AIB INTERNATIONAL®

Consolidated Standards for Inspection

Prerequisite & Food Safety Programs for Beverage Facilites

Consolidated Standards
for
Inspection

Prerequisite & Food Safety Programs
for
Beverage Facilities

North America
Latin America
Europe/Middle East/Africa
Asia/Pacific

www.aibinternational.com

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Preface

Document Description

The AIB International Consolidated Standards for Inspection of Beverage Facilities is a collection of information gathered to help a reader understand:

- What an inspection is
- The difference between an inspection and an audit
- How to read and use the AIB International Consolidated Standards
- How an AIB International inspection is scored
- How to prepare for and participate in an AIB International inspection
- Additional sources for understanding, implementing, and expanding Prerequisite and Food Safety Programs

Document Structure

For ease of use, this document is structured as follows:

- Consistent terminology used throughout the document
- Clear, unambiguous language that can be globally understood
- Current-use language and not "regulation speak"
- Standards constructed with the same hierarchy:
  - ◊ Category
    - Standard
      - » Requirement

Definitions of Inspection and Audit

An ***inspection*** is a thorough physical review of a food facility to assess what is actually happening in a facility at a moment in time. This snapshot gives a realistic assessment of conditions that can be both positive and negative for food processing. An inspection focuses on ***physical review*.**

An ***audit*** is a systematic evaluation of food facility documentation to determine if programs and related activities achieve planned expectations. An auditor looks at data over time to see if positive or

negative trends are developing. An audit focuses on ***documentation review*.**

These standards are a combination of inspection and auditing with a focus on inspection.

Introduction to the Standards

The AIB International Consolidated Standards for Inspection of Prerequisite and Food Safety Programs are statements that represent key requirements a facility must meet in order to keep the food products in its facility wholesome and safe. The Standards also reflect what a Food Safety Professional would expect to see in a facility that maintains a food-safe processing environment.

The Categories

The Standards include five categories:

1. Operational Methods and Personnel Practices

The receipt, storage, monitoring, handling, and processing of raw materials to manufacture and distribute safe final product.

Standards in this category are related to food handling and processing. Facilities need to be confident that personnel, processes, and conditions do not introduce a food safety concern as raw materials are received, transferred, stored, transported, manipulated, or processed to deliver a final product. The Operational Methods and Personnel Practices Standards show how a facility can prevent people and processes from contaminating a product.

2. Maintenance for Food Safety

The design, upkeep, and management of equipment, buildings, and grounds to provide a sanitary, efficient, and reliable manufacturing environment.

Standards in this category are related to equipment, grounds, and structures. The design, construction, and maintenance of equipment and buildings are critical to providing and maintaining a food-safe environment. The Maintenance for Food Safety Standards provide best practices for optimizing the design and care of the facility and equipment so that they are easy to manage and do not create sanitation or food safety issues.

3. Cleaning Practices

The cleaning and sanitizing of equipment, utensils, and buildings to provide a wholesome and food-safe processing environment.

Standards in this category are related to cleaning and sanitizing. The methods of cleaning and sanitizing, types of chemicals used, frequency of cleaning activities, and control of microbes must all be done expertly to protect products from food safety issues. The Cleaning Practices Standards provide cleaning guidelines to prevent contamination.

4. Integrated Pest Management (IPM)

The assessment, monitoring, and management of pest activity to identify, prevent, and control conditions that could promote or sustain a pest population.

Standards in this category are related to pest management. While it is important to remove pests from a facility, it is more important to prevent pests from ever having the opportunity to thrive in a food environment. The Integrated Pest Management Standards provide strategies for managing multiple approaches to ensure that pests do not adulterate food products.

5. Adequacy of Prerequisite and Food Safety Programs

The coordination of management support, cross-functional teams, documentation, education, training, and monitoring systems to ensure all departments of the facility work together effectively to deliver a wholesome and safe final product.

Standards in this category are related to management and food safety culture. It is important to have programs in place, but if a program is not formalized through designing, planning, management, documentation, and review, then Prerequisite Programs will depend on who is undertaking a given activity or task that day. The Adequacy Standards make sure that Prerequisite Programs are carefully designed and implemented to ensure consistency across the entire facility.

Note: While other categories focus mainly on inspection, this category largely involves evaluation of program documentation (audit). However, the observations made, and documents

reviewed in the first four categories will directly affect how the Food Safety Professional assesses the facility in the Adequacy category. Findings on the floor are a direct reflection of how well programs have been implemented.

How to Read the Standards

Category Name

Category Description
A full sentence describing how the Standards in the category are related.

Standard
The key point of the Standard.

Standard Description
Why a facility would want to implement the Standard.

Minor Requirements
These are the minor requirements against which a facility is scored. Minor requirement observations are assessed as Minor Issues Noted. A 4-place number with
a 3rd place value of "2" identifies Minor Requirements.

Critical Requirements
These are the critical requirements against which a facility is scored. Critical requirement observations are assessed as Improvement Needed, Serious, or Unsatisfactory unless there is an alternate program in place that meets the intent of the requirements. A 4-place number with a 3rd place value of "1" identifies Critical Requirements.

2. Maintenance for Food Safety

The design, upkeep, and management of equipment, buildings, and grounds to p
sanitary, efficient, and reliable manufacturing environment.

2.1 Facility Location

Selection and management of the facility location allows personnel to
control potentially negative impacts of surrounding operations.

Critical Requirements

2.1.1.1 The facility identifies and takes measures to prev
product contamination from local activities that
adverse impacts.

Minor Requirements

2.1.2.1 Facility boundaries are clearly defined and con

2.2 Outside Grounds and Roof

The facility grounds are maintained in a way that prevents food a

Critical Requirements

2.2.1.1 Equipment stored outside is placed to prever
harborage, make the inspection process easi
equipment from deterioration and contamin

2.2.1.2 Litter and waste are removed from the prop
necessary to maintain sanitary conditions.

2.2.1.3 Vegetation such as trees, shrubs, weeds, an
not provide pest harborage or access to the

2.2.1.4 Roads, yards, and parking areas are mainta
dust, standing water, and other potential c

2.2.1.5 Adequate drainage is provided for ground
areas.

2.2.1.6 Outside wet and dry waste or scrap comp
and containers are installed in a way that
contamination. Containers are maintaine
contain leakage and are removable so th
cleaned.

2.2.1.7 Waste containers and compactors are c
located on a concrete pad or in a manne
attraction and harborage.

Θ — Indicates Standards Not Applicable to Beverage Facilities

The Consolidated Standards for Inspection of Beverage Facilities is a targeted version of the more general AIB International Consolidated Standards for Inspection of Prerequisite and Food Safety Programs. The numbering convention from the Prerequisite and Food Safety Programs Standard is preserved in the Beverage Facilities Standard in order to keep numbering consistent.

However, any Standards or requirements from the Prerequisite and Food Safety Program Standard that are not applicable to the beverage industry are not included in this document. A symbol, Θ, signifies that missing numbers in the series of Standards or requirements are intentional.

Scoring

The scoring of the facility occurs in five steps:

1. The Inspection
2. Determining Risk and Assigning Category Scores
3. Evaluating the Adequacy of the Food Safety Program
4. Total Score
5. Recognition

The Inspection

1

Like a chain, the strength of a Food Safety Program depends on its weakest link.

To assess the food safety risks in a facility, an AIB Food Safety Professional conducts a thorough, physical inspection of the facility and concludes with a review of written programs. The Food Safety Professional notes observations based on the five categories of The AIB International Consolidated Standards for Inspection:

1. Operational Methods and Personnel Practices
2. Maintenance for Food Safety
3. Cleaning Practices
4. Integrated Pest Management (IPM)
5. Adequacy of Prerequisite and Food Safety Programs

2 Determining Risk and Assigning Category Scores

The AIB Food Safety Professional will then assign a level of risk and a Category score to the five categories shown above. Use Table 1 as a guide.

Table 1—Risk Assessment

Risk Assessment	Description	Category Score Range
No Issues Observed	No identified risk	200
Minor Issues Noted	No potential for contamination or program failure	180–195
Improvement Needed	A potential hazard, partial program omission, or food safety finding that is inconsistent with the standards; if this hazard, omission, or finding is not corrected, it could lead to a program failure	160–175
Serious	A significant food safety risk or risk of program failure	140–155
Unsatisfactory	An imminent food safety hazard, program failure, or departure from the Good Manufacturing Practices	≤135

The Food Safety Professional uses a three-step process to determine risk. The Food Safety Professional:

1. Determines the most significant observation(s) in a category and assigns a score range.
2. Determines the severity of the most significant observation(s) and decides whether the initial score should be at the top or bottom of the score range assigned.
3. Lowers the initial score in five-point increments for each additional observation if the assigned score is at the top of the score range.

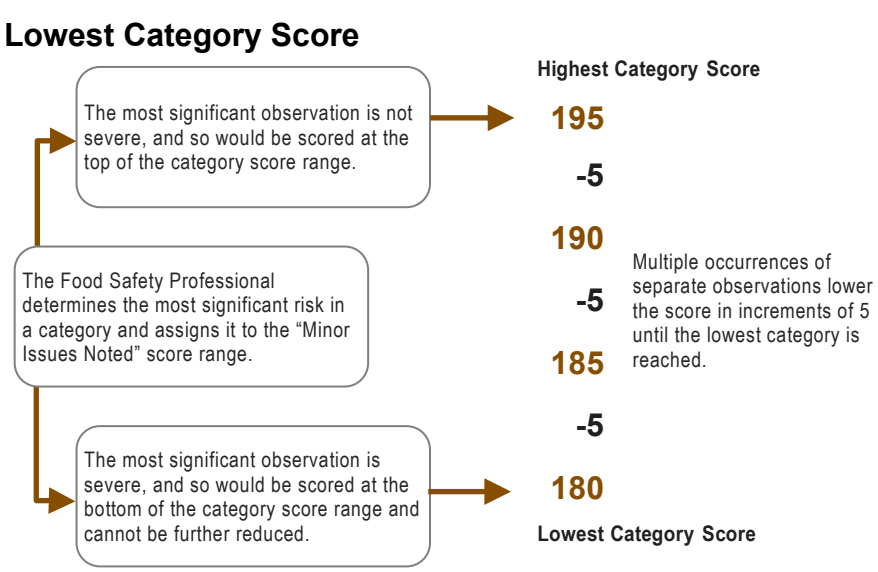

Figure 1—Example of Risk and Category Score Determination in the Minor Issues Noted Range

Here are some scoring guidelines:

- The initial score for a category is always either at the top or the bottom of the range.
- A category score can be adjusted from the top of the range, but will never go below the bottom of the range.
- All critical or minor findings associated with a single Standard of a category would be grouped together as a single observation. For example, any findings (single or multiple) noted under the following Standard and related requirements would only be counted as one observation:

  1.6 Pallets
  1.6.1.1
  1.6.1.2
  1.6.1.3
  1.6.2.1

- Findings assigned to several Standards within a category would be considered distinct and separate observations. For example, any findings (single or multiple) noted for each of the following Standards would be counted as two observations:
  - 1.1 Receipt/Rejection of Dry Goods
  - 1.3 Storage Practices
- A single observation in a category may be severe enough to require the category to be scored at the bottom of the score range. Severity can be due to a single significant observation, or it can be due to multiple findings establishing a pattern within a single observation.
- Observations of Minor Requirements are always assessed in the Minor Issues Noted score range.
- If the initial score is at the top of the assigned score range, each additional observation lowers the score in five-point increments. Possible scores are listed in Table 2.

Table 2—Lowering an Initial Category Score for Multiple Observations

# of Observations	Category Scores for All Risk Assessments			
	Minor Issues Noted	Improvement Needed	Serious	Unsatisfactory
1	195	175	155	135
2	190	170	150	130
3	185	165	145	125
4	180	160	140	120
5+	180	160	140	115*

* Will be lowered an additional 5 points for additional observations.

Evaluating the Adequacy of the Food Safety Program

The evaluation of the written programs is not limited to determining if a written program and its records are in place and current. What the AIB Food Safety Professional sees in the facility determines whether or not the written Food Safety Programs actually work. A facility cannot have

perfect programs if food safety observations are noted during the inspection.

The Food Safety Professional reviews the observations in the facility against the written programs to determine where the gaps in the program exist and what should be done to alleviate these conditions.

The score for the Adequacy Category is determined using the same method that is used for calculating the other four category scores. The Adequacy Score, however, is also guided by four additional rules.

Rules to Determine the Adequacy Score

Rule 1: The Adequacy Score cannot be the highest score. How can the programs that manage outcomes in the other categories be scored higher than the categories themselves?

Rule 2: The Adequacy Score can be no more than one Risk Level higher than the category with the worst observation. In other words, if the worst Risk Categorization is Serious, how could the Adequacy section be said to have only minor issues with its operation? Again, this relates to how well the program functions in a facility. See Table 3.

Table 3—Maximum Adequacy Score Based on Rule 2

Worst Risk Assessment	Related Score Range for Worst Risk Assessment	Maximum Adequacy Score Range
Minor Issues Noted	180–195	195*
Improvement Needed	160–175	180–195
Serious	140–155	160–175
Unsatisfactory	≤135	140**

*Rule 4 applies | **Rule 3 applies

Rule 3: If the worst score is at the bottom of the score range, the Adequacy Score can be no higher than the bottom category score, one level above. If observations require the score to be at the bottom of the category score range, this indicates that the related program is not effective.

Table 4—Maximum Adequacy Score Based on Rule 3

Worst Risk Assessment	Score of Worst Risk Categorization at Lowest Number in the Score Range	Maximum Adequacy Score
Minor Issues Noted	180	195*
Improvement Needed	160	180
Serious	140	160
Unsatisfactory	≤ 135	140

*Cannot be the highest category score

Note: This rule does not apply if scoring a category where the worst risk level is "Minor Issues Noted."

