 117.40(d).

2. Freezers and cold storage compartments used to store food capable of supporting microbial growth shall be fitted with appropriate and accurate temperature-measuring device, with added continuous recording and alarms optimal. 21 CFR § 117.40(e).

3. Ensure refrigeration unit drip pans are adequately sized, properly drained, contain sanitizing blocks, and are located to avoid being above stored materials.

4. Tanks or other vessels containing food products should be covered where the potential exists for contamination.

5. Thermometers, recording charts, and pressure gauges should be accessible and convenient to read and provided with calibration procedures to ensure accurate readings.

6. ASTA does not recommend the use of wooden food-contact surfaces, as they are potential contaminants, near impossible to be cleaned and sanitized, and are a potential harborage for microbial contamination.

7. It is not unusual in the spice and herb industry for wooden frames screen decks to be used in box or plan sifters. If this is the case, then an inspection program when the sieve is assembled, plus when the sieve is disassembled for cleaning, should be in place and should be documented.

IV. Raw Materials Receiving and Handling

All raw materials and other ingredients shall identify all relevant biological, physical, and chemical hazards through their hazard analysis, specifying whether the control falls with the supplier or the receiving facility.

Supply Chain Program and Foreign Supplier Verification Program

A. Under 21 CFR Part 117 Subpart G, the receiving facility shall establish, implement, and document a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control. The supply-chain program shall provide assurance that a hazard requiring a supply-chain-applied control has been

significantly minimized or prevented. If the facility/company is an importer of materials, a foreign supplier verification program is also required to assure and verify hazard control and compliance of foreign suppliers.

Raw Material Receiving/Storage/Initial Process Steps

A. The first opportunity to minimize the chance that a raw material might introduce a potential hazard into the facility is when the raw material arrives on site. A formal inspection procedure shall be established and consistently executed to minimize this risk. This procedure should include:

    1. Assure materials received are from approved suppliers and where required appropriate verification documentation is received such as Certificates of Analysis. As contingency, outline acceptance and verification activities required for use of materials from unapproved suppliers on a temporary basis only and develop a program to move these suppliers to an approved status when appropriate.

    2. Record all material lot numbers upon receipt and at time of use for traceability.

    3. All raw materials, other ingredients, and work in progress material (WIP) shall be held in their original packaging or appropriate storage containers to protect against contamination or pest infestation and held under conditions appropriate for that material as per supplier specifications or recommendations. For example, perishable materials shall be stored frozen or refrigerated, and dry or hygroscopic materials shall be protected from high humidity or moisture sources.

    4. For materials that have a history of infestation, this inspection should occur before the pests can gain access to the storage facility. This may require opening the delivery vehicle in a covered remote area where pest ingress will not occur.

    5. At a minimum, the container inspection should include evaluating: the vehicle condition; holes and/or water damage; any condensation caused by the varying temperature zones the product may have gone through while being delivered; any damage to product packaging; any type of contamination to the packaging; non-food items on the truck; presence of excess debris/foreign matter, potential for contaminants (i.e. mixed allergens) or strong off-odors from previous load, etc. The transport history may be requested as necessary.

B. Allergen containing raw materials and other ingredients shall be accurately identified, labeled to call out the associated allergen(s), and properly stored to prevent cross-contact. Establish procedures and verification of sanitation after accidental spills of material containing allergens.

    1. Raw materials with a history of potential infectious pathogens that require an inactivation step by the receiving facility should be held and handled in a manner that provides containment and protects against cross contamination of RTE product.

2. If items of stock are to be sampled for testing, there should be a way of re-sealing the package to prevent product leakage or the ingress of water or pests.

3. Periodically review material to determine if material is near or past its shelf life.

4. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. 21 CFR § 117.80(b)(1).

5. Raw materials, other ingredients susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. 21 CFR § 117.80(b)(4).

Considerations for Packaging Materials

A. When purchasing food contact packaging, the supplier should be made aware of any particular characteristics of the food (e.g., high fat content, pH, volatile oils) that may affect packaging suitability.

B. Food-grade certificates should be available on site for all food-contact packaging.

C. Product liners and bags for use directly with raw materials should be appropriately colored and resistant to tearing to prevent accidental contamination.

D. Inspect incoming secondary packaging to assure that it is clean and free from potential hazards such as staples, etc.

E. Where packaging may be re-used for raw material delivery, great care should be given to ensure that the previous use of the packaging does not give rise to any product contamination. For this reason, agro-chemical bags, other non-food bags, especially those that may have contained non-declared allergens, should not be used for raw material delivery, unless there are documented steps to show that the contamination risk has been managed.

F. All packaging should have or receive a traceability number when it arrives on site. This number should be documented when the packaging is used.

V. Personal Hygiene

General

Personal hygiene standards shall be adopted by all personnel, including management, contractors, and visitors entering the production facility.

A. All persons entering food processing areas shall conform to hygienic practices and maintain personal cleanliness. 21 CFR § 117.10(b)(2).

B. Eating food, chewing gum, drinking beverages, or using tobacco shall be confined to designated areas away from food processing or storage such as breakrooms and picnic areas. 21 CFR § 117.10(b)(8).

C. Prohibit watches, jewelry (with the exception of a plain wedding band), false eyelashes, false fingernails, nail polish, and loose items that may fall into the product in the facility. For employees and visitors that cannot remove jewelry for physical or religious beliefs, an approved glove shall be used to cover the item.

D. Use hairnets and beard-nets to contain all hair at all times in the facility.

E. Breakrooms and food preparation areas should meet restaurant standards for sanitation and cleanliness. Suitable refrigeration units should be provided if employees are permitted to bring in their own meals. If used, these fridges should be on a cleaning and inspection program and should have temperature monitoring devices.

F. Store clothing or other personal belongings in designated areas or lockers. 21 CFR § 117.10(b)(7).

G. Signs should be posted informing employees of what is permitted or banned within their locker. Periodic locker inspections should be in force for hygiene purposes.

Uniforms

A. Whether employee-owned clothing or company provided uniforms, outer garments shall be clean and suitable to protects against contamination. 21 CFR § 117.10(b)(1).

B. Clearly communicate and enforce the rules regarding use of protective clothing, emphasizing the fact that protective clothing is used to protect the product from employee contaminants or those that could be carried on or come from the garments.