Rule 4: A 200 may only be assigned for Adequacy if the other four category scores are all assigned a 200; e.g., the only way it can be said that the programs are working perfectly is if there are no observations to indicate otherwise.

Total Score

The Total Score is the sum of the points assigned to each category: Operational Methods and Personnel Practices, Maintenance for Food Safety, Cleaning Practices, and Integrated Pest Management, but is not complete until aligned with the Adequacy of Prerequisite and Food Safety Programs because written programs drive the results from the other four categories.

Recognition

Recognition is based on the Total Score assigned to the facility. A recognition document will be awarded to the facility when:

- The inspection is based solely on the AIB International Consolidated Standards for Inspection (not customer-defined interpretations or guidelines)

- There is:
  - No category score less than or equal to 135
  - There are no unsatisfactory findings (even if the Total Score is at or above 700)

The AIB International Recognition Document:

- Recognizes that on the day of the inspection, the facility achieved a certain score according to the AIB International Consolidated Standards for Inspection
- Is not a certificate of compliance (like an ISO certificate)
- Expires after one year
- Is labeled as announced, unannounced, or announced to corporate
- Is labeled as Hybrid or Virtual if not fully conducted as an onsite inspection
- Defines which areas of the facility were included in the inspection

Sample Scoring with Explanations

Category Score Range	180–195	160–175	140–155	≤ 135	
Category	# Minor Issues Noted Observations	# Improvement Needed Observations	# Serious Observations	# Unsatisfactory Observations	Category Score
Operational Methods and Personnel Practices	6	0	0	0	180 A
Maintenance for Food Safety	8	3	0	0	165 B
Cleaning Practices	8	1	0	0	160 C
Integrated Pest Management	2	4	3		145
Adequacy of Prerequisite and Food Safety Programs	0	3	0	0	165
				Total Score	815

D E

A The Food Safety Professional noted six observations at the lowest risk of severity, but the category score does not go lower than the lowest possible score for the Minor Issues Noted category (180).

B Three observations are documented. There were actually five findings, but three of the findings were related to the same requirement in the Standard and were therefore grouped together as a single observation.

C The severity of the single observation was significant, so the score at the bottom of the score range (160) is assigned.

D The Serious observations that posed the most potential for contamination were at the lowest severity of risk, so the category score begins with the first observation at 155. There were two additional observations, so the score was lowered by five points for each to 145.

E The Adequacy Score is determined using the most constraining rules that apply:

- The observation with the most significant risk is in the Improvement Needed category so the score should fall in the 160–175 range.
- The most significant observation is not severe, so the initial score is 175.
- There are three separate observations, so five points are deducted for each additional observation beyond the first (175 to 170 to 165).
- **Rule 1:** The highest score in the other four categories is 180, but that is outside the 160-175 range so Rule 1 does not apply.
- **Rule 2:** The lowest score in the other four categories is 145, so the Adequacy Score can be no higher than the 160-175 range.
- **Rule 3:** The lowest category score (145) is not at the bottom of the range, so Rule 3 does not apply.
- **Rule 4:** The other four categories are not assigned a 200, so Rule 4 does not apply.

Automatic Assessment of Unsatisfactory

The following list includes examples of a few commonly found conditions that require an assessment of Unsatisfactory. This list *only represents examples* of unsatisfactory conditions and is not complete. Similar conditions not specifically stated will be assessed by the Food Safety Professional.

1. Operational Methods and Personnel Practices
   a. Holding temperatures (refrigerators or coolers) in excess of 40°F or 4°C for microbiologically sensitive ingredients or products (Note: the exact temperature limit may vary depending on country regulation)
   b. Open sores or boils on personnel who have direct contact with product, ingredients, or product zones
   c. Torn liquid receiving strainer
   d. Ingredients that are internally infested
2. Maintenance for Food Safety
   a. Flaking paint, rust, or other materials in the product zone where product contamination is likely
   b. Maintenance activity or equipment condition resulting in oil, metal, or other foreign material in or over a product zone
3. Cleaning Practices
   a. The presence of extensive amounts of mold either on or near product zones
   b. Widespread infestation above sensitive or exposed ingredients, above product zones, or in equipment
   c. The presence of allergen-containing materials either on or above product zones while running product that does not contain the allergen
4. Integrated Pest Management
   a. Insects
      i. Any insect activity where product contamination is likely
   b. Rodents, Wildlife, Domestic Animals
      i. Visual presence of live animal inside the building
      ii. Evidence of animal excreta or gnaw marks on raw materials or finished product
      iii. Decomposed animal inside the building
   c. Bird activity in processing areas
      i. Bird activity in processing areas

ii. Bird excreta on product zones, raw materials, or finished product
iii. Resident birds in warehouses

d. Pesticides used inconsistently with label directions

5. Adequacy of the Prerequisite and Food Safety Programs
   a. Non-compliance with written programs
      i. Failure to comply with HACCP critical limits, HARPC Preventive Controls limits, monitoring, or validation requirements
   b. Poorly defined written Prerequisite Programs
      i. Inadequate or ineffective implementation of a Prerequisite Program resulting in actual or likely product contamination (Program Failure)
   c. Failure to comply with regulatory mandates

Consolidated Standards for Inspection

1. Operational Methods and Personnel Practices

The receipt, storage, monitoring, handling, and processing of raw materials to manufacture and distribute safe final product.

1.1 Receipt/Rejection of Dry Goods

Materials including but not limited to raw materials, ingredients, processing aids, finished products, returned goods, as well as equipment and/or returned containers, trays, and carts are inspected prior to receipt. Potentially contaminated materials are rejected.

Critical Requirements

1.1.1.1 Damaged, infested, or dirty vehicles and their contents are rejected and reasons for rejection are documented.

1.1.1.2 Damaged, infested, or dirty materials are rejected and reasons for rejection are documented.

1.1.1.3 Shuttle vehicles are in good condition, clean, and free of holes and infestation.

1.1.1.4 Raw materials, ingredients, processing aids, packaging, finished products, returned goods, as well as equipment and/or returned containers, pallets and trays are inspected during receipt.

1.2 Rejection of Shipments/Receipt of Perishables

Perishable materials are inspected prior to receipt. Potentially contaminated or temperature abused materials are rejected.

Critical Requirements

1.2.1.1 Damaged, infested, or dirty vehicles and their contents are rejected and reasons for rejection are documented.

1.2.1.2 Damaged, infested, or dirty materials. are rejected and reasons for rejection are documented.

1.2.1.3 Perishable or frozen materials meet specific minimum temperature requirements at points of shipment, transportation, and receipt.

1.2.1.4 Temperature requirements for perishable or frozen materials are not compromised during the reception/receiving process.

1.2.1.5 The facility maintains documentation of temperature checks for perishable goods at receiving points.

1.2.1.6 Shuttle vehicles are in good condition, clean, and free of holes and infestation, and maintaining food safe temperatures.

1.2.1.7 Perishable materials are inspected during receipt.

1.3 Storage Practices

Raw materials, packaging materials, and finished products are stored in a way to meet program requirements for food-safe storage of materials.

Critical Requirements

1.3.1.1 Materials, including but not limited to raw materials, packaging, work-in-process, finished products, and food contact processing aids, etc., are stored and removed from storage in a manner that prevents contamination.

1.3.1.2 Materials are stored off the floor on pallets, slip-sheets, or stands.

1.3.1.3 A clear, unrestricted perimeter is provided at floor-wall junctions to ensure adequate access for cleaning, inspection, and IPM activities.

1.3.1.4 Adequate spacing is provided between rows to allow for cleaning and inspection.

1.3.1.5 If materials are stored outside, they are adequately protected against deterioration, pest activity, and contamination.

1.3.1.6 Dates used for stock rotation are on a permanent part of the raw material packaging (i.e., not on the stretch wrap), where applicable.

Minor Requirements

1.3.2.1 Storage slots and traffic lanes are provided for items stored at floor level.

1.4 Storage Conditions

Raw materials, packaging materials, and finished products are stored in a clean storage area and protected from contamination.

Critical Requirements

1.4.1.1 Storage areas are clean, well ventilated, and dry. Stored materials are protected from condensate, sewage, dust, dirt, chemicals, or other contaminants.

1.4.1.2 Partially used packaging materials or raw materials are protected before being returned to storage.

1.4.1.3 All chemicals, including cleaning and maintenance compounds, and non-product materials, including equipment and utensils, are stored in a separate area. Chemicals are labeled and secured as defined in the Chemical Control Program.

1.4.1.4 Research and Development items and infrequently used raw materials, packaging supplies, and finished products are regularly inspected for signs of infestation and properly maintained.

1.4.1.5 Special handling procedures are followed for packaging materials that pose a product safety risk if mishandled (e.g., glass packaging). Failures and corrective actions are documented.

1.4.1.6 Returned products are not available for use until they are inspected and dispositioned by authorized personnel.

Minor Requirements

1.4.2.1 Packaging is stored away from raw materials and finished product or in a way that will not be negatively impacted by raw materials and finished product.

1.4.2.2 Materials and supplies staged for use are inspected for damage, contamination, and specification compliance, as applicable, prior to use.

1.5 Raw Material/Packaging/Finished Product Inventory

Raw material, packaging, and finished product inventories are maintained at reasonable volumes to avoid excessive age and insect infestation.

Critical Requirements

1.5.1.1 Ingredients, packaging supplies, work-in-process, finished products, and other materials are rotated on a First- In, First-Out (FIFO) basis or other verifiable method (such as First Expired, First Out [FEFO]) to ensure stock rotation.

1.5.1.2 Insect-susceptible materials in storage longer than four weeks are regularly inspected, but no less than every four weeks.

1.5.1.3 Food contact containers are covered or inverted while in storage to protect against contamination.

Minor Requirements

1.5.2.1 A system is defined and followed for identifying and tracking the inspection of insect-susceptible materials (e.g., aged stock inventory, re-palletizing dates, etc.).

1.6 Pallets

Pallets are clean and well-maintained to minimize opportunities for contamination.

Critical Requirements

1.6.1.1 Pallets are clean, in good repair, and used in a way that does not create hazard to materials.

1.6.1.2 When pallets are stored outside, they are inspected for evidence of contamination (i.e., insects, mold, chemicals) before being brought into the facility for use.

1.6.1.3 Clean slip-sheets are placed between pallets and bags of ingredients, and between double-stacked pallets to protect ingredients from damage by the pallet.

Minor Requirements

1.6.2.1 Pallets and other wooden surfaces are properly dried after being washed.

1.7 Carry-over and Rework

Raw materials, rework, work-in-process, and carry-over are identified and managed to prevent food safety issues.

Critical Requirements

1.7.1.1 There is a designated rework storage area that is segregated from usable materials.

1.7.1.2 There is an established maximum storage time for rework material. Rework is processed often enough to keep rework quantities at minimal levels and not past established expiration dates.

1.7.1.3 Carry-over is minimal and used at the first opportunity.

1.7.1.4 Carry-over product, work-in-process, rework, and raw materials are properly identified and dated for traceability purposes. Expiration dates are included as applicable.

1.7.1.5 Reworked and carry-over materials are lot traceable.

1.7.1.6 Reworked materials are strained/sifted prior to use, as applicable, based on a risk assessment.

1.7.1.7 A break in the rework process is defined. Records demonstrate that the break and clean process is followed.

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1.9 Bulk Material Handling

Bulk systems, unloading areas, and loading areas are managed through proper shipping and receiving practices to ensure product protection during unloading and loading activities.

Critical Requirements

1.9.1.1 Outside receiving lines or caps for bulk dry and liquid ingredients are locked, identified, or otherwise secured.

1.9.1.2 Air is filtered or inspection hatches are covered when bulk materials are unloaded to eliminate the potential for foreign material contamination during the process.

1.9.1.3 Security seals on bulk container hatches or other shipping containers are checked against the seal number on the shipping document to verify that the numbers match during shipping and receiving.

1.9.1.4 Conveying tubes or hoses are on supports off the ground or floor to prevent contamination or submersion in water.

1.9.1.5 Pneumatic systems or blowers are provided with air filters.

1.9.1.6 Hoses, caps, and couplings are cleaned before storage in a secured area.

1.9.1.7 Tanker wash tags or other documentation of cleaning/washing and/or prior load verification are reviewed and records are maintained.

1.10 Sampling Procedures

Because sampling involves direct contact with raw materials, finished product, or work-in-process, procedures are defined to prevent product contamination.

Critical Requirements

1.10.1.1 The facility has documented appropriate sampling procedures in place for obtaining samples of incoming raw materials in a manner that does not contaminate product.

1.10.1.2 All openings created for sampling in bags, boxes, or containers are properly resealed and identified as having been sampled.

1.10.1.3 Staples and other items likely to cause product contamination are not used to reseal packaging materials.

1.11 Processing Aids

Processing aids are food contact materials and therefore managed to prevent contamination of product.

Critical Requirements

1.11.1.1 All food contact processing aids, such as antifoam and release agents, are segregated from nonfood materials.

1.11.1.2 Processing aids are labeled for their intended use.

1.11.1.3 Food approval documentation for food contact processing aids is on file.

1.11.1.4 All processing aids are evaluated to determine if they contain allergens. If the processing aid contains an allergen, control procedures consistent with the Allergen Control Program are followed.

1.12 Material Transfer

Once received, raw materials are transferred to points of use within the facility. Sometimes, the raw materials are put into smaller containers to facilitate handling. The transfer of raw materials is carefully managed to avoid introduction of contaminants.

Critical Requirements

1.12.1.1 The facility follows procedures for transferring and handling materials and includes a system to provide traceability information throughout the process.