1. Keep protective clothing reasonably clean during the shift.

2. Do not wear protective clothing with pockets above the waist.

3. Buttons are a potential contamination risk; snaps or Velcro are preferred.

4. Use an approved contractor or in-house laundry for cleaning company provided uniforms and protective clothing. The laundry should use unscented detergent (and possibly a laundry sanitizer) and should ensure:

4.1 Effectiveness of the laundering process.

4.2 Segregation between dirty and clean clothes.

4.3 Commercial sterilization should be used where appropriate (e.g., for garments worn in higher risk/high contact RTE areas).

5. Post signs instructing employees to remove protective clothing before entering the toilet facilities.

6. Change protective clothing at an established frequency, based on risk or if it becomes a potential source of filth.

7. Clean and sanitize personal protective clothing that is not suitable for laundering (e.g., chain mail, gloves, aprons) at an established frequency based on risk.

8. Consideration should be given to color-coding protective clothing between areas of different risks or operator function, to facilitate easier management of the employee's activity.

Footwear

A. Hygienic transition areas that go from a lower to a higher hygiene care area should consider footwear treatments where appropriate. This may involve shoe changes (with facilitating benches or barriers), disposable booties, shoe sanitizers (i.e., alcohol w/quat), or floor granules.

B. When a facility's hygienic zoning program requires dedicated footwear for higher hygiene care areas, the dedicated footwear should not be worn outside those designated areas, unless there are adequate sanitation methods for the footwear upon re-entry.

C. In addition to ensuring employee safety, footwear should be designed for easy cleaning with special attention to tread design to avoid deep tight grooves.

D. Environmental monitoring results should be used to verify the effectiveness of footwear sanitation controls.

Hand/Gloves

A. To protect product from potential cross contamination from employee hands, establish facility handwash and glove policies and procedures with documented training for all employees.

1. Educate the employees and visitors on risk of product contamination when touching face, wiping forehead, or placing fingers in the mouth, nose, or ears.

2. Ensure that employees keep fingernails clean and properly trimmed.

B. Post signs in locker rooms, toilet facilities, and at entrances to work areas instructing and reminding employees on the proper hand washing and sanitizing procedures and frequencies.

1. Hands shall be washed before starting work, when leaving toilet facilities, after each absence from work stations, and whenever hands may have become soiled. For higher hygiene care/RTE zones, consider secondary hand sanitizing using an approved alcohol-based sanitizer. Alcohol concentration should be greater than 60%.

2. Use hand wash stations/sinks for hand washing only (utensil washing sinks should be separate and properly designated as such).

3. Recommend the following hand washing method:

3.1 Rinse hands with warm water.

3.2 Apply soap to fully cover hands.

3.3 Rub hands to obtain thorough coating of soap and continue rubbing contacting all hand surface areas including fingernails for at least 20 seconds.

3.4 Rinse with warm water until soap is removed.

3.5 Dry hands thoroughly using clean disposable paper towels.

C. Personnel directly handling product should wash hands or change gloves after touching any non-food contact surfaces.

D. Gloves used in food handling shall be intact, clean, and in sanitary condition. Once put on, gloves basically become hands and they should be changed similar to handwashing frequencies. 21 CFR § 117.10(b)(5).

E. Adhere to guidance in Table 1, which summarizes GMPs regarding use, storage, and replacement of single- and multi-use gloves.

Table 1. Glove Use, Storage, and Replacement Requirement

Requirement	**Single Use (SUDG)**	**Multi-Use, Food Contact**	**Multi-Use, Non-Food Contact**
Made of impermeable material (non-latex)	Yes	Yes	Yes
Kept clean and sanitary at all times	Yes	Yes	Yes
Worn over clean hands	Yes	Yes	Yes
Disposed of before going to break/restroom	Yes	No	No
Properly stored before going to break/restroom	No	Yes	Yes
Cleaned with soap/water/sanitizer (non-cloth)	No	Yes	Yes
Laundered (cloth only)	No	Yes	Yes
Stored under sanitary conditions	Yes	Yes	Yes

Inspected periodically during use, checking for rips/holes	Yes	Yes	Yes

Illness/Injury

A. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g., by an impermeable cover). Personnel shall be instructed to report such health conditions to their supervisors. 21 CFR § 117.10(a).

B. Set up procedures to ensure that no one with open sores, infected wounds, or other potential sources of microbiological contamination has access to any work area.

C. Prohibit any person who is affected with, has been exposed to, or is a carrier of communicable disease from entering the production environment.

D. Notify all employees that they should report any communicable disease or injuries to their supervisor to ensure that food safety is maintained at all times. Consideration should be given to relocating the employee to non-food activities, thus supporting the reporting program. Adhere to public health guidelines as appropriate when allowing employees to return to work.

E. Cover all minor cuts and grazes on exposed skin by a blue plaster, which is metal-detectable. Gloves may also be used to minimize risk of losing the bandage. The effectiveness of the metal detection of the plasters should be verified when each batch is delivered. If in exceptional circumstances non-metal detectable dressings are used their presence and condition should be recorded at the start and end of each shift.

Visitors

A. There should be a formalized system for the management of all visitors to the site. At minimum, read facility GMP rules and sign-off before entering the facility. All visitors should, as a minimum, follow the same procedures as any employee.

B. Each visitor should be informed of the food safety and quality requirements associated with their visit and should sign to verify their health condition.

C. If visitors, auditors, etc. wish to take any item into the production or storage areas, these items should have a documented procedure that verify their condition before and after visiting, to ensure that no contamination has occurred.

VI. Sanitary Operations

Sanitation

Sanitation in food processing is the effective and timely cleaning (removing soils) and sanitizing (disinfecting) of surfaces to minimize risk of product contamination. Improper sanitation has been cited frequently as the root cause of food poisoning incidents and a significant number of food-related recalls.

A. Premises and equipment shall be maintained in a clean and hygienic condition. Sanitation is the first step of the manufacturing process to ensure that the line is in sanitary condition and ready to produce food.

B. Establish a master sanitation schedule, which shows the frequency that all parts of the facility are cleaned. Track and trend compliance and use means such as internal GMP audits to help adjust cleaning frequencies as needed.

C. Validated sanitation standard operating procedures (SSOPs) shall be detailed to facilitate adequate training and consistent execution between personnel. The use of pictures is encouraged. SSOPs should include:

    1. Purpose
    2. Scope - Item/area to be cleaned
    3. Person(s) responsible for cleaning
    4. Frequency of cleaning
    5. Chemicals and concentrations to be used
    6. Tools, utensils, and materials needed
    7. Safety precautions
    8. Detailed steps for cleaning including dismantling of equipment when required, where to clean the equipment (e.g., in place or moved to a wash bay), and how to handle and protect equipment and parts.
    9. Cleaning records and responsibility for verification (e.g., Pre-Op Checklist)
    10. Sign-off by all responsible parties

D. The SSOP frequency and methods of cleaning shall be based on risk.

1. Verification of SSOP effectiveness may be visual inspection using a flashlight, microbiological testing, allergen testing, and/or chemical testing such as ATP or protein swabs. Acceptance limits and corrective actions shall be established for each method of verification. At minimum, visual inspection shall be conducted, and all areas found to be acceptable (i.e., no visible food residues or presence of moisture) before the line can start-up. Where sanitation procedures are part of a defined Hazard Analysis and Critical Control Point (HACCP) pre-requisite program or preventive control, the sanitation procedures and frequency should be validated and records maintained.

2. Equipment, tools, and utensils used for sanitation should be:

    2.1 Hygienically designed.

    2.2 Color-coded or labeled for their specific areas of use (i.e., food contact surfaces (FCS), non-FCS, or drains).

        i) All colors should be in contrast to the general color of the product so that bristles are easy to identify if they become detached.

        ii) Equipment Tools used for cleaning in higher hygiene care/RTE areas should be visually distinctive and dedicated for use in that area.

    2.3 Cleaned and stored in a hygienic manner to prevent contamination.

3. The facility shall assign an appropriately trained and qualified individual to oversee and supervise the sanitation of the facility, including any sanitation duties assigned to third party contractors. 21 CFR § 117.80(a)(3).

E. Wet Cleaning in Dry Production Areas

1. When it is required to conduct wet cleaning in a dry production area, care should be given to control water/liquid usage to avoid promoting microbial growth. The minimum amount of water should be used to accomplish the cleaning task followed by effective and rapid drying of all surfaces.

2. Remove dust and residues from surfaces through the use of vacuum cleaners (with filtered exhaust), brushes, scrapers, etc. before any liquid is used.

    2.1 Avoid the use of high-pressure hoses in production areas as these can create aerosols that can spread bacterial contamination. They should never be used while a line is running and with care during sanitation. Low pressure water flow is preferred.

2.2 The same principle applies to the use of compressed air guns which can blow foreign matter, microbes, or allergens onto adjacent surfaces. They should never be used while a line is running and with care during sanitation.

3. If parts are to be wet-cleaned, they should be removed to an area where this can be conducted, without the risk of the dry process area becoming wet.

4. Procedures should be in place to verify that any wet cleaned equipment is fully dry before being returned to the manufacturing area. This may require the use of a hot box, to ensure that difficult to dry items, like fine screen meshes, are dried completely. Alternatively, drying may be facilitated by the use of an alcohol-based sanitizer, once the majority of the water has been removed.

Environmental Hygiene and Hygienic Zoning

The main objective of environmental hygiene and hygienic zoning is to minimize the risk of cross contamination by pathogens (i.e., *Salmonella*) by keeping the processing environment clean, dry, and segregating areas by risk.

A. General Facility Hygiene

1. Control of Water – Water in dry process environments is fuel for microbial growth. The unnecessary presence of water shall be diligently monitored and controlled. This can be done through internal GMP inspections, during environmental monitoring program (EMP) sampling, rainy day audits looking for roof leaks, and through encouraging employees to notify supervisors of any observed water leaks or pooling. Work orders should be written immediately for any leaks identified.

2. Maintain floors in a clean and dry condition, with no standing water.

3. The roof of the facility should be clear of clutter, standing water, bird, and pest harborages.

4. Ceiling surfaces as well as other overhead equipment, e.g., ventilation units, light fixtures, conveyors, pipes, and catwalks should be clean, in good repair, free of flaking paint, free of mold/mildew, rust, holes, unsealed openings, or other conditions that could result in product contamination.

Hygienic Zoning

Refer also to Section III “Hygienic Design Standards”, Subpart “Facility”, Subpart B: “Designing for Hygienic Zoning.”

A. When a lethality step is needed to inactivate potential contaminants such as Salmonella, post-processing controls are required to prevent recontamination. These controls may include enhanced sanitation, restricted traffic flows, modified employee practices, dedicated tools/equipment, etc.

Controls to be employed should be determined using a hygienic zoning assessment involving a cross functional team.

B. Identified transition areas shall be adequately designated and control steps displayed.

C. Employees shall be trained on hygienic zoning and control measures required. Compliance should be part of internal GMP audits.

D. Restrict unnecessary traffic from lower hygiene to higher hygiene care areas.

E. Careful consideration should be given to transfer equipment as forklifts, pallets, conveyors, scales, trans-pallets, and sewing machines that may be used in multiple zones. Risks should be clearly identified and measures taken. Dedicate/restrict to same hygiene level when possible.

F. For personnel entering the higher hygiene care/RTE areas, it is recommended to have a separate colored-coded uniform and dedicated footwear. The access should be through a separate additional hygienic entrance into these areas.

Waste and By-Product Management

A. Waste materials have the potential to be contaminants and to be a harborage for pests. For this reason, there should be a formalized waste management system for all types of waste within a facility.

    1. It is recommended that each type of waste container be clearly marked to show the type of waste that should go into the container.

    2. Waste bins themselves should be on a master sanitation schedule to ensure that they do not become the harborage for bacteria or pests.

    3. If the waste bin is to have a lid, then it is recommended that this lid is foot operated so that employees do not have to soil their hands by lifting the dirty waste bin lid. Strong plastic liners/bags may also be used to help contain waste.

    4. Larger waste bins that are located outside of the building should be fitted with lids to prevent pest activity and should be located away from doors that open regularly to prevent any pest activity becoming an issue within the facility.

    5. Consideration should be given to protective clothing contamination if process operators are required to access exterior waste containers.

    6. Under no circumstances should finished product containers, i.e., bags, cartons, be used for holding waste products.

B. By-product management - Items such as mill tailing (oversize material) or materials that are generated during physical cleaning, large or small leaf, etc. may still have an intrinsic value and thus these products are often classified as by-products.

    1. All by-products shall be clearly marked to make sure that they are not used or dispatched by mistake.

    2. Normally by their nature these products require further processing and thus they are classified as non-conforming products. There should be documentation that explains the nature of the non-conformance and what remedial action is required to remove the non-conformance or the further processing that is necessary.

    3. These products should still be managed correctly in terms of shelf-life, especially where a product may be reworked more than one time. In this case the original shelf-life of the product should be taken into consideration.

    4. It is important that full traceability is maintained if product is re-used.

C. If waste or by-products are to be sold, e.g., animal food, they shall be clearly marked to avoid misuse and protected from contamination from cleaning chemicals, foreign matter including floor sweepings and trash.