1.12.1.2 Containers are always kept off the floor and other walking surfaces and covered when not in use.

1.12.1.3 Raw material, work-in-process, and finished product containers are properly identified to maintain the materials' integrity and traceability.

1.12.1.4 Protective outer wrapping is removed from raw materials and packaging in a manner that eliminates potential contamination.

1.12.1.5 Conveying tubes or hoses used to transfer raw materials, ingredients, and product are on supports off the ground or floor to prevent contamination or submersion in water.

1.12.1.6 All containers used for raw materials, work-in-process, finished product are properly labeled or color coded to identify contents.

1.12.1.7 Materials selected for transport to processing areas are visually inspected and cleaned prior to transport.

1.12.1.8 Drums, barrels, bags, pails, and boxes are cleaned prior to opening. Observation demonstrates that raw material containers are opened in a manner that prevents the introduction of foreign material.

Minor Requirements

1.12.2.1 Personnel quickly address spills, leaks, and waste caused by transfer of raw materials.

1.13 Material Sifting

Dry materials are sifted to identify and eliminate foreign material or insects. The equipment used for sifting is monitored to ensure effectiveness.

Critical Requirements

1.13.1.1 All bulk dry materials are sifted before use.

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1.13.1.4 Sifters, sieves, rebolters, and scalpers for finely milled dry materials are inspected for torn screens and other defects at least weekly.

1.13.1.5 The facility maintains records of equipment inspections.

1.13.1.6 Reject materials (tailings) are visually inspected no less than daily.

1.13.1.7 The source of any unusual foreign material in sifter tailings is identified and addressed.

1.13.1.8 The facility maintains records of tailing findings and corrective actions.

1.13.1.9 If foreign material that could damage the sifter, sieve, rebolter, or scalper screens is found in the tailings, those screens are immediately inspected for damage.

1.14 Receiving Filters and Strainers

Liquid materials (including processing aids) are strained during receipt and strainers are regularly checked to identify foreign material and prevent contamination of liquids.

Critical Requirements

1.14.1.1 All bulk liquid materials are filtered with inline receiving strainers.

1.14.1.2 Strainers are cleaned and inspected for integrity after each load.

1.14.1.3 Strainer mesh sizes are sufficiently restrictive to remove foreign material from liquid materials handled. Strainers are properly installed in the housing without gaps to prevent bypass.

1.14.1.4 Strainers used to remove foreign material are inspected, and findings and corrective actions are documented and kept on file.

1.14.1.5 If strainers are provided on the truck, or portable strainers are used at the site, the presence of a clean and intact strainer is verified prior to pumping of material.

1.15 Foreign Material Control Devices

Sifters, magnets, strainers, X-ray machines, metal detectors, etc. are installed at appropriate locations to monitor and prevent the inclusion of metal, wood, glass, and other foreign materials.

Critical Requirements

1.15.1.1 Precautions are taken to minimize product contamination when staples or similar items are used in packaging materials.

1.15.1.2 Foreign material control devices are located at the last possible point on all production lines.

1.15.1.3 Metal detectors or X-ray machines incorporate an alarm and/or an automatic rejection device that diverts contaminated product into a secured and controlled area accessible only to authorized personnel, or otherwise maintain control of the rejected product.

1.15.1.4 Product rejections or unusual foreign material findings are investigated, and corrective actions are taken to identify and eliminate contamination issues.

1.15.1.5 Foreign material control devices such as metal detectors, strainers, X-Ray devices, etc. are appropriate to the product or process, and detect metal wear or other physical contamination.

1.15.1.6 The facility follows procedures to operate, monitor, and test foreign material control devices.

1.15.1.7 Foreign material control devices are regularly monitored and documented.

1.15.1.8 The facility follows Corrective Action and Reporting Procedures to respond to foreign material control device failures. These procedures may address but are not limited to:

- Isolating
- Quarantining
- Re-testing all food produced since the last acceptable test of the device

1.16 Waste Material Disposal

Waste materials and their removal are managed to avoid contamination.

Critical Requirements

1.16.1.1 Waste is stored in properly identified containers.

1.16.1.2 Waste is managed to prevent pest and microbial issues. Management techniques may include cleaning, covering, and emptying containers regularly.

1.16.1.3 Traffic routes for waste disposal do not place food or food contact surfaces at risk.

1.16.1.4 Trash or inedible waste is handled in a way that does not cause cross-contact or contamination to raw materials, work-in-process or finished product at any time.

1.16.1.5 Licensed contractors remove waste, where required.

1.16.1.6 Waste disposal meets food regulatory requirements.

1.16.1.7 Human food by-products for use as animal food are stored in clean, labeled, and covered containers to protect against contamination

1.17 Ingredient Containers, Utensils, and Tools

Ingredient containers, utensils and tools are managed to prevent cross-contamination and cross-contact issues.

Critical Requirements

1.17.1.1 All in-use ingredient containers have individual transfer scoops, as needed based on risk assessment, to prevent cross-contamination and/or cross-contact.

1.17.1.2 Ingredient scoops, tools, and utensils are color-coded or otherwise identified, in a manner that does not allow a cross-contamination and/or cross-contact.

1.17.1.3 Containers and utensils used to transport, process, hold, or store raw materials, work-in-process, rework, or finished products are constructed, handled, and maintained in a way that prevents contamination.

1.17.1.4 Containers for materials, including but not limited to raw materials, work-in-process or finished products, are only used for their designated purposes.

1.17.1.5 Containers are legibly labeled with contents.

1.17.1.6 Snap-off blades are not used in production, packaging, or raw material storage areas.

1.18 Allergen Handling

Allergen containing materials are identified and handled in a way to prevent cross-contact with different allergens or non-allergens.

Critical Requirements

1.18.1.1 An identification system (i.e., color coding or other) is in place for allergen containing materials.

1.18.1.2 Items containing allergens do not cause a food safety issue. Examples include but are not limited to processing aids, food contact lubricants, and hand washing soaps.

1.18.1.3 Allergen containing materials are not stored above non-allergen or different allergen containing materials, or are appropriately segregated, as defined by the Allergen Control Program.

1.18.1.4 Product labels or primary packaging materials are verified as correct for the specified production run.

1.18.1.5 All necessary precautions are taken to eliminate the risk of allergen cross-contact, including personal hygiene and handling of outer garments.

1.19 Workspace Arrangement

The movement of materials, products, waste and people, and the layout of equipment is designed to protect against potential contamination sources.

Critical Requirements

1.19.1.1 Production equipment and supplies are arranged and maintained to protect against potential contamination sources.

1.19.1.2 Adequate workspace and storage areas are provided to enable operations to be performed in food-safe, hygienic conditions.

Minor Requirements

1.19.2.1 Portable infrequently used equipment is not stored in production or raw material storage areas

1.20 Single-Service Containers

Reuse of single-service containers is managed to avoid any risk of contamination.

Critical Requirements

1.20.1.1 Single-service containers are not reused without a risk assessment and procedures to maintain food safety.

1.21 Hand Contact

Direct hand contact in food processing is minimized where possible and practical to eliminate potential sources of contamination.

Critical Requirements

1.21.1.1 Production facilities, equipment, and accessories are designed so that minimum hand contact is made with raw materials, work-in-process, and finished product, where possible and practical.

1.22 Controlled Temperature for Food Safety

Temperature controls are used prevent the growth of pathogens in susceptible materials.

Critical Requirements

1.22.1.1 Raw materials, work-in-process, and finished product capable of supporting the rapid growth of pathogenic microorganisms are properly stored.

1.22.1.2 Temperature limits for food safety, based on science and regulation as applicable, are defined and followed, including but not limited to storage, thawing, tempering, and holding of hot or cold food.

1.22.1.3 The facility maintains a record of temperature monitoring activities.

1.22.1.4 Corrective actions are defined and implemented for materials affected by controlled temperature storage failures that could affect food safety.

1.22.1.5 Continuous recording thermometers or other monitoring systems are provided inside coolers, freezers, and other temperature-controlled storage areas.

Minor Requirements

1.22.2.1 Temperature monitoring probes are placed at the warmest parts of temperature-controlled storage facilities.

1.22.2.2 Freezers and coolers are provided with vinyl strip doors, self-closing devices, or other methods to maintain temperatures.

1.23 Cross-contamination Prevention

Operational controls and handling methods are established to prevent cross-contamination from incompatible and/or hazardous materials.

Critical Requirements

1.23.1.1 Incompatible materials (such as raw and cooked products) are stored under conditions that prevent cross-contamination.

1.23.1.2 Measures are taken to prevent cross-contact by hazardous ingredients, such as allergens.

1.23.1.3 Systems are set up and operating procedures are implemented to reduce any potential physical, chemical, or microbiological contamination risks.

1.23.1.4 Hand sanitizers, foot baths, or automatic floor sanitizer sprays are provided and used to prevent microbiological contamination of product and processing areas, as necessary based on risk assessment or regulatory requirement.

1.23.1.5 When used, verification of effective concentration of the foot bath or sanitizers is monitored and documented, including Corrective Action and re-verification of concentration, as required.

1.23.1.6 Where foot baths and sanitizers are not used for cross-contamination control in a sensitive operation, a captive shoe program is defined and implemented to prevent microbial contamination of product and processing areas.

1.23.1.7 Measures are taken to prevent cross-contamination that can cause customer complaints, such as meat in vegetarian products, non-organic ingredients in organic foods, or product placed in the wrong packaging.

1.24 Cans, Bottles, and Rigid Packaging

Cans, bottles, and other rigid containers used for packaging are managed in storage and cleaned to prevent foreign material contamination.

Critical Requirements

1.24.1.1 If cans, bottles, food contact barrels, or other rigid packaging containers are used, the rigid container is inverted and cleaned with an air or water blast before filling to remove foreign material.

1.24.1.2 Filtering systems or air/water traps are provided on cleaning systems used with rigid packaging and are regularly monitored and maintained as part of the Preventive Maintenance Program.

1.24.1.3 After cleaning, rigid packaging is maintained in an inverted position, covered, or overhead structures are maintained to prevent foreign material contamination through the conveying, filling, and capping processes.

1.24.1.4 Box liners and other liners used in product containers or packaging materials are suitably durable to prevent risk of product contamination.

1.24.1.5 Single-service containers that are not washed, air-rinsed, or water-rinsed prior to use, are received with a tight-fitting cover that protects them from contamination.

1.25 Finished Product Transportation

Finished products and shipping vehicles are inspected and handled to prevent product contamination.

Critical Requirements.

1.25.1.1 Finished products are handled and transported in a way that prevents actual or potential contamination.

1.25.1.2 The staging and loading of perishable materials are conducted in a manner that maintains temperature control for food safety.

1.25.1.3 Prior to loading, all shipping vehicles and products are inspected for cleanliness, damage, or defects that could jeopardize the product. Shipping vehicle inspections are documented.

1.25.1.4 Local delivery trucks and route trucks are inspected and cleaned at least weekly, or as defined by a risk assessment, to identify potential sources of foreign material contamination.

1.25.1.5 Transport refrigeration devices have recording devices. In the absence of recording devices, manual temperature checks are documented at appropriate frequencies to ensure maintenance of refrigeration temperatures.

1.25.1.6 Security measures in the form of seals, padlocks, or other devices are provided on shipping vehicles and documentation of their use is maintained.

1.25.1.7 Transport vehicles have not hauled garbage/waste or nonfood items that may cause product contamination. If nonfood items, such as chemicals, are shipped, then adequate barriers to prevent contamination of food products must be used.

1.25.1.8 Interior light bulbs in finished product transports are shielded or coated to prevent breakage.

1.25.1.9 Adequate free air circulation is provided all around the load during perishables transportation. Pallets with slip-sheets or other ways to allow adequate air circulation are in place unless the transport has a channeled floor to maintain air circulation.

1.26 Hand Washing Facilities

Suitable facilities are provided to personnel for routine handwashing to remove contamination from hands.

Critical Requirements

1.26.1.1 Suitable and properly maintained hand washing facilities are located at the entrance to production areas, and at other appropriate sites.

1.26.1.2 Single-use towels or air dryers are provided at hand washing stations.

1.26.1.3 Hand sanitizing stations are provided, as appropriate, based on risk assessment.

1.26.1.4 Hand sanitizers that require mixing are routinely monitored for proper concentration to ensure effectiveness.

1.27 Washrooms, Showers, Locker Rooms, and Other Welfare Areas

All washrooms, showers, locker rooms, and other employee welfare areas are maintained in a sanitary condition.

Critical Requirements

1.27.1.1 All washrooms, showers, locker rooms, and other employee welfare areas are maintained in a sanitary condition.

1.27.1.2 There are no food, drinks, or items that pose a risk to food safety in lockers or locker rooms.

1.27.1.3 "Wash hands" signs are displayed in all restrooms, lunchrooms, and smoking areas. Wash hands signs appear above sinks and entries to production areas.

Minor Requirements

1.27.2.1 Company-owned personnel lockers are inspected and cleaned on a defined frequency as allowed by national or local regulations.

1.28 Personal Hygiene

Personnel practice good hygiene to avoid becoming a source of contamination.

Critical Requirements

1.28.1.1 Personnel wash hands before beginning work, and after eating, drinking, smoking, using the restroom, or otherwise soiling hands.

1.28.1.2 Personnel are required to always practice good personal hygiene as verified through observation.

1.29 Work Clothes, Changing Facilities, and Personnel Areas

Clothing worn in the facility is managed to prevent product contamination.

Critical Requirements

1.29.1.1 Personnel wear suitable, clean outer garments or uniforms and footwear.

1.29.1.2 Personnel wear effective hair restraints to fully contain hair, if applicable. Hair restraints may include head, beard, or moustache covers.