Chemical Controls

The main objective is to ensure that potentially hazardous chemicals necessary for facility operations are well controlled to prevent product contamination.

A. Ensure the following to manage the use, storage, and handling of non-food chemicals to prevent chemical contamination

    1. Establish a list of all chemicals that are on site. Include those used for sanitation (processing and non-processing), pest control, laboratory, maintenance, processing operations, and warehouse.

    2. Define which chemicals are allowed in a food-processing environment and which are not.

    3. Identify which chemicals are food-grade and which ones are not.

    4. Ensure each chemical has a material safety data sheet and a specification.

    5. Label and/or identify containers of chemicals at all times. Toxic, flammable, and corrosive chemicals should be clearly labeled as such.

    6. Designate storage area with restricted access (preferably locked) to authorized personnel.

7. Limit use of chemicals to trained personnel only.

8. Avoid strongly scented sanitation products. Where strongly scented or taint-forming materials have to be used, necessary attention shall be given to prevent the risk of taint contamination of products.

9. Cleaning chemicals used on food contact surfaces shall be free from undesirable microorganisms. Obtain certificates or analysis or letters of guarantee where appropriate.

10. Sanitation procedures shall also ensure no residual chemical residues above regulatory or application limits (per labeling) are present on processing equipment.

Pest Control

Since pests can be vectors for pathogens and can present a physical hazard in foods, the objective of a pest control program is to properly and effectively avoid the entry and/or infestation of pests in and around the food manufacturing facility. In addition, chemicals used for pest control shall be adequately secured and used only as directed to avoid product contamination.

A. Establish facility inspections (interior and exterior) to assess and address any possible points of ingress or harborage.

B. The pest control program should list all pests that are covered by the program and consideration shall be given to local pests that might be applicable, e.g., lizards or frogs.

C. As pest control devices and chemicals are potential contaminants, it is important that proper care is given to the use of all pest control equipment.

D. The use of toxic chemicals should be avoided if possible. If they are used, they should be carefully controlled to prevent product and process contamination. Store pesticides in a designated, locked room.

E. Employees should report any evidence of pest activity to a designated supervisor.

F. Personnel should be educated on pesticide safety including knowing that most are toxic and could be inadvertently inhaled, ingested, or absorbed through the skin if the appropriate precautions and personal protective equipment are not used.

G. Only certified contracted pest control operators, or employees trained as pest control technicians should apply pesticides; both shall follow all local laws and regulations and shall strictly adhere to the instructions on the pesticide labels.

H. Limit and control applications of pesticides in food areas, and keep pesticides, traps, and other devices away from open food products.

I. Institute a method for tracking each trap/bait device number, date and time of each inspection, and all activity for each device.

J. Set up a protocol of what to do when pest activity has been identified at one of the devices.

K. Establish a method and location for storing and maintaining all records relating to pest control services. At a minimum, these records should include a site plan noting the locations of all traps, bait devices, and other pest control equipment, as well as locations where use of pesticides is permitted.

L. Maintain an approved pesticide list, indicating for each the storage location, level of toxicity, and labeled instructions for proper use. An accurate log should be kept of:

    1. All chemicals used and the stock balance.

    2. Entries detailing each inspection/service (what was used, where, how much, and by whom).

    3. Tracking data and trend data for each device.

        3.1 If trends are identified, or variations from trends are identified, investigate the reason and take appropriate corrective or preventive action.

M. Fly killer devices and/or pheromone traps shall be placed correctly. If there is a danger of insects being expelled from these devices and contaminating the product, the units should be relocated or fitted with a catch tray that prevent insect fragment ingress into the product or the process.

N. In the event of an infestation or any evidence of pest infestation, immediate action should be taken and any potentially affected products should be handled according to non-conforming product procedure.

O. Table 2 summarizes potential methods to control insects, rodents, and birds.

    1. The pest control devices should be situated using a risk assessment and thus areas that contain items with a historical problem should have more pest control devices than areas that do not have this issue.

    2. If electronic fly killing or insect light trap units are used in the storage areas they should be located so that they are not above product, thus eliminating the risk of contamination with insect fragments. They shall also not be visible from outside the building to avoid attracting outdoor insects.

P. Take measures to protect outdoor bulk storage vessels used for food product or ingredients.

    1. Provide secured access.

2. Eliminate harborages for pests around and over the vessels.

3. Clean and inspect on a schedule based on the type of material in the vessel and expected pests and their life cycles.

4. Closely inspect any sifter tailings for evidence of pest activity.

Q. Check all items stored outdoors for evidence of pest activity before bringing them into the facility. Ensure full chemical sanitation is performed on the item(s).

Table 2. Pest Control Measures

Pest	Pest Control Measures
Insects	Exclusion • Use screens on windows and doors. • Ensure doors are kept closed when not in use. • Fit pedestrian doors with self-closers. • Fit larger doors with rapid rollers or strip curtains. Electronic fly catchers – electrocuting or sticky boards Pheromones traps • Ensure pheromone is replaced at a frequency based on risk assessment. Pesticides • Dust pesticides • Residual pesticides • Aerosols • Emulsifiable concentrates • Wettable powder • Encapsulated Pesticides Insect light traps – Light attractant to sticky boards
Rodents	Exclusion • Store trash bins and items that hold water away from the building. • Use strip curtains to “seal” doorways that are often left open. • Attach brittle strip to fill gaps under doors. • Put screens over drain channels. • Use exterior/perimeter baiting and trapping. Interior control • Multi-catch automatic traps • Snap traps • Glue boards Exterior control • Bait stations (solid baits preferred to avoid spillage)
Birds	Exclusion • Remove ledges. • Use variable tone speakers or bird of prey decoys. • Attach netting under canopies. • Eliminate food/water sources.

	• Look for and remove roosting locations. Interior control • Live trapping and relocation • Mist nets • Narcotic seed baiting

Maintenance and Preventative/Predictive Maintenance

Hygienic standards and regulations outline that facilities and equipment shall be well maintained in order to successfully achieve sanitary conditions and protect product from biological, chemical, allergenic, and physical hazards. A sound preventative maintenance program will help to proactively avoid contamination risks. Additionally, maintenance activities shall be done in a manner which effectively remediates problems but shall also avoid creating a cross-contamination risk.

A. Preventative/Predictive Maintenance (PM)

1. It is good practice to have a fully documented preventative maintenance program that takes food safety into consideration. This should include all equipment within the facility and should prescribe the frequency at which the preventative maintenance should be carried out.