1.29.1.3 If worn, gloves are adequately controlled to avoid product contamination.

1.29.1.4 Items such as pens, pencils, and thermometers are carried in pockets or pouches below the waist in production areas.

1.29.1.5 Changing facilities are provided for all employees, visitors, and contractors to allow personnel to change clothes before entering food-processing areas, if necessary.

1.29.1.6 Work clothes and shoes are stored separately from outdoor clothing, shoes, and personal items in changing facilities as applicable to the site.

1.29.1.7 Where protective clothing is required, it is always available, and laundered or cleaned in a controlled environment.

1.29.1.8 Changing facilities, where provided, are located near or with direct access to production, packaging, and storage areas.

1.29.1.9 There are no pockets above the waist on outer garments worn around exposed product where product contamination is likely

Minor Requirements

1.29.2.1 Suitable break rooms and dining facilities are provided for all personnel.

1.30 High-Risk Clothing Management

Work clothing in high-risk operations is distinctive for different processes and is managed to prevent product contamination.

Critical Requirements

1.30.1.1 Personnel in high-risk operations follow specified procedures for dressing in visually distinctive clean outer garments, headwear, and footwear.

1.30.1.2 Personnel enter high-risk operations through specially designated changing areas.

1.30.1.3 High-risk work clothing is only removed in a specially designated changing area.

Minor Requirements

1.30.2.1 All high-risk protective clothing is regularly cleaned on-site or by a contract laundry.

1.31 Personal Items and Jewelry Control

Personal items and jewelry are controlled and managed to prevent product contamination.

Critical Requirements

1.31.1.1 Personnel in contact with food products remove jewelry and cosmetic items including, but not limited to:

- Visible or exposed piercings and body jewelry
- Watches
- Earrings
- Necklaces
- Bracelets
- Rings with settings
- False fingernails
- False eyelashes
- Fingernail polish

1.31.1.2 Personnel eat, drink, chew gum, and use tobacco products only in designated areas.

1.31.1.3 Personal food and belongings are not brought into production or storage areas.

1.31.1.4 All personal property is stored in a designated area.

1.31.1.5 The facility Personnel Practices Program defines and explains any exceptions to personal items and jewelry control.

Minor Requirements

1.31.2.1 Personnel in contact with food products are prohibited from wearing perfume and aftershave.

1.32 Health Conditions

Facility policies are in place and enforced to prevent disease, illness, or infection from contaminating product.

Critical Requirements

1.32.1.1 No person with exposed boils, sores, infected wounds, or any other infections or communicable disease is permitted to contact food.

1.32.1.2 Exposed cuts and grazes are required to be covered by a bandage under gloves or otherwise secured to prevent loss. If applicable, metal detectable strip bandages are provided by the facility.

1.32.1.3 All personnel health cards are current and properly posted if required by local regulations.

1.32.1.4 The facility follows procedures requiring personnel, including temporary workers, to notify supervisory personnel of any relevant infectious disease or conditions to which they may have been exposed.

Minor Requirements

1.32.2.1 If appropriate, the facility uses metal detectable bandages, detectable gloves, earplugs, or other detectable protective equipment. If used, detectable equipment is regularly tested and documented.

1.33 Non-Facility Personnel

Visitors and contractors are required to comply with facility policies to protect product from contamination.

Critical Requirements

1.33.1.1 Non-facility personnel conform to the facility Personnel Practices and company policies programs. Non-facility personnel include, but are not limited to:

- Visitors
- Temporary personnel
- Regulatory authorities
- Outside contractors
- Tour groups
- Family and friends of personnel

1.33.1.2 Where appropriate, visitors and contractors undergo medical screening and appropriate training before entering raw material, preparation, processing, packaging, and storage areas.

1.34 Glass Container Breakage

Procedures are in place to address glass container breakage at receiving, storage, depalletizing, washing, rinsing, filling, and capping stages to prevent product contamination.

Critical Requirements

1.34.1.1 Effective glass container breakage procedures are demonstrated by the lack of broken glass in manufacturing, packaging, and storage areas.

1.34.1.2 Records are current and document that procedures for glass breakage cleanup in storage, handling, production, and packaging areas are effectively followed.

1.35 Filling, Capping, and Sealing

Filling, capping, and sealing of single-service or multiple-service containers is monitored to meet specifications.

Critical Requirements

1.35.1.1 Performance of the filling, capping, and sealing operations is monitored visually or electronically. Visual or electronic inspections indicate that filled containers are sound and properly sealed.

1.35.1.2 Sealed and filled containers that do not meet specifications are reprocessed or rejected. Documentation is maintained.

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1.37 Cleaning of Multiple-Service Cans, Bottles and Rigid Packaging

Cleaning of multiple-service cans, bottles, or other rigid packaging materials, as applicable, is conducted following defined procedures to ensure food safety.

Critical Requirements

1.37.1.1 Refillable or multiple-service primary containers are cleaned, sanitized, and inspected before filling, capping, and sealing.

1.37.1.2 Containers that are determined to be unsanitary or defective after inspection are reprocessed or discarded.

1.37.1.3 All multiple-service primary containers are washed, rinsed, and sanitized following a defined program, using a functional mechanical washer or other method that will adequately clean and sanitize the container for use.

1.37.1.4 Washing parameters, such as temperature and concentration of the solutions, are clearly defined and monitored.

1.37.1.5 The cleaning process is shown to be complete by testing for chemical residue on a defined frequency.

1.37.1.6 Mechanical washers are regularly monitored and maintained as part of the preventive maintenance program.

1.37.1.7 An indicating thermometer is installed on the mechanical washer to record the temperature of the caustic wash solution.

1.38 Pasteurized Beverages

Pasteurized and thermally processed beverages have records indicating that pasteurization/heat treatment met defined requirements.

Critical Requirements

1.38.1.1 Critical parameters (e.g., time, temperature, pressure differential) are established using scientific data and regulatory requirements or equipment manufacturer recommendations as applicable.

1.38.1.2 Heat treatment effectiveness is verified.

1.38.1.3 Records demonstrate that critical parameters (e.g., time, temperature, flow, pressure differential) have been met and are maintained on file.

1.39 Unpasteurized Beverages

Defined methods such as preservatives, carbonation, acidification, disinfection of product prior to extraction or other methods are used to reduce microorganisms in finished products.

Critical Requirements

1.39.1.1 Methods to reduce or eliminate microorganisms and prevent spoilage or pathogen development are defined and in place.

1.39.1.2 Records that demonstrate effective reduction or elimination of microorganisms are maintained and current as applicable.

2. Maintenance for Food Safety

The design, upkeep, and management of equipment, buildings, and grounds to provide a sanitary, efficient, and reliable manufacturing environment.

2.1 Facility Location

Selection and management of the facility location allows personnel to identify and control potentially negative impacts of surrounding operations.

Critical Requirements

2.1.1.1 The facility identifies and takes measures to prevent product contamination from local activities that could have adverse impacts.

Minor Requirements

2.1.2.1 Facility boundaries are clearly defined and controlled.

2.2 Outside Grounds and Roof

The facility grounds are maintained in a way that prevents food adulteration.

Critical Requirements

2.2.1.1 Equipment stored outside is placed to prevent pest harborage, make the inspection process easier, and protect equipment from deterioration and contamination.

2.2.1.2 Litter and waste are removed from the property as necessary to maintain sanitary conditions.

2.2.1.3 Vegetation such as trees, shrubs, weeds, and tall grass do not provide pest harborage or access to the building.

2.2.1.4 Roads, yards, and parking areas are maintained to be free of dust, standing water, and other potential contaminants.

2.2.1.5 Adequate drainage is provided for grounds, roofs, and other areas.

2.2.1.6 Outside wet and dry waste or scrap compactors, modules, and containers are installed in a way that prevents product contamination. Containers are maintained to minimize and contain leakage and are removable so that the area can be cleaned.

2.2.1.7 Waste containers and compactors are closed or covered and located on a concrete pad or in a manner to minimize pest attraction and harborage.

2.2.1.8 The roof, structures, and outside grounds are well maintained.

Minor Requirements

2.2.2.1 Truck bays and garage areas are maintained and cleaned to prevent pest attraction or harborage.

2.3 Layout

The layout and placement of equipment, materials, and structures facilitates inspection, cleaning, and maintenance activities.

Critical Requirements

2.3.1.1 Space is maintained between equipment and structures to enable dismantling and maintenance activities.

2.3.1.2 Adequate space is provided between equipment or structures to allow access for cleaning, inspection, and IPM activities.

2.4 Floors

The floors of the facility are designed and maintained to provide structural integrity, facilitate cleaning, prevent contamination, and eliminate pest harborage or entry.

Critical Requirements

2.4.1.1 Floors are impervious and easily cleaned.

2.4.1.2 Wall/floor junctions and corners are maintained to facilitate cleaning.

2.4.1.3 Holes, cracks, and crevices in floor surfaces are repaired to prevent debris from lodging and to avoid pest or microbial harborage.

2.4.1.4 Floors are designed, constructed, and maintained to meet the demands of facility operations and withstand cleaning materials and methods.

2.4.1.5 Floors are sloped to direct the flow of water or effluent toward drains.

2.4.1.6 All elevated platforms, cross-over stairs or walking surfaces located over product zones are constructed (i.e., solid base surface, kick plates) and maintained to prevent potential contamination.

2.5 Drains

The drains in the facility are designed and maintained to provide structural integrity, facilitate cleaning, prevent contamination, and eliminate pest harborage or entry.

Critical Requirements

2.5.1.1 Drains are made of materials that are easily cleaned and kept in good repair.

2.5.1.2 Floor drains are installed, accessible, maintained, and operational in all wet processing or wash areas. Grates are easily removable for cleaning and inspection.

2.5.1.3 Drainage is designed and maintained to minimize the risk of product contamination. Drainage flows away from high-risk areas (e.g., raw vs. cooked).

Minor Requirements

2.5.2.1 Equipment and drains are placed in a way that any processing discharge or overspill goes directly into a drain rather than on the floor.

2.6 Walls

The walls of the facility are designed and maintained to provide structural integrity, facilitate cleaning, prevent contamination, and eliminate pest harborage or entry.

Critical Requirements

2.6.1.1 Walls are made of materials that are easily cleaned and kept in good repair.

2.6.1.2 Holes, cracks, and crevices in wall surfaces are repaired to prevent debris from lodging and to avoid pest or microbial harborage.

2.6.1.3 Walls are designed, constructed, finished, and maintained to:

- Prevent dirt accumulation
- Reduce condensation and mold growth
- Facilitate cleaning
- Withstand operation environment (e.g., high moisture)

2.7 Ceilings and Overhead Structures

Structural elements such as ceilings, beams, supports, fixtures, ducts, or pipes do not threaten food product with leaking, loose, chipping, flaking, or peeling material.

Critical Requirements

2.7.1.1 Ceilings are made of materials that are easily cleaned and kept in good repair.

2.7.1.2 Access to the void in hollow or suspended ceilings is provided to facilitate cleaning, maintenance, and inspection activities.

2.7.1.3 Ceilings and overheads are designed, constructed, finished, and maintained to:

- Prevent dirt accumulation
- Reduce condensation and mold/microbial growth
- Facilitate cleaning

2.7.1.4 Roof leaks are promptly identified, controlled, and repaired.

2.7.1.5 Overhead fixtures, ducts, pipes, and structures are installed and maintained so that drips, leaks, and condensation do not contaminate foods, raw materials, or food contact surfaces.

2.7.1.6 Drips and condensation are controlled to prevent establishment of an environment suitable for microbial growth.

2.7.1.7 There is no flaking paint or rust on overhead structures. Only normal mild oxidation on nonfood contact surfaces is acceptable.

2.7.1.8 Other materials (such as loose insulation) do not threaten food products or food contact surfaces.

2.8 Glass, Brittle Plastics, and Ceramics Control

The Glass, Brittle Plastics, and Ceramics Program manages not only lighting to ensure that it is adequate for the safe production of food products, but the program also takes into consideration breakable materials that are used for other purposes within the facility.

Critical Requirements

2.8.1.1 Adequate lighting is provided in all areas.

2.8.1.2 Light bulbs, fixtures, windows, mirrors, skylights, and other glass suspended over product zones, product areas, raw material storage areas, and any other exposed product areas, are of the safety type or are otherwise protected to prevent breakage.

2.8.1.3 Light fittings and glass are replaced in a way that minimizes the potential for product contamination.

2.8.1.4 Only essential glass, brittle plastics (acrylic), and ceramics are present in the facility. If these materials must be used, they are addressed in the Glass, Brittle Plastics, and Ceramics Program.

2.9 Air Makeup Units

Air used in the facility is filtered or screened, and filters and screens are maintained to prevent product contamination.

Critical Requirements

2.9.1.1 Air makeup units are fitted with clean filters and are free of mold and algae.

2.9.1.2 Air return ducts for HVAC systems and air makeup units are fitted with cleaning and inspection hatches.

2.9.1.3 Fans, blowers, filters, cabinets, and plenums are on the Preventive Maintenance Schedule to prevent mold, the development of microbes, insect activity, and foreign material collection.

2.9.1.4 Air blowing equipment is located, cleaned, and operated in a way that does not contaminate raw materials, work-in-process, packaging materials, food contact surfaces, and finished products.

2.9.1.5 Filters are capable of removing particles of 50 microns/Minimum Efficiency Reporting Value [MERV] 4 equivalent or larger.

2.9.1.6 Adequate dust extraction equipment for dry powder handling equipment is installed and maintained.

Minor Requirements

2.9.2.1 Ventilation is provided in product storage and processing areas to minimize odors, fumes, steam, and vapors.

2.10 Pest Prevention

The materials, structure, and maintenance of the building and equipment support the Integrated Pest Management Program.