2. The program should be documented and verified by a designated person.

3. A critical measure for environmental control is protecting against roof leaks. Frequent roof inspections should be conducted and contractors pre-arranged to make roof repairs or replacements quickly.

4. Utilize internal GMP audits and employee observations to guide PM frequencies and priorities.

5. Special attention should be given to food contact equipment including gaskets and seals. Food contact equipment repairs shall be prioritized.

6. PM is using knowledge of the life cycle of the equipment, valves, gauges, etc. to schedule PM activities ahead of break downs and helps to prevent equipment damage that can cause food safety/quality issues. This includes using manufacturer's recommendations for lubrication, maintenance activities, and/or replacement of critical parts.

B. Maintenance Activities

1. Priority should be given to safety/food safety/GMP related work orders.

2. All equipment should be inspected for hygiene and damage on a regular basis. A line start-up check is suggested so that any damage to equipment, which cannot be repaired before

the production line is started, can be documented so that any further damage that could occur can be identified and immediate corrective or preventive action taken.

3. There should be a risk assessment carried out on the program to ensure that this maintenance activity does not give rise to the introduction of hazards. For example, all lubricants should be food-grade.

4. Maintenance tools shall be cleaned and sanitized prior to working on product handling equipment to prevent cross contamination.

5. If the maintenance must be conducted while production is in progress, there should be a formalized documented program to show that the risks are being managed and to ensure that any debris created by the activity is removed from the area.

6. After maintenance is completed, the area/equipment shall be cleaned, sanitized, and inspected.

7. If outside contractors are required for preventive maintenance or equipment repair, there should be a formalized system for the management of food safety and appropriate GMPs.

8. It is important to provide appropriate GMP training to contractors and share food safety procedures/requirements with them before commencing work.

9. The facility sanitation team should assess any risks associated with the tools and equipment to be used in planned maintenance work to determine if they acceptable for use or if additional cleaning and sanitizing is required.

10. Maintenance areas should be inspected and cleaned following work.

11. Maintenance activities in higher hygiene/RTE areas should respect the segregation requirements of the area. If possible, there shall be dedicated tools and equipment for each area.

C. Temporary Repairs

1. Temporary repairs are not encouraged and should be a key focus during any GMP audit.

2. Temporary repairs should be recorded in a temporary repair log and permanent repairs made promptly.

3. Categorize temporary repairs as critical, i.e., a food contact part or location at imminent risk of product contamination.

4. Assure that critical repairs will not add a food safety or quality risk, and decide what additional product testing, if any, is required for the batch being processed.

5. Make critical repairs only to allow a batch of material to be processed to completion and then make a permanent repair. Inspect the repair at the end of the batch to ensure intact.

6. All non-critical temporary repairs should be dated and inspected on a weekly basis.

7. Where possible, all temporary repairs should be made using blue/metal detectable materials, or other food-safe items. The use of temporary fasteners such as string, wire, cardboard or clear tape should not be permitted.

General Hygienic Process Controls

Adequate precautions shall be taken to ensure that the immediate process environment and the process itself does not present a risk for product contamination or deterioration.

A. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination. 21 CFR § 117.80(a)(2) and (5).

B. Adequate precautions shall be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source. 21 CFR § 117.80(a)(4).

C. All food processing operations shall be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms and against contamination. Food shall be protected from contaminants that may drip, drain, or be drawn into the food. 21 CFR § 117.80(c)(2) and (10).

D. Food that can support the rapid growth of undesirable microorganisms shall be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding. 21 CFR § 117.80(c)(3).

E. Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated (i.e., filtered) in such a way that food is not contaminated with unlawful indirect food additives. 21 CFR § 117.40(g).

F. Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of aw for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. 21 CFR § 117.80(c)(14).

G. Provide appropriate heating, ventilation, or refrigeration to maintain proper environmental and sanitary conditions for ingredients, finished product, equipment, and packaging materials.

H. Balance heating, air flow and ventilation to prevent condensation on walls or ceiling in product areas.

I. Set up a system for documented monitoring of humidity and temperature where hygroscopic products are processed.

J. For processing of high water activity material, controls should be in place to minimize the growth of undesirable microorganisms. This may be accomplished through adjusting intrinsic properties where possible (i.e., acidity) or controlling temperature and/or frequency of sanitation/hold time limits.

K. Water used in processing and sanitation shall meet potable water standards.

L. Rework material shall be appropriately labeled with material identification, allergens, date of manufacture, and any expirations dates.

M. Close windows when outside conditions exist that may expose the facility to airborne contamination; any window that can open should be insect screened. All skylights, transoms, windows, or similar openings shall be free of damage, tight fitting and properly screened.

N. Equipment should be free of flaking paint, rust, or other contaminants that could become detached.

O. Keep walls free of dust, dirt, and flaking paint, as well as cracks, holes and crevices that would inhibit cleaning or provide harborage for soil or pests.

P. Inspect ingredient bags and containers prior to use and clean as necessary to remove potential contaminants that could fall into a product hopper when that product is used.

VII. Specific Hazard Controls

Allergen Management

Equipment, utensils, and food contact surfaces shall be maintained in a manner to prevent allergen cross-contact. This includes ensuring that sanitation and storage practices are conducted in a manner that protects food from allergen cross-contact and that product meets legal requirements for labeling in the country of sale. Additional allergen information may be found in “FAQs for the American Spice Trade Association (ASTA) on the Potential Risks Related to Allergens in Spices” and ASTA’s “HACCP Guide for Spices & Seasonings”.

A. Ensure that allergen education and control programs/procedures are included in employee training.

B. Insist that suppliers and third-party processors maintain allergen control programs to prevent cross-contact, including proper labeling of allergen-containing raw materials per appropriate country regulations. Utilize tools such as allergen checklists, questionnaires and/or on-site audits to assess

risks.

C. Identify and document all allergen-containing materials, e.g., raw materials, processing aids, semi- or finished-products and allergens run on each process lines.

D. As part of hazard analysis, conduct a documented risk assessment to identify routes of allergen cross-contact. This should include:

    1. Consideration of the physical state of the allergenic material (i.e., powder, liquid, particulate) as it relates to means of spread (i.e., dusting) and difficulty of removal during sanitation.

    2. Identification of potential points of cross-contact through the process flow and employee practices. Be sure to include use of any rework.

    3. Assessment of the risk of allergen cross-contact at each process step to include assessing the hygienic design of equipment and effectiveness of SSOPs.