Critical Requirements

2.10.1.1 The building has barriers in place to protect against birds, rodents, insects, and other pests.

2.10.1.2 External doors, windows, or other openings are close-fitting or otherwise pest-proofed to less than 6 mm or ¼ inch.

2.10.1.3 Windows, doors, and skylights that are open are screened to prevent pest entry.

2.11 Lubrication Management

Equipment lubrication is managed so it does not contaminate food products.

Critical Requirements

2.11.1.1 The facility prevents, identifies, and eliminates leaks (oil and lubricants) and excessive lubrication.

2.11.1.2 Catch pans, deflector plates, or other means of control are provided in areas where drive motors, gearboxes, and bearings are mounted over product zones and where conveyors cross or run parallel at different levels.

2.11.1.3 There are no grease smears or excess lubricant on equipment.

2.12 Lubricants

Lubricants that are essential for effective equipment operation are used according to label directions and properly stored to protect integrity.

Critical Requirements

2.12.1.1 Only food grade lubricants are used on food processing and packaging equipment, or on any other equipment where incidental food contact may occur.

2.12.1.2 Lubricants are labeled, segregated, and stored in a designated, secure area. Food grade and nonfood grade lubricants are kept separate from each other.

2.13 Cross-contamination Prevention

Operations are segregated to minimize opportunities for contamination.

Critical Requirements

2.13.1.1 Operations are separated based on risks posed by process flow, material types, equipment, personnel, airflow, air quality, and services needed.

2.13.1.2 The process flow, from receiving to shipping, is arranged to prevent product contamination. High-risk and low-risk operations are segregated to minimize product cross-contamination.

2.13.1.3 Areas for washing and cleaning are located away from production activities, as appropriate based on risk.

2.13.1.4 Toilet rooms are provided with functional exhaust fans that exhaust to the outdoors or do not open directly into production, packaging, or raw material storage areas.

2.13.1.5 Cleaning and production areas are segregated with air curtains, partitions, doors, or other sanitary exclusionary systems.

2.13.1.6 Water installations and equipment are constructed and maintained to prevent back siphonage and backflow.

2.13.1.7 The sewage disposal system is adequate for the process and maintained to prevent direct or indirect product contamination.

2.13.1.8 Clean-In-Place systems meet the following design requirements to prevent contamination:

- Allow proper drainage
- No dead ends
- No cross-connections
- Contain line disconnects for cleaning access

2.13.1.9 Airborne contaminants and condensation are controlled in filling and sealing areas.

2.13.1.10 Water intended for bottling is carried in identified and completely separate lines from water not intended for bottling.

2.13.1.11 Syrup tanks and bottle washing rooms are located separately from filling rooms, if required by regulatory agencies.

Minor Requirements

2.13.2.1 Control measures include the enclosures around the filling and sealing areas.

2.14 Equipment and Utensil Construction

Equipment and utensils are designed for easy maintenance ensure compliance with Prerequisite and Food Safety Programs.

Critical Requirements

2.14.1.1 Equipment and utensils are maintained so there is no risk of contamination.

2.14.1.2 Observation demonstrates that the facility has an effective mechanism in place to ensure that sanitary design principles are considered as part of all structural and equipment designs, repairs, modifications, or purchases to reduce the potential for contamination, cross-contact, pest infestations, and to facilitate cleaning efforts.

2.14.1.3 Food contact surfaces are corrosion-free, durable, and made of non-toxic materials.

2.14.1.4 Seams on food contact surfaces are smooth and free of spot or tack welds.

2.14.1.5 Pipelines, mixing tanks, and holding tanks are free of defects, have smooth seams, and are self-draining.

2.14.1.6 Processing equipment for exposed raw materials, work-in-process, and unwrapped finished product is not made of wood, wherever possible and practical. If processing equipment is made of wood, it is maintained.

2.14.1.7 Equipment is maintained to prevent leaks or product overflow outside the product zone.

2.15 Temporary Repair Materials

Temporary repairs are sometimes needed or unavoidable and are applied in a manner that prevents product contamination.

Critical Requirements

2.15.1.1 Tape, wire, string, cardboard, plastic, and other temporary materials are not used for permanent repairs. If used for emergency repairs, they are dated, controlled and replaced with a permanent repair as soon as possible.

2.15.1.2 Any temporary repairs on food contact surfaces are constructed of food-grade material.

2.15.1.3 Temporary repair issues are resolved as soon as possible and practical.

2.16 Equipment Calibration

Equipment used to maintain food safety is calibrated to ensure functionality and accuracy.

Critical Requirements

2.16.1.1 Temperature measuring devices, including thermometers, regulating, and recording controls, are installed on any equipment that sterilizes, pasteurizes, or otherwise prevents pathogenic microorganism growth. These devices are routinely calibrated based on risk assessment, regulatory requirements, or manufacturer's recommendations, as applicable.

2.16.1.2 If used in a process critical to food safety, temperature measuring devices are calibrated to a national standard.

2.16.1.3 Temperature and other measuring devices (i.e., flowmeters, pressure gauges, foreign material detection equipment, pH-meters, manometers, etc.) critical to product safety are monitored on a frequency, as defined by risk assessment.

2.16.1.4 The facility uses monitoring systems that trigger alarms when deviations from critical limits occur.

2.16.1.5 Magnets, where present, are tested for strength on a defined frequency. Deviations from manufacturer requirements or specifications are addressed.

2.17 Compressed Air/Product Contact Gases

Compressed air or other gases are filtered or otherwise managed to remove particulate matter, microbes, mold, water, oil, etc.

Critical Requirements

2.17.1.1 Compressed air used in processing areas is properly filtered to remove particles of 5 microns or larger. Compressed air equipment does not contain dirt, oil, or water.

2.17.1.2 Air traps and filters are inspected and changed routinely. Air traps and filters are located and designed so that when inspected or changed, they do not contaminate product.

2.17.1.3 Other gases used for product contact are of suitable purity to protect the finished material or are filtered to remove contaminants, as applicable.

2.17.1.4 Records of filter inspection and replacement are maintained.

Minor Requirements

2.17.2.1 Filters for air used on food contact surfaces are located as close to the point of use as practical.

2.18 Transporting Equipment

Equipment such as forklifts are maintained to prevent contamination of products and the environment.

Critical Requirements

2.18.1.1 Transporting equipment, pallet jacks, carts, and forklifts, are maintained to prevent contamination.

2.19 Maintenance Shop/Parts Storage

Maintenance shops and parts are properly maintained to prevent a risk of product contamination from improper storage or cleaning.

Critical Requirements

2.19.1.1 All food contact parts are stored in a clean environment off the floor.

2.19.1.2 Only clean repair parts, equipment, conveyor belts, motors, etc. are stored in parts storage areas.

2.19.1.3 The maintenance shop is organized and maintained to prevent the transfer of foreign material into production or storage areas.

2.19.1.4 The maintenance shop perimeter access is maintained to facilitate cleaning and inspection activities

2.20 Hand Washing Facilities Design

Handwashing stations are identified and provided with appropriate water supply, hands-free equipment, and mix valves.

Critical Requirements

2.20.1.1 An adequate supply of hot and cold running water with mix valves are provided in all washrooms, hand sinks, and locker rooms.

2.20.1.2 Hand washing facilities are labeled and separated from utensil washing facilities.

2.20.1.3 Hands-free hand washing equipment and paper towel dispensers or air dryers are provided in production area locations where essential to product safety.

2.21 Bulk Systems, Unloading Areas, and Loading Areas

Bulk systems, unloading areas and loading areas are installed and maintained to prevent product contamination.

Critical Requirements

2.21.1.1 Bulk systems, unloading areas, and loading areas are maintained to prevent contamination of raw materials and finished product (e.g., roof, covering, canopy, umbrella, inclement weather procedures, etc.).

Minor Requirements

2.21.2.1 Dock cushions, canopies, or other covers are provided, as applicable, to protect raw materials and finished products during loading and unloading activities.

2.22 Ammonia Control

Ammonia systems are maintained and managed to prevent product contamination.

Critical Requirements

2.22.1.1 Procedures are in place to identify and prevent ammonia leaks in the process.

2.22.1.2 Inspection records with documented corrective actions are current.

2.23 Wastewater Treatment and Sewage Disposal

Wastewater treatment and sewage disposal systems are managed to prevent contamination or pest management issues that impact the facility, materials, or products.

Critical Requirements

2.23.1.1 Wastewater treatment systems are managed and maintained to prevent development of microbial or pest management issues.

2.23.1.2 Sewage disposal systems are adequate and maintained to prevent direct or indirect product contamination.

3. Cleaning Practices

The cleaning and sanitizing of equipment, utensils, and buildings to provide a wholesome and safe processing environment.

3.1 Cleaning

Cleaning methods and scheduling take food safety into account.

Critical Requirements

3.1.1.1 Cleaning is done in a way that prevents contamination of raw materials, products, and equipment.

3.2 Cleaning Compounds and Sanitizers

The use of cleaning compounds and sanitizers is managed to follow label directions, as appropriate, and prevent product contamination.

Critical Requirements

3.2.1.1 All cleaning compounds and sanitizers used to clean food contact surfaces have food contact surface approval documentation.

3.2.1.2 Sanitizer concentrations are tested to make sure they are consistent with the product label.

3.2.1.3 The facility follows verification procedures and maintains records of chemical concentration testing, retesting, and corrections.

3.2.1.4 All cleaning chemicals are properly labeled.

3.2.1.5 All cleaning chemicals are stored in a secure compartment away from production and food storage areas when chemicals are not in use.

3.2.1.6 Equipment is rinsed as required by label directions to remove chemical residues.

3.3 Cleaning Tools and Utensils

Cleaning tools and utensils are managed and maintained to prevent product contamination.

Critical Requirements

3.3.1.1 Appropriate cleaning tools and utensils are available for use.

3.3.1.2 Cleaning tools and utensils are maintained and stored in a way that does not contaminate foods, packaging, or production equipment.

3.3.1.3 Separate and distinct tools and utensils are used to clean food contact surfaces (product zones) and structures (product areas).

3.3.1.4 Tools and utensils used to clean restrooms or floor drains are never used for any other cleaning purpose.

3.3.1.5 Only clean tools and utensils are used for cleaning purposes. All cleaning tools and utensils are cleaned and properly stored after use. Proper storage includes segregation to ensure that cross-contamination does not occur.

3.3.1.6 A color-code or other type of classification is in place to identify and separate cleaning tools and utensils based on their intended usage.

3.3.1.7 Cleaning tools and utensils that may create debris, such as wire brushes, sponges, and scrub pads, are not used unless absolutely necessary. If used, the area is inspected after use to identify and eliminate any remaining debris that could contaminate the product.

3.3.1.8 Separate and distinct tools and utensils are used to clean food contact surfaces between different allergens or non-allergens.

3.4 Cleaning Methods/Equipment

Cleaning methods and cleaning equipment are properly managed to prevent product contamination.

Critical Requirements

3.4.1.1 Water used for cleaning in wet production areas is restricted and used in a way that does not contaminate raw materials, work-in-process, packaging, or production equipment with droplets, mist, or direct contact.

3.4.1.2 Compressed air used for cleaning is restricted and used in a way that does not contaminate materials, packaging, equipment, and overheads.

3.4.1.3 Designated ladders and cleaning equipment are used in contact with interior product contact surfaces and bulk transport vessels (e.g., rail cars, tankers). This equipment is stored in a clean and sanitary manner.

3.4.1.4 Suitable clothing, head coverings, and foot coverings are worn when entering rail cars, storage tanks, product contact equipment, or other vessels for cleaning, repair, or other purposes to prevent contamination of internal product contact surfaces with hair or foreign material

3.4.1.5 Auxiliary equipment (e.g., forklifts, pallet jacks, aerial lifts, and similar equipment) is cleaned on a defined frequency.

3.5 Daily (Housekeeping) Cleaning

Daily cleaning is focused on keeping the facility clean.

Critical Requirements

3.5.1.1 Routine housekeeping activities are ongoing throughout operating hours in production and support areas to maintain a sanitary environment.

3.5.1.2 Daily cleaning tasks are clearly assigned and completed.

3.5.1.3 Daily cleaning tasks ensure that work and support areas remain clean during working hours.

3.6 Operational Cleaning

Operational cleaning tasks such as line change-over cleaning, are properly executed to prevent cross-contact and cross-contamination.

Critical Requirements

3.6.1.1 Operational cleaning tasks are completed in a way that keeps equipment and production lines clean during working hours.

3.6.1.2 Line change-over cleaning is completed, verified as to the cleanliness of equipment and absence of chemical residues, and documented as defined based on risk assessment.

3.6.1.3 Allergen cleaning is completed, verified, and documented.

3.7 Periodic Cleaning Tasks/ Product Zone Cleaning

Periodic cleaning tasks that involve deep cleaning are conducted when the area is not in production. These tasks require personnel who have been trained and may require the assistance of maintenance or production personnel to properly disassemble equipment and effectively clean the product zone.

Critical Requirements

3.7.1.1 Periodic cleaning tasks comply with applicable equipment cleaning procedures, which are being followed.

3.7.1.2 Equipment guards, trims, and panels are removed and replaced to inspect and clean the interior of all equipment, as applicable.

3.7.1.3 Equipment and structural overheads (including lights, pipes, and beams) are scheduled for periodic cleaning on the Master Cleaning Schedule to prevent mold, insect development, or other product contamination issues.

3.7.1.4 Air blowing equipment, ventilation equipment, air extracting ducts and vent grids are dismantled and cleaned on a defined frequency to prevent contamination issues.

3.7.1.5 Food contact surfaces, product zones, and equipment that require sanitizing are cleaned and then sanitized.

3.7.1.6 Equipment and utensils that do not require sanitizing are cleaned on a predetermined schedule.

3.7.1.7 Utensils and containers are washed and dried between uses, or as appropriate, and stored in an inverted position off the floor.

3.7.1.8 Product handling equipment and product zones are cleaned often enough to prevent residue from being transferred to products.

3.7.1.9 Idle lines and equipment that are not regularly used are kept clean to eliminate pest and microbial issues.

3.7.1.10 Product contact trays are cleaned and maintained in a way that prevents product adulteration.

3.7.1.11 Equipment or other ice contact surfaces used for production, storage, and transport of ice used for cooling of product or as an ingredient are cleaned and sanitized on a predetermined schedule.

3.7.1.12 Pipelines, mixing tanks, and holding tanks are flushed, cleaned, and sanitized, as needed.

3.8 Maintenance Cleaning

Cleaning is conducted after maintenance work is completed and before line start up to remove debris, small parts, and tools.

Critical Requirements

3.8.1.1 Maintenance cleaning tasks are completed in a way that does not compromise product safety. This includes, but is not limited to, removal of debris (such as nuts, bolts, washers, wire pieces, tape, welding rods, and other small items) after maintenance tasks are complete that could contaminate product, and accounting for these materials.

3.9 Non-Product Zone and Support Area Cleaning

Cleaning of non-product zones and support areas is conducted to eliminate contaminants and product residues that may allow insects, mold, and bacteria development.

Critical Requirements

3.9.1.1 Electrical panels and boxes are cleaned frequently enough to prevent product accumulations or insect development

3.9.1.2 Equipment guards, trims, and panels are removed and replaced to inspect and clean the interior of all equipment that is not in direct product zones.

3.9.1.3 Support areas that may impact equipment, production, or storage of raw materials or finished products (e.g., washrooms, maintenance shops, tray or pan wash areas, etc.) are cleaned to prevent product contamination or insect development.

3.9.1.4 Non-production areas used for the storage of equipment, raw materials, finished products, packaging, or product contact utensils and dock/staging areas are cleaned and maintained to prevent contamination of product, materials, or equipment.

3.9.1.5 Dock leveler pits are cleaned frequently enough to prevent excessive accumulation of debris, product spillage, or other materials.

3.9.1.6 Racks and storage shelves are cleaned frequently enough to prevent excessive accumulation of debris, product spillage, or other materials.

3.9.1.7 Damaged product storage and salvage areas are cleaned on a frequency to control spillage and prevent development of sanitation issues that could lead to product contamination or pest activity.

3.9.1.8 Refrigeration equipment (e.g., condensers, fans, drain pans, etc.) is cleaned on a defined frequency to prevent microbial and dirt accumulation.

3.9.1.9 Drains are routinely cleaned and sanitized to prevent microbial and pest development.

3.9.1.10 Nonfood contact surfaces outside of product zones such as floors, processing equipment, walls, and other product areas are cleaned routinely to maintain hygienic conditions.

3.10 Clean-In-Place (CIP) Systems

CIP systems are maintained to allow efficient and effective cleaning of product contact surfaces.

Critical Requirements

3.10.1.1 Indicating and recording thermometers and pressure sensors are used to monitor the CIP system.

3.10.1.2 Requirements for time/temperature and flow rate are established, monitored, and documented.

3.10.1.3 Chemical concentration requirements are established and documented.

3.10.1.4 Spray balls, pipes, clamps, couplings, and connections are completely disassembled on a defined frequency to allow proper cleaning and inspection.

3.10.1.5 Tanks, lines, fillers, etc., are emptied, cleaned, and sanitized to comply with regulatory or industry standards.

3.10.1.6 The system is completely cleaned out during changeover from allergen containing formulas to non-allergen containing formulas or formulas that contain different allergens.

3.10.1.7 CIP records (paper or electronic) and/or recording charts are maintained and current.

3.10.1.8 CIP records and/or recording charts are reviewed to determine if defined time/temperature, flow rate, and chemical concentration requirements, as applicable to the process, are being met.

3.10.1.9 CIP operators are trained on the use of cleaning compounds and sanitizers, and proper operation of CIP equipment.

3.10.1.10 Effective cleaning is verified and documented.

3.10.1.11 Verification of proper rinsing is completed and documented on a defined frequency.

3.10.1.12 Strainers are provided in the CIP system to prevent foreign material contamination of the spray balls or product contact surfaces.

3.10.1.13 CIP strainers are opened, inspected, and cleaned as part of the CIP process or as defined in CIP procedures. Documentation of strainer condition, findings, and corrective actions is maintained.

3.11 Clean-Out-Of-Place (COP) Systems

COP systems and activities are maintained to allow efficient and effective cleaning of product contact surfaces.

Critical Requirements

3.11.1.1 Reuse of COP solutions does not pose a risk to product safety due to excessive residue, allergens, debris, etc.

3.11.1.2 Tanks (i.e., soak, boiling, COP) used to clean production equipment, parts, tools, or utensils are cleaned in a manner and frequency to prevent contamination.

3.11.1.3 Dry or wet cleaning processes or an inspection program are in place to identify and remove contaminants so that multiple-service shipping containers are maintained in a clean and satisfactory condition.

3.12 Beverage Facility Equipment

Properly designed and followed COP activities and programs allow efficient and effective cleaning of product contact surfaces.

Critical Requirements

3.12.1.1 Periodic cleaning includes disassembly of the pasteurizer and examination of the cleanliness and condition of the gaskets.

3.12.1.2 Air valves are disassembled and examined for cleanliness and the condition of the valve seats and O-rings.

3.12.1.3 Gaskets are inspected on a defined frequency and replaced as needed to allow effective cleaning and prevent contamination issues.

4. Integrated Pest Management

The assessment, monitoring, and management of pest activity to identify, prevent, and control conditions that could promote or sustain a pest population.

4.1 Facility Assessment

An annual assessment of the facility is conducted to provide an evaluation of the IPM Program to ensure that it is effective.

Critical Requirements

4.1.1.1 Internal or external trained IPM personnel conduct an assessment of the facility at least annually. Training includes at a minimum Pest Biology and applicable IPM regulations.

4.1.1.2 The assessment evaluates all areas inside and outside the facility, and includes, but is not limited to:

- Historical data from prior 12 months at a minimum
- Identification of pest species present, including extent and distribution of presence
- Assessment of the environment that could provide opportunity for pest harborage and proliferation
- Previously applied corrective actions and their effectiveness

4.1.1.3 Assessment results and Corrective Actions are documented and used to develop and update the IPM Program.

4.2 Scope of Service

The clearly defined scope of service details all applicable pest management activities and responsibilities and serves as the foundation for an effective IPM program.

Critical Requirements

4.2.1.1 The defined scope of service includes:

- Both the facility and the IPM company name
- IPM contact person both for the facility and the contractor
- Frequency of services
- Description of contracted services and how they will be completed

- Term of the contract
- Equipment and material storage specifications, where applicable
- List of approved chemicals, prior to use
- Emergency call procedures (when, why, whom to call)
- Service records to be maintained
- Requirement to notify facility of any changes in service or materials used

4.3 Credentials and Competencies

The facility protects its food products by verifying that IPM service providers, whether in-house or contractors, are qualified.

Critical Requirements

4.3.1.1 The facility keeps a copy of the certification or registration document for each person who performs pest management services in the facility, as required by regulation.

4.3.1.2 If regulation does not require certification or registration, IPM service providers are trained in the proper and safe use of pest management materials by attending a recognized seminar or some other documented training. Evidence of training is on file or available electronically.

4.3.1.3 Persons conducting IPM services have documented GMP Training.

4.3.1.4 IPM service providers are supervised by a licensed applicator, if required or allowed by regulation.

4.3.1.5 The facility maintains a current copy of the pest management company license issued by the appropriate government body, if required.

4.3.1.6 The facility maintains a current copy of the certificate of insurance that specifies the liability coverage, where available.

Minor Requirements

4.3.2.1 IPM service providers maintain evidence of competency by exam from a recognized organization.

4.4 Pesticide Documentation

The facility maintains current pesticide label and other technical information as applicable, to ensure proper usage of the pesticide chemicals and eliminate food safety issues.

Critical Requirements

4.4.1.1 Pesticide specimen labels are on file for all pesticides used in the facility. Documentation is available for review on request as hard copy or electronic files.

Minor Requirements

4.4.2.1 The language of the country is taken into consideration when providing technical data sheets and labels.

4.5 Pesticide Application Documentation

The facility maintains records to identify, verify, and document compliance to regulatory and IPM requirements.

Critical Requirements

4.5.1.1 Documented pesticide application activities include:

- Product names of materials applied
- The national product registration number (e.g., EPA, PMRA) as required by law
- Target pest
- Rate of application or percent of concentration
- Specific location of application
- Method of application
- Amount of pesticide used at the application site
- Date and time of application
- Printed name and signature of applicator

Minor Requirements

4.5.2.1 The facility keeps a record of additional information that may be required by regulation, including lot number of product used and the applicator's certification or registration number.

4.6 Pesticide Control

Pesticides are managed as part of the Chemical Control Program to prevent misuse.

Critical Requirements

4.6.1.1 Pesticides are stored in a limited access, locked area. Storage areas are adequate in size and construction and are properly ventilated.

4.6.1.2 Pesticides are stored according to label directions.

4.6.1.3 Pesticide containers and application equipment are labeled to identify contents. Application equipment is not used across multiple pesticides.

4.6.1.4 Pesticide containers are disposed of according to label directions and regulatory requirements.

4.6.1.5 Warning signs are posted at the entrance of each pesticide storage area.

4.6.1.6 The facility maintains a complete inventory of all stored pesticides.

4.6.1.7 Spill control materials and procedures are available.

4.7 Trend Analysis

Documentation of pest sightings and activity are reviewed and used to identify and eliminate pests in areas where pest activity is observed.

Critical Requirements

4.7.1.1 Accurate and complete service records describe current levels of pest activity and recommendations for additional Corrective Actions.

4.7.1.2 The pest-sighting log or reporting system provides information about the response taken by pest management personnel.

4.7.1.3 All records pertaining to pest management activities are available as hard copy or electronic files for review on request.

4.7.1.4 The pest-sighting log or reporting system is available to facility personnel.

4.7.1.5 Information gathered through the pest-sighting log or reporting system includes:

- Date

- Time
- Type of pests observed
- Location
- Actions taken
- Names of reporting personnel

4.7.1.6 Pest sightings and activity evidence are reviewed by pest management personnel at least quarterly or more frequently to identify trends. A report of findings is submitted to designated facility personnel.

4.8 Monitoring Device Documentation

Monitoring device documentation is maintained to ensure that devices are properly placed and inspected, and to allow trend analysis of activity.

Critical Requirements

4.8.1.1 A detailed survey of the entire facility is completed, and the results are documented and used to determine placement of monitoring devices.

4.8.1.2 A current and accurate site map that lists the locations of all monitoring devices used for target pests is on file.

4.8.1.3 Temporary placement of any pest monitoring devices for short-term monitoring is also mapped. Device checks are documented according to the frequency defined by the IPM Program. Devices that are no longer needed are accounted for and removed.

4.8.1.4 Records of all services performed on all pest-monitoring devices are available.

4.8.1.5 Service records for monitoring devices match IPM Program requirement.

4.9 Exterior Rodent Monitoring Devices

Exterior rodent monitoring devices are effectively managed to deter rodents from entering the facility.

Critical Requirements

4.9.1.1 The placement of exterior rodent monitoring devices (including remotely monitored devices) is based on the detailed facility survey and activity history or as required by country or local regulatory requirements. In the absence of an assessment, devices are placed at intervals of 15–30 m or 50–100 ft.

4.9.1.2 All exterior monitoring devices are inspected at least monthly, or as otherwise defined in the IPM program based on the detailed facility assessment if the facility can demonstrate the consistent performance of the equipment and efficacy of the IPM program.

4.9.1.3 Exterior monitoring devices containing rodenticides are locked with single-use plastic ties, padlocks, or devices provided by the manufacturer, such as key systems.

4.9.1.4 Exterior rodent monitoring devices are tamper-resistant and are positioned, anchored in place, locked, and labeled.

4.9.1.5 Only baits that are approved by the regulatory body with authority for IPM (e.g., EPA in the United States) or that are labeled for use in a food facility are used in exterior bait stations.

4.9.1.6 Baits are secured inside bait stations, in good condition, and replaced as needed based on the label directions or manufacturer recommendation to avoid deterioration.

4.9.1.7 When mechanical traps or non-toxic bait are used for exterior monitoring, they are checked frequently enough to identify rodent pressure outside the plant and provisions are in place for the detection of rodent activity, effectiveness, cleanliness, and placement of the devices.

4.9.1.8 Where prohibited by regulations, rodenticides are not used for routine monitoring.

Minor Requirements

4.9.2.1 Evidence of non-target wildlife feeding at the exterior monitoring locations, where rodenticides are used, is evaluated and addressed.

4.10 Interior Rodent Monitoring Devices

Interior rodent monitoring devices are effectively managed to identify activity and capture rodents that gain access to the facility.

Critical Requirements

4.10.1.1 Toxic bait is not used for routine interior monitoring.

4.10.1.2 Based on the detailed facility survey, interior monitoring devices are placed in sensitive areas specific to the rodent species, and other areas of rodent activity, which may include:

- Incoming materials warehouses or primary storage areas for raw materials
- Maintenance areas with exterior access
- Staging areas where materials are placed after delivery from the warehouse
- Finished product warehouse areas
- Areas with the potential for rodent access due to traffic patterns or activities that take place
- Overhead areas where roof rat activity is evident or likely
- High traffic areas
- Both sides of doors that open to the exterior of the facility.