E. Establish procedures to prevent cross-contact into products not containing the allergen. This may include:

    1. Physical or time segregation from allergen-containing materials being stored, processed, or packed.

    2. Use of separate or additional protective over clothing when handling allergenic materials.

    3. Use of dedicated, color-coded utensils and dry sanitation tools such as brushes. Where practical, use dedicated equipment and process lines to further improve segregation.

    4. Ensure reworking “like” into “like”, meaning that allergen rework may only be reworked into product with same allergen profile. Basic rework handling procedures would include clear labeling, clear tracking of allergenic product, and storage in a separate area.

    5. Scheduling of production to reduce changeovers from products containing an allergen to products not containing the allergen.

    6. Providing systems/traffic patterns that restrict the movement of airborne dust containing allergenic material.

    7. Avoiding introduction of allergens into a system that cannot be wet or effectively cleaned.

    8. Providing protected waste handling and spillage controls. Color coding may also be employed for allergen containing waste bins.

F. It is FDA's policy that advisory labeling (e.g., "may contain" statements) may not be used as a substitute for GMPs and these statements shall be truthful and not misleading. Manufacturers may consider the use of advisory labeling if a risk of allergen presence exists after GMPs are followed. It may be prudent to consult with legal counsel on these decisions.

G. Where a claim is made regarding the suitability of a food for individuals with allergies or food sensitivities (e.g., gluten free), conduct and document a validation of the production process that supports the stated claim and institute adequate ongoing monitoring.

H. Develop and consistently execute SSOPs to effectively remove potential cross-contact by allergens. When identified as a preventive control, the procedures shall be validated and ongoing verification established, such as visual inspection and ATP testing.

I. Provide procedures/policies to mitigate the risk of cross-contact from allergens in food brought by employees or from vending machines. These would include handwashing, changing protective outer clothing, and prohibiting employee food and beverages from the processing areas. Include vended product when assessing facility allergen risks and executing appropriate mitigation strategies.

J. Procedures shall be in place to ensure that the products are packed into correct packaging and correctly labeled. These will be at the start, during the run, when changing batches and at the end of each production.

    1. Documented checks should be carried out at product changes to ensure that packaging from the previous production have been removed from the line before changing to the next production. Only the packaging for immediate use should be available at the packaging machines.

    2. When online vision equipment is used to check labels, procedures should be in place to ensure the system is correctly set up and capable of alerting or rejecting the product when packaging information is out of spec.

K. Labels shall meet the legal requirements for the designated country of use; and there shall be a process to verify that ingredient and allergen labeling is accurate, based on the product recipe.

L. Allergen statements and labeling graphics shall be reviewed whenever changes occur to the product recipe, raw materials, suppliers, legislation, or country of origin.

Pathogen Control/Environmental Monitoring

Refer to ASTA's "Guidance on Environmental Monitoring" and "Clean, Safe Spices" documents for additional information and detailed recommendations.

A. When receiving raw materials that have been identified per hazard analysis as having the potential to be contaminated with infectious pathogens, measures such as roasting, steaming, irradiating, or

fumigating may be utilized as control steps.

1. Such controls shall be validated for effectiveness and included in the facility's Food Safety Plan.

2. Critical process parameters for pathogen inactivation shall be measured and documented using instrumentation that is fit for purpose, properly calibrated at an appropriate frequency to ensure accuracy, and well maintained.

B. Once treated, whether on-site or by the supplier or other third party, the RTE product shall be protected against cross contamination through sanitary operations and environmental controls as noted in the previous section of this document.

C. An EMP shall be established to verify and document the effectiveness of environmental controls. An EMP should use a seek and destroy objective to successfully detect and address environmental pathogens and their means of harborage and spread to minimize the risk of cross contamination. This requires thorough sampling of the facility environment using zone designations, aggressive corrective action plan driven by root cause analysis and vector sampling, and the use of tracking and trending to drive continuous improvement.

Foreign Matter Control

The exclusion of foreign material, such as metal, glass, plastic, and string is essential to producing a clean, safe product. Adequate measures shall be taken to protect against the inclusion of metal or other extraneous material in food. 21 CFR § 117.80(c)(8). Magnets, metal detectors, and sieves are often designated as critical control points or operational controls within a manufacturing environment. Proper location and maintenance of these devices are also critical to their effectiveness.

A. Magnets

1. Assess the depth of field of the magnet to determine the depth of product that can pass over the magnet or the gap between the magnetic bars, thus ensuring all products passes through the magnetic field.

2. When installing magnets:

2.1 Set the product flow over the magnet at a slow rate and control the depth of the product.

2.2 Pay particular attention to the corners of conveying lines or process hoppers to ensure that there is no gap where material can avoid the magnetic field.

2.3 Consider staggering magnets, especially when product bridging is an issue.

2.4 Ensure magnets can be easily taken out of the product flow for cleaning.

3. Because fine metal dust can be difficult to remove from rare earth magnets, consider use of:

    3.1 Magnets that are equipped with removable outer stainless steel housings; when these housings are removed, the metal falls away from the magnets.

    3.2 Self-cleaning magnets.

4. Establish cleaning intervals (usually no less than once per shift)

    4.1 Document each cleaning.

    4.2 Retain and investigate any item detected and take corrective action.

B. Metal Detection

1. Use the appropriate size metal detection equipment for the product and process application.

2. Limit risk of recontamination by placing the metal detector at the end of the production line and designate all areas after the metal detector as ‘high-care’ for metal control to ensure that recontamination does not occur.

3. Establish metal detection system standard operating procedure that includes measures to verify and maintain equipment performance:

    3.1 Maintain equipment cleanliness.

    3.2 Control rejected items to ensure that they are not mistaken for approved products.

4. Ensure all metal detectors are calibrated on at least an annual basis by an approved certification body. During this calibration, identify the least sensitive part of the field within the metal detector (usually the center of the induction coil) per HACCP guidelines; this should be the designated location for the application of the test pieces.

5. Use test pieces made from ferrous, non-ferrous and stainless steel to confirm accurate performance of the detector prior to use.

6. Recalibrate any time a test piece is not detected.

6.1 The detector cannot be used in production until the test piece application check is satisfactory.

6.2 All products manufactured since the last successful test piece application shall be isolated, identified and put on hold. This isolated material shall be reprocessed through the metal detector.

7. Document all tests, results, and corrective actions.

C. Glass and Brittle Plastic

1. Exclude or protect from breakage glass/brittle plastic in areas where open products are handled.

2. Identify, document, and protect/cover all glass and brittle plastic within the factory (except packaging material) and check against breakage with frequency based on the level of risk to the product.