In the absence of an assessment, monitoring devices are placed at intervals of 6-12 m or 20–40 ft along exterior walls and are strategically placed in sensitive areas toward the interior of the facility.

4.10.1.3 Interior monitoring devices are placed along perimeter walls. The spacing and number of traps are based on activity levels.

4.10.1.4 Interior monitoring devices are appropriately positioned, cleaned, and inspected at least weekly, or as otherwise defined in the IPM program based on the detailed facility assessment if the facility can demonstrate the consistent performance of the equipment and effectiveness of the IPM program.

4.10.1.5 Unless prohibited by regulation, interior monitoring devices include:

- Mechanical traps
- Extended trigger traps
- Glue boards

4.10.1.6 Alternative devices may be used to monitor for rodent activity. These devices may include:

- Gassing traps (e.g., CO2) traps
- Live catch traps
- See-saw tubes
- Electrocution traps
- Remotely monitored traps that send alert e-mails or text messages

4.10.1.7 When non-toxic monitoring/tracking bait is used for interior monitoring, a documented proactive program is in place that defines frequency of inspections, identification of non-toxic bait placement, use according to label directions, and corrective action plans for identification and tracking of resident pest populations and elimination of activity when detected.

4.11 Insect Light Traps

Insect light traps are used, as applicable, to assist in the identification and monitoring of flying insects.

Critical Requirements

4.11.1.1 Insect light traps, when used, are installed farther than 3 m or 10 ft from food contact surfaces, exposed products, packaging, and raw materials in processing and storage areas.

4.11.1.2 Insect light traps are installed in a way that does not attract insects into the facility or near open food.

4.11.1.3 Service checks are routinely performed on all units including remotely monitored devices on a risk-based frequency. In the absence of an assessment, devices are checked weekly during the active season and on a monthly basis during colder seasons or as dictated by climate and activity rates. These checks include:

- Emptying collection devices
- Cleaning the units
- Repairs
- Checks for light breakage

4.11.1.4 Shatter-resistant lights are used in all units located in raw materials and production areas. Other lights are managed in the facility's Glass, Brittle Plastics, and Ceramics Program.

4.11.1.5 All services provided to light traps are documented.

4.11.1.6 Insect light traps are used to monitor flying insect activity at locations identified by the annual IPM assessment.

4.11.1.7 The facility documents the types and quantities of insects found in the light traps and uses the information to identify and eliminate the source of activity. This can include but is not limited to identifying insect types (e.g., night-flying insects, flies, stored product insects, etc.) and quantities captured (specific or relative numbers [e.g., high, medium, low]) to evaluate the risks and determine appropriate control measures to be taken.

Minor Requirements

4.11.2.1 Insect light trap lights are changed at a frequency based on the manufacturer's recommendations.

4.12 Pheromone Monitoring Devices

Pheromone monitoring devices are used as applicable to assist in the identification of stored product insect pests in products prone to this type of infestation (e.g., grains, cereals, spices, or herbs).

Critical Requirements

4.12.1.1 When appropriate for the targeted pest species, pheromone monitoring devices are installed, maintained, and replaced according to label requirements and the annual IPM assessment.

4.12.1.2 Pheromone monitoring devices are inspected on a defined frequency based on risk assessment and threshold levels.

4.12.1.3 The facility documents the types and quantities of insects found during device inspections and uses the information to identify and eliminate the source of activity.

4.13 Bird Management

Bird management is addressed as part of the IPM Program to prevent contamination of food products.

Critical Requirements

4.13.1.1 Birds are managed by exclusion with:

- Nets
- Traps
- Appropriate structural modifications
- Hazing and misting devices
- Lasers and optical deterrents
- Other approved legal methods

4.13.1.2 Avicides are used only if legal.

4.14 Wildlife Management

Wildlife such as squirrels, raccoons, reptiles, cats, dogs, etc. is managed to prevent site entry.

Critical Requirements

4.14.1.1 Wildlife establishing habitat on the facility grounds or in the facility is removed in accordance with regulations and local ordinances. Wildlife can include dogs, cats, or other domestic animals.

Minor Requirements

4.14.2.1 Wildlife control measures are considered, where appropriate. Optional devices include:

- Wire
- Netting
- Distracting devices
- Repellents
- Materials that prevent entry

4.15 Identified Pest Activity

Pest activity and habitat in or around the facility, is promptly identified and eliminated to prevent an impact to the facility and food safety of the product.

Critical Requirements

4.15.1.1 The facility addresses and eliminates any rodent burrows, rodent runs, and conditions that provide harborage or may attract rodents or other pests to the facility or outside grounds.

4.15.1.2 Implementation of an effective pest management program is demonstrated through the lack of identified pest activity. This applies only to pest activity whose identification and control are managed as part of the IPM program and not related to other program gaps (i.e., cleaning gaps, stock rotation, receiving gaps, etc.).

5. Adequacy of Prerequisite and Food Safety Programs

The coordination of management support, cross-functional teams, documentation, education, training and monitoring systems to ensure all departments of the facility work together effectively to deliver a wholesome and safe final product.

5.1 Accountability

Management authorizes and supports qualified, supervisory-level personnel to ensure compliance to programs, laws, and regulations.

Critical Requirements

5.1.1.1 Trained management and supervisory personnel monitor the effectiveness of the implementation of the Prerequisite and Food Safety Programs.

5.1.1.2 The facility has documented procedures to keep the Prerequisite and Food Safety Programs current and accurate, which include accountability and compliance to statutory and regulatory laws and guidelines pertaining to food safety and legality. Important new information could include:

- Legislation
- Food safety issues
- Scientific and technical developments
- Industry codes of practice
- Current registration with appropriate government agencies

5.2 Support

Management supplies human and financial resources to support the Prerequisite and Food Safety Programs.

Critical Requirements

5.2.1.1 Adequate resources are provided to support effective implementation, maintenance, and improvement of the Prerequisite and Food Safety Programs.

5.3 Training and Education

Training and education are conducted for all personnel, from entry level workers to management. This is regularly scheduled and tracked to ensure understanding of food safety.

Critical Requirements

5.3.1.1 There are written procedures for developing and delivering regulatory training and education to all personnel that could include, but is not limited to:

- Prerequisite Food Safety
- Food Defense
- Allergens

If mandatory training is not required by regulation, food safety training is implemented annually to develop the food safety culture.

5.3.1.2 Training and education records for all personnel are maintained according to the procedure and job description requirements.

5.3.1.3 The training includes established means for verification of competency of the information presented (e.g., testing, supervisor verification, verbal responses, etc.).

5.3.1.4 Prior to beginning work, new employees, temporary personnel, and contractors are trained and educated on Prerequisite and Food Safety Programs, as related to their job function and level of responsibility. These personnel are then supervised for compliance.

5.3.1.5 Refresher training and education are done at a minimum of annually or more often as needed.

5.4 Self-Inspections

Responsible personnel regularly inspect and assess how well the facility complies with Prerequisite and Food Safety Programs.

Critical Requirements

5.4.1.1 The facility has a formal Food Safety Committee.

5.4.1.2 The Food Safety Committee schedules and conducts self-inspections of the entire facility and outside grounds at least monthly.

5.4.1.3 The Food Safety Committee documents the results of the self-inspection. The documentation includes:

- Identified observations
- Corrective Actions
- Root Cause Analysis and preventive actions for significant food safety risks
- Specific assignments
- Actual accomplishments

5.4.1.4 Results of the self-inspection are brought to the attention of the personnel responsible for the activity inspected.

5.4.1.5 The Food Safety Committee and the responsible key personnel set deadlines for corrective action implementation and preventive action as applicable.

5.4.1.6 The results of corrective and preventive actions are verified to ensure satisfactory completion.

5.4.1.7 Self-inspections include down time assessments to ensure in-depth inspection of equipment and structures.

Minor Requirements

5.4.2.1 The Food Safety Committee has members from multiple functions of the facility.

5.5 Integrated Pest Management (IPM) Program

The written IPM Program ensures the facility has effective controls and processes in place to minimize pest activity.

Critical Requirements

5.5.1.1 The facility has a written Integrated Pest Management Program.

5.5.1.2 The IPM Program incorporates the requirements of the facility's other written Prerequisite and Food Safety Programs.

5.5.1.3 The IPM Program is written and implemented by trained in-house personnel or by registered, trained, or licensed contractors.

5.5.1.4 If the IPM Program development and implementation is outsourced to contractors, the program includes responsibilities for both in-house personnel and contractors. An in-house, technically responsible person is appointed to monitor the execution of the program.

5.5.1.5 Corrective actions for identified issues on service records, pest sighting logs, and trend reports are applied and documented as complete.

5.6 Customer Complaint Program

The written program evaluates customer complaints and allows the facility to respond to customer concerns. Complaints involving food safety issues, such as adulteration, require an immediate response.

Critical Requirements

5.6.1.1 The facility has a written Customer Complaint Program. Complaint information is used to implement ongoing improvements to ensure product safety.

5.7 Chemical Control Program

A written Program is in place to manage all chemicals in the facility and provide a centralized approach to identify and control purchase and use of nonfood chemicals.

Critical Requirements

5.7.1.1 The facility has a written Chemical Control Program that addresses all chemicals used in the facility (i.e., chemicals for Integrated Pest Management, Maintenance, Sanitation, Hygiene, and Laboratories).

5.7.1.2 Procedures address, as applicable:

- Chemical approval
- Purchase authority
- Controlled and segregated storage
- Handling
- Labels/labeling and/or technical data sheets
- Identification of where and how the chemicals are to be used
- Concentration verification
- Prevention of cross-contamination

- Training and education
- Actual usage
- Inventory control
- Chemical disposal
- Container disposal
- Contractor chemicals
- Allergen declarations

5.8 Microbial Control Program

The microbial program is developed to prevent pathogen contamination of raw materials, packaging materials, work-in-process, and finished product.

Critical Requirements

5.8.1.1 The facility has completed a risk assessment and has a written Microbial Control Program that addresses microbiological analysis for raw materials, finished product, production, and packaging as dictated by the assessment.

5.8.1.2 Based on risk assessment and/or regulatory requirements, the Microbial Control Program includes monitoring that may include, but is not limited to, procedures to address:

- Sanitation/hygiene practices
- Harborage site detection
- Corrective/preventive actions
- Raw materials
- Finished product
- Laboratory practices

5.8.1.3 Records are maintained of laboratory analyses and/or environmental samples that document compliance with the Microbial Control Program.

5.8.1.4 All products being tested for pathogens are placed on hold and not released until results indicating the food safety of the product have been obtained.

5.8.1.5 A written policy specifies the procedures for handling/disposition of food or product contact surfaces that have come into contact with blood or other bodily fluids.

5.8.1.6 Where a sterilization process for packaging is used, such as for low-acid or other aseptic beverages, the process is validated and verified on defined frequencies and records are kept on file.

5.9 Allergen Control Program

The Allergen Control Program has defined controls for known allergens throughout the production process from receiving to distribution to prevent cross-contact.

Critical Requirements

5.9.1.1 An Allergen Control Program is in place that addresses allergens as handled in the facility and as required by regulations in the country of manufacture and country of export.

5.9.1.2 Procedures address:

- Identification and segregation of allergens during storage and handling
- Prevention of cross-contact or contamination during processing by using measures such as:
  - ◊ Production run scheduling
  - ◊ Control of rework
  - ◊ Dedicated production lines
  - ◊ Comprehensive changeover procedures
  - ◊ Equipment and utensils management
- Product label reviews and control
- Personnel awareness training and education
- Verification of cleaning procedures for food contact equipment
- Approved Supplier Program for ingredients and labels
- Validation as applicable or available

5.9.1.3 The Program is updated when there are changes in:

- Ingredients
- Processing aids
- Ingredient suppliers
- Products
- Processes

- Labeling
- Applicable regulations

5.9.1.4 Records demonstrating program conformance and effective corrective actions are maintained.

5.10 Glass, Brittle Plastics, and Ceramics Program

The control of glass, brittle plastics and ceramics in the facility is managed through defined procedures to minimize contamination risks.

Critical Requirements

5.10.1.1 The facility has a written Glass, Brittle Plastics (acrylic), and Ceramics Program.

5.10.1.2 The program includes the following policy statements:

- No glass, brittle plastics, or ceramics are to be used in areas where potential for contamination might exist, except where absolutely necessary or where removal is not immediately feasible.
- No glass, brittle plastics, or ceramics will be brought in with personal belongings.

5.10.1.3 Procedures address:

- Handling breakage (including stored glass, brittle plastics, and ceramics)
- A register/list of essential glass, brittle plastics, and ceramics where potential for contamination might exist
- Scheduled inspections of essential glass, brittle plastics, and ceramics to check for accidental breakage or damage

5.10.1.4 Procedures are defined to address glass container breakage in manufacturing, packaging, and storage areas.

5.11 Cleaning Program

The Cleaning Program has defined schedules and procedures for accomplishing tasks to maintain a safe food-processing environment.

Critical Requirements

5.11.1.1 The facility has a written Cleaning Program.

5.11.1.2 The written Cleaning Program includes the following schedules:

- A Master Cleaning Schedule (MCS) for periodic cleaning assignments
- A Housekeeping Schedule for daily cleaning assignments

5.11.1.3 The Master Cleaning Schedule addresses periodic cleaning assignments for all equipment, structures, and grounds that impact food products. The MCS is current and accurate, and includes the following:

- Frequency of activities
- Personnel responsible
- Post-cleaning evaluation techniques, which could include:
  - ◊ Visual inspections
  - ◊ Allergen testing
  - ◊ Preoperative inspections
  - ◊ Adenosine triphosphate (ATP) testing
  - ◊ Equipment swabs
- Documented corrective actions

5.11.1.4 The facility has written cleaning procedures for all equipment, structures, and grounds that impact the storage, processing, and packaging of food products.