3. Segregate storage of product packed in glass/brittle plastic containers from raw materials and other packaging materials (e.g., paper bags, cartons).

4. In the case of a broken glass/brittle plastic:

4.1 Stop production and quarantine the affected area.

4.2 Alert the supervisor.

4.3 Remove broken material.

4.4 Clean the area using dedicated cleaning materials and use dedicated waste bins with lids.

4.5 Discard any potentially contaminated product.

4.6 Uniforms should be changed and footwear inspected.

4.7 Document the incident and the cleanup.

D. Sieves

1. Number all sieves with a permanent identification system.

2. Record sieve number against each batch of product manufactured so there is full traceability to allow for any potential corrective actions.

3. Use sieves (and their housings) that are made of stainless steel and food-grade nylon; mild steel sieves can be used in dry environments, provided there is no risk of product contamination

4. Ensure that sieves that have nylon mesh have their edges heat-sealed to prevent fibers from falling into the product; metal sieves can have their edges soldered or glue sealed.

5. Assign sieves with wooden parts to the highest level of control due to the risk of wood contamination, as well as the presence of staples and other fastening devices. The operator should be trained and educated on the risk of wood and other contaminants. A picture showing all these potential contaminants helps the operator to undertake a suitable check

6. Inspect sieves for hygiene and damage before each production run, document inspection, and label and isolate defective sieves.

7. If visual inspection is not possible, use a check sieve to verify the particle size of the material being produced. Large particles indicate sieve damage.

8. If damage is discovered at the end of a batch, the batch shall be quarantined for reconditioning.

9. If stainless steel sieves are found to be damaged, check the reject box at the metal detector to ensure that missing metal was successfully rejected.

10. Routinely clean and thoroughly dry sieve screens, with care to separate dirty and clean screens.

11. Use a hot box to dry fine mesh screens after wet cleaning.

12. Set up a program of documenting and investigating the presence of any exceptional item that is found during the screening operation.

13. Ensure that clean sieves that are stored ready for use are off the floor and away from potential contamination.

E. Sharp Objects

1. Make knives, blades, and similar sharp objects available in designated checkout areas only.

    1.1 Register each item in a logbook and number each item for easy identification.

1.2 Require employees to sign the logbook on checkout and check-in, designating the tool used.

2. Do not allow employees to replace blades or disassemble knives while working on a project. If a blade dulls or breaks, the employee shall return the knife and check out a new one. There should be 100% recovery of the pieces from any broken item to ensure no foreign matter entered the product.

3. Blade breaks should be reported to a supervisor immediately; the supervisor will report the incident and recommend corrective actions if necessary.

4. After every workday, a designated employee should replace all dull or broken blades, and ensure all tools are returned.

5. If any tools are missing at the end of the workday, the supervisor should report the incident and recommend corrective actions, which may include stopping all shipments until the tool is located.

F. Bag Stitcher

1. Designate the area immediately prior to packing (e.g., a metal detector area post-induction coil) as a high-care area, as any potential contamination in this area would not be detected by any further processing.

2. If a stitcher is in use, label it for use in high-care areas only.

3. The stitcher needs to have a part count and the needle (because it is metal and very sharp) should be checked after each batch.

4. A needle can lose the tip of its point and still operate; make sure the tip is intact.

5. Ensure that the bag stitcher is clean with no oil or grease leaks.

6. Never store the bag stitcher on the floor between uses.

7. Use blue stitching for easy detection of any fibers that may fall when the bag is opened.

8. Establish a sanitation program for the part of the stitcher that touches the bag.

9. Document all stitcher checks.

10. When online vision equipment is used to check labels, procedures should be in place to ensure the system is correctly set up and capable of alerting or rejecting the product when packaging information is out of spec.

VIII. Finished Product

QA Testing and Hold/Release

A. QC/QA testing shall be established and executed per ingredient, process and/or product specifications to verify compliance and effectiveness of controls.

B. Products should only be positive released after necessary controls are verified and specification limits are achieved.

C. When testing is conducted for hazards that could result in a product recall (i.e. Salmonella), a hold and release protocol should be established to where the associated product is electronically and physically on hold until released by QA based on results to prevent premature release.

Handling Non-conforming Materials

A. All out-of-specification or non-conforming products shall be clearly identified, labeled, quarantined, and placed on hold to prevent unauthorized release.

B. Products may be reported as non-conforming as a result of quality control/quality assurance activities, critical production deviations, customer complaints, or external audits.

1. Initiate root cause analysis and corrective actions as appropriate based on severity, frequency, and/or trending of findings.

2. Consult with ingredient or packaging suppliers if root cause probability may include these suppliers.

3. If non-conformance does not affect the use or safety of the product, then product disposition can be determined and any corrective action(s) executed.

4. Product deemed to be adulterated shall be properly destroyed with documentation or reconditioned using a validated process if appropriate. If reconditioned, the product shall be reexamined and found to be non-adulterated using a statistically valid sampling plan and accepted methodology. Seek regulatory approval where appropriate.

C. If any of the affected product has left the manufacturer's control, the recall plan and team should be engaged to determine appropriate actions and notifications. For the U.S., this may include reporting the event through the Reportable Food Registry.

D. If a recall is initiated, product from the same lot (and any potentially associated lots) cannot be shipped and shall be quarantined.

E. Where customer-branded products not meeting specifications are sold to staff or passed on to charities, this shall be with the prior consent of the brand owner, and shall be fit for consumption,

meeting the legal requirements.

F. Clearly define the individuals/roles responsible for decisions pertinent to non-conformance, release, rework, reconditioning, or destruction of product.

Warehousing and Distribution

The storage and transport of food shall be under conditions that will protect against allergen cross-contact, cross contamination, and deterioration. 21 CFR § 117.93.

A. Pallet Management

1. A formalized procedure for the purchasing and management of pallets should be established.

2. Pallets, whether plastic or wooden, should only be purchased from approved suppliers that can give assurances on the hygiene and structural soundness.

3. Upon arrival on site, the pallets should be inspected to ensure that they meet the purchasing specification. Wooden pallets need to be checked to ensure that they are clean, dry, free from wooden or metal contamination, have not been treated with unsuitable chemicals (as a wood preservative), and show no signs of infestation.

4. Wooden splinters are a concern and should be inspected immediately before use. Wet, severely damaged, or splintered pallets should not be used. A hygiene slip sheet should be put on the pallet to prevent moisture or minor splinters from damaging the product packaging.

5. If product is to be double-stacked, a slip sheet should also be put on the top of the lower pallet, to prevent the bottom of the top pallet contaminating the product/packaging.

6. Plastic pallets should be inspected to ensure they are clean and dry, have no or only minor damage and scarring, and no holes or cracks in the pallet that may harbor water or other contaminants.

B. Warehouse Storage

1. Storing products on pallets should allow for easy inspection and cleaning and help prevent any risk of product dampness from condensation from the floor. Plastic overwrap should be considered to protect palleted product from the environment.

2. In the event of a water or roof leak, affected pallets of product shall be inspected for impact/damage.

3. Palleted ingredients or product should never be stepped upon.

4. Damage caused by forklifts shall be cleaned-up and addressed immediately.

5. Product storage and alignment shall be arranged in a manner to allow proper pest management, cleaning and inspection.

6. Warehouse employees shall be trained on proper warehouse GMPS and hygienic requirements.

C. Dispatch and Transport

1. Before dispatching a product, the vehicle or container should be inspected to ensure it is suitable for food use.

    1.1 This inspection should be documented and should include: holes that can allow pests or rain to get onto the product, aroma of the container, flaking paint, door seals, presence of allergenic material, presence of non-food residues, condition of any wooden part to check for damage or insect activity, presence of any oil, grease or other liquid.

2. There should be a system in place to ensure that only the designated items go into the container and that the container is suitably sealed to ensure that the material within cannot be tampered with. Suppliers should have systems in place to ensure that there is no risk of accidental or deliberate contamination during transport.

3. There should be a documented vehicle breakdown or damage procedure that ensures that product is protected in these instances. This should be communicated to the transport company so that they know what to do in the event of a breakdown or damage.

4. Only food items are allowed to be delivered in any container or any vehicle. They should not be mixed with non-food items.

5. Ensure that suppliers take appropriate steps to prevent condensation and protect product from moisture during transportation.

6. Where temperature control is required, transport shall be capable of maintaining product temperature within specification with data-loggers or monitoring systems.

7. Maintenance and cleaning procedures shall be maintained for all vehicles and equipment used for loading/unloading.

8. Where third-party contractors are employed, all the requirements indicated here shall be defined in the contract and verified.

Animal Food Handling/Distribution

D. By-products held for distribution as animal food without additional manufacturing or processing by the processor shall be held under conditions that will protect against contamination, including the following: 21 CFR § 117.95.

1. Containers and equipment used to convey or hold animal food before distribution shall be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against contamination including trash.
2. Labeling that identifies the by-product by the common or usual name shall be affixed to or accompany the animal food when distributed.
3. Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute animal food shall be examined prior to use to protect against contamination.

IX. Food Safety & Quality Assurance

Training

A. The facility's management shall ensure that all individuals working in receiving, production, warehousing, maintenance, QA, and sanitation are adequately trained and qualified to perform their assigned duties. 21 CFR § 117.4(a)(1).

B. All employees shall receive training in the principles of food hygiene and food safety, including the key principles of this guidance; and their role in protecting against contamination and adulteration. 21 CFR § 117.4(b)(2).

C. Responsibility for ensuring compliance by individuals shall be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food. 21 CFR § 117.4(c).

D. Under Part 117, one or more preventive controls qualified individuals shall do or oversee the activities related to the food safety plan. 21 CFR § 117.126(a)(2). Per 21 CFR § 117.180, to be a preventive controls qualified individual, the individual 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.

Internal GMP Auditing

A. A robust internal auditing system is one of the best tools available to ensure that safe, legal, and good-quality spices are manufactured. Company employees know where systems need improvement and should be encouraged to identify failings in the company's systems so that alternatives can be established. A GMP audit covers both food safety and quality, with a focus on the manufacturing environment. A good GMP auditing program ensures that the facility is operated in accordance with GMPs on a day-to-day basis.

B. Perform GMP audits according to a designated schedule and with a formalized output and corrective action system. Audits are more effective utilizing a cross functional team approach including inspections by facility leadership. Lead auditors should be trained and independent of the area they are auditing.

C. Audit one department at a time rather than the whole facility at once. Table 3 provides an example audit schedule using this concept.

D. The audits should focus on facility inspection and observations but also include document review for completeness and compliance. At a minimum, include the following attributes within the scope of the audit:

    1. CCP/Preventive control monitoring documentation
    2. Pest control and proofing
    3. Condition of building infrastructure
    4. Glass and brittle plastic management
    5. Personal practices and operating methods
    6. Hygienic zoning compliance
    7. Tool condition, design, and control
    8. Equipment condition and maintenance; temporary repairs
    9. Product inventory control, labeling and storage
    10. Master Sanitation Schedule (MSS) compliance and SSOPs with verification
    11. Allergen management

12. Process control and record keeping

13. Contract services, water, air, etc. and their food safety risk

14. Warehouse, ingredient and packaging storage and segregation, and pallet conditions

E. It is recommended that a numerical (rather than yes/no) scoring system be implemented to provide metrics for trending facility performance. Define the scoring system to drive consistency between audits and auditors.

F. Review the output from GMP audits carefully, perform root cause analysis, and allocate resources for corrective action where needed. Consider sharing results in team meetings to reinforce a culture of food safety.

Table 3. Sample audit staging

Audit Stage	**Area**
1	Building exterior and land
2	Raw material and finished product storage
3	Primary cleaning department
4	Milling or blending department
5	Laboratory, locker rooms, facility entrance, and other ancillary areas

Records

A. Records are critical to document training, calibration, monitoring, validation and verification and other activities to demonstrate program compliance.

B. Company policy on record retention should consider minimum relevant regulatory requirements.

C. As a reference per 21 CFR § 117.305 and 117.315, records shall:

1. Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;

2. Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities;

3. Be accurate, indelible, and legible;

4. Be created concurrently with performance of the activity documented;

5. Be as detailed as necessary to provide history of work performed; and

6. Include:

    6.1 Information adequate to identify the facility (e.g., the name, and when necessary, the location of the facility);

    6.2 The date and, when appropriate, the time of the activity documented;

    6.3 The signature or initials of the person performing the activity; and

    6.4 Where appropriate, the identity of the product and the lot code, if any.

7. All records required by Part 117 shall be retained for at least 2 years after the date they were prepared.

8. Records that a facility relies on to support its status as a qualified facility shall be retained at the facility as long as necessary to support the status.

9. Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, shall be retained by the facility for at least shelf-life plus one year or minimum 2 years after their use is discontinued.

10. Except for the food safety plans, records may be stored offsite if they can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan shall remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.

11. Records obtained by regulators may be subject to the public disclosure requirements.

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