5.11.1.5 Equipment cleaning procedures address as applicable:

- Chemicals
- Chemical concentrations
- Tools
- Disassembly instructions

Minor Requirements

5.11.2.1 The cleaning tasks are divided into three general areas and are included on the appropriate schedule:

- Daily (Housekeeping Schedule)
- Periodic (Master Cleaning Schedule)
- Maintenance (Master Cleaning Schedule)

5.12 Preventive Maintenance Program

The Preventive Maintenance Program addresses building, utensil, and equipment maintenance to ensure a food-safe, production environment.

Critical Requirements

5.12.1.1 The facility has a written Preventive Maintenance Program and work order system that prioritizes structural, equipment or utensil maintenance problems that could cause food contamination.

5.12.1.2 Procedures address:

- Post-maintenance cleaning
- Notification to production, sanitation, hygiene, and/or quality assurance personnel as appropriate
- Tools and parts reconciliation
- Records of evaluation and sign-off by authorized personnel

5.12.1.3 The facility maintains a record of work orders or repair requests, which include progress and status.

5.12.1.4 The facility follows temporary repair procedures, which include a list of materials approved for use as temporary repairs.

5.12.1.5 Back siphonage and backflow prevention units are identified in the Preventive Maintenance Program.

5.12.1.6 Routine checks verify that back siphonage and backflow prevention units are functioning properly. Results are documented.

5.13 Receiving and Shipping Program

The Receiving and Shipping Program ensures that inbound and outbound vehicles and materials are inspected to prevent product contamination.

Critical Requirements

5.13.1.1 The facility has written programs for handling Receiving and Shipping operations. This includes written procedures for inspecting incoming and outgoing materials and vehicles.

5.13.1.2 Trained personnel, using appropriate equipment, inspect all incoming/outgoing materials and vehicles.

5.13.1.3 Procedures for tractor trailer, lorry, and rail car inspections include steps for evaluation of:

- Raw material condition
- Finished product condition
- Presence of pest evidence
- Presence of other objectionable materials
- Trailer or rail car condition
- Temperatures, as applicable for food safety

5.13.1.4 Procedures for bulk material vehicle inspection include steps as applicable for:

- Presence of pest evidence
- Presence of other objectionable materials
- Visual inspection of ports, hatches, hoses, and transport interiors before and after bulk deliveries
- Collection of current wash tickets or supplier proof of prior load guarantees if inspection of top hatches is not possible
- Installation of receiving strainers and inspection after each delivery
- Inspection of portable strainers (if used) before and after delivery
- Inclement weather

5.13.1.5 Incoming and outgoing vehicle procedures include handling Less Than Load (LTL) vehicles.

5.13.1.6 Documented results of inspections include:

- Date of receipt
- Carrier
- Lot number
- Temperatures, as applicable
- Amount
- Intact and verified seal numbers/padlocks
- Product condition
- Trailer, lorry, or transport condition

5.13.1.7 Documentation validates that temperature-sensitive products are loaded into pre-cooled vehicles that are designed to sustain required temperatures during delivery.

5.13.1.8 Temperatures of vehicles, for temperature-controlled transports, are checked and recorded before loading.

5.13.1.9 If critical to food safety, continuous temperature monitoring is in place in temperature-controlled vehicles and the facility maintains documentation of temperature during transport. An alternate method on delivery routes is to check and document the temperature at each delivery point.

5.13.1.10 The facility enforces transportation breakdown procedures to maintain load integrity and temperature control, as applicable.

5.14 Regulatory Affairs and Inspections Program

The Regulatory Affairs and Inspections Program defines the procedures for the facility to handle regulatory, third-party, and customer inspections.

Critical Requirements

5.14.1.1 The facility has a written Regulatory Affairs and Inspections Program that includes:

- A list of personnel delegated to accompany all Inspectors
- A policy regarding recording devices and cameras
- A policy regarding record and sample taking

5.15 Food Defense Program

The Food Defense Plan identifies and reduces the risk of intentional harm to food products.

5.15.1.1 The facility has a written Vulnerability Assessment, which is performed by person(s) trained in Food Defense. The Vulnerability Assessment is reviewed on a defined frequency or when significant changes occur.

5.15.1.2 The Food Defense Plan defines written mitigation measures based on the Vulnerability Assessment that may include as applicable:

- Monitoring for identified risks
- Monitoring frequencies
- Corrective actions
- Plan-reassessment on a defined frequency
- Record keeping

Records indicate that the plan is executed as written.

5.15.1.3 All food defense team members receive documented food defense training.

5.15.1.4 All site employees receive documented annual food defense awareness training.

5.16 Regulated Food Defense Program

The regulated Food Defense Program is required for those operations that must comply with US 21 CFR Part 121 Subpart C and considers intentional adulteration to include biological, chemical, physical, and radiological contaminants.

Critical Requirements

5.16.1.1 A written Food Defense Plan is in place where required by regulation.

5.16.1.2 For products that are required to have a regulated Food Defense Plan, the plan includes the following:

- Documented Vulnerability Assessment (developed or overseen by a Food Defense Qualified Individual (FDQI))
- Mitigation Strategies for Actionable Process Steps/significant vulnerabilities
- Application of Mitigation Strategies, where required
- Food Defense Monitoring
- Food Defense Verification overseen by Food Defense Qualified Individuals
- Record Keeping Procedures.

Records indicate that the plan is executed as written.

5.16.1.3 Only qualified individuals overseen by a Food Defense Qualified Individual who has defined responsibility for program compliance authorize the following:

- Amendments to records
- Food Defense corrective actions
- Food Defense Verification of corrective actions

5.16.1.4 Food Defense Plans and procedures are re-analyzed when changes occur or at least every three years per regulation.

5.17 Traceability Program

The Traceability Program has defined procedures to locate suspect raw materials, food contact packaging materials, rework, and related finished product.

Critical Requirements

5.17.1.1 The facility has a written Traceability Program that is regularly reviewed.

5.17.1.2 The facility identifies and documents lot numbers and traceability information for:

- Raw materials
- Rework
- Food contact packaging materials
- Work-in-process
- Finished product
- Distribution to the customer
- Processing aids

5.17.1.3 All finished products are coded with legible code marks that are easily seen by consumers. Code marks satisfy regulatory packaging requirements and lot definitions and are recorded.

5.17.1.4 The facility tests the program twice annually and documents the results:

- Actual test results (including a test for ingredients or food contact packaging material)
- Success rate
- Test timings
- Corrective actions and process improvements where gaps in the program have been identified

5.17.1.5 Agricultural products (e.g., fruits, vegetables, herbs, etc.) that are received identify the grower location and picking date for traceability.

5.17.1.6 Traceability tests are conducted one step backward to identify components (i.e., ingredients, processing aids, packaging) and one step forward to identify initial point of distribution of the finished product.

5.18 Recall/Withdrawal Program

The Recall or Withdrawal Program defines procedures to direct the controlled removal of suspect product from the market.

Critical Requirements

5.18.1.1 The facility has a written Recall/Withdrawal Program that is regularly reviewed.

5.18.1.2 The facility maintains distribution records of the initial point of distribution for all food products by specific lot.

5.18.1.3 The written Recall/Withdrawal Program includes current information related to:

- Recall/Crisis Management team contact information: corporate, emergency, and after hours
- Roles and responsibilities for team members
- Type of crisis: food safety/food defense
- Key regulatory agency representative emergency contact information
- Supplier (including food contact packaging) and customer emergency contact information
- Sample recall/withdrawal notification letters

5.19 Non-Conforming Product Program

The Non-Conforming Product Program defines criteria to isolate, investigate, and disposition of raw materials, packaging materials, work-in-process, returned goods, and finished products that do not meet food safety requirements.

Critical Requirements

5.19.1.1 The facility has a written Non-Conforming Product Program.

5.19.1.2 Procedures address:

- Investigation of the cause of non-conformity and whether there is a food safety risk
- Time-sensitive corrective actions based on the seriousness of the risk identified
- Documentation of actions taken
- Handling and disposal according to the nature of the problem and/or the specific requirements of the customer

- Personnel authorized to determine product disposition
- Traceability information for dispositioned product for recall or withdrawal
- Inventory adjustments for damaged or destroyed materials

5.19.1.3 Products that test positive (or above set legal limits) for pathogens are appropriately reprocessed or destroyed. Documentation of the disposition of these materials is maintained.

Minor Requirements

5.19.2.1 Disposition can include:

- Rejection
- Acceptance with restrictions
- Regrading
- Reprocessing
- Destruction

5.20 Approved Supplier Program

The Approved Supplier Program defines the criteria used to evaluate suppliers of goods and services that impacts the safety of food products.

Critical Requirements

5.20.1.1 The facility has a written Approved Supplier Program.

5.20.1.2 Procedures address:

- A current and accurate list of approved and non-approved suppliers based on food safety and economically motivated adulteration risks (food fraud)
- Evaluation, selection, and maintenance of approved suppliers
- Actions to take when inspections or monitoring have not occurred (exception handling)
- Standards of performance and criteria for initial and ongoing assessment of suppliers
- Supply chain control program as required by regulations

- Importers have risk-based activities to verify that human and/or animal food imported has been produced in a manner that meets national/local regulation and is not adulterated or misbranded with respect to allergen labelling, as applicable (Example: Foreign Supplier Verification Program)

5.20.1.3 Methods and frequency of supplier performance monitoring is based on risk to the facility.

5.20.1.4 Documentation from the supplier states that bag and box materials were sifted and liquid ingredients were strained prior to packaging. In the case that sifting and straining is not the appropriate or recognized method of foreign material control for the product, documentation from the supplier is provided stating the method of foreign material control used.

5.21 Regulated Processing Records

Regulated processing records are maintained to support food safety practices and demonstrate compliance in facilities with regulated process steps.

Critical Requirements

5.21.1.1 Written procedures are in place for all identified regulated process steps. Records demonstrate compliance with the regulated process steps.

5.21.1.2 For regulated programs, only qualified personnel who have defined responsibility for program compliance authorize the following:

- Amendments to records
- Corrective actions
- Verification of corrective actions

5.21.1.3 The facility retains records for an appropriate amount of time, defined with consideration given to regulations and product shelf life.

5.22 Hazard Analysis Critical Control Points (HACCP)

The HACCP plan evaluates hazards associated with the raw materials and process steps related to a product or product category. It includes a Hazard Analysis which typically assesses risk by determining the severity of a hazard and its likelihood of occurrence. The goal of a HACCP plan is to prevent, eliminate or reduce hazards to an acceptable level.

Critical Requirements

5.22.1.1 The facility has identified all applicable regulatory requirements for the HACCP Plan(s).

5.22.1.2 A written HACCP plan is in place where required by regulation. Personnel responsible for regulated HACCP plans have the required training credentials, as applicable.

5.22.1.3 For products that are not required to have a regulated food safety plan, a HACCP Program, based on Codex Alimentarius, must be written and implemented. The HACCP Program includes the five preliminary tasks and seven HACCP principles as defined by FAO:

- Assemble the HACCP Team and identify the scope
- Describe the Product
- Identify the product's intended use and users
- Construct the flow diagram
- Conduct on-site confirmation of the flow diagram
- Conduct a hazard analysis and identify control measures
- Determine the critical control points
- Establish validated critical limits for each CCP
- Establish a monitoring system for each CCP
- Establish corrective actions for identified deviation
- Validate the HACCP Plan and verification procedures
- Establish documentation and record keeping

5.22.1.4 Records demonstrate compliance with the HACCP plan.

5.22.1.5 Only qualified personnel who have defined responsibility for the HACCP plan compliance authorize the following:

- Amendments to records
- Corrective actions
- Verification of corrective actions

5.22.1.6 The HACCP plan and procedures are reviewed as required on a frequency as defined by regulation. In the absence of regulation, reviews are conducted when there are product or process changes and at least annually.

5.23 Hazard Analysis Risk-Based Preventive Controls (HARPC)

The HARPC plan applies to products that are required to have a regulated HARPC plan under US 21 CFR Part 117 Subpart C and Subpart D.

Critical Requirements

5.23.1.1 The facility has identified all applicable regulatory requirements for HARPC plans.

5.23.1.2 Written HARPC plans are in place where required by regulation. Personnel responsible for HARPC plans have the required training credentials, as applicable.

5.23.1.3 The HARPC food safety plan includes the following:

- Documented Hazard Analysis to include biological, chemical, physical, radiological, and economically motivated adulteration hazards
- Preventive Controls for reasonably foreseeable hazards
- Application of Process Preventive Controls, Food Allergen Preventive Controls, Sanitation Preventive Controls, Supply Chain Preventive Controls, where required
- Verification and Validation
- Verification and Validation Procedures overseen by a Preventive Controls Qualified Individual (PCQI)
- Record Keeping Procedures
- Recall plan for products with identified Preventive Control(s)

5.23.1.4 Only qualified individuals overseen by a Preventive Control Qualified Individual who have defined responsibility for program compliance authorize the following:

- Amendments to records
- Corrective actions
- Verification of corrective actions

5.23.1.5 The HARPC plan and procedures are re-analyzed when changes occur or at least every three years per regulation.

5.24 Positive Hold and Release Procedures

The facility defines and follows hold and release procedures for materials placed on positive hold. Examples could include but are not limited to, pending receipt of food safety testing results, document review, or other protocols.

Critical Requirements

5.24.1.1 The facility defines and follows procedures for materials put on positive hold pending receipt of results, time frames or other criteria for shipment release.

5.24.1.2 Raw materials, work-in-process, and/or finished product are only released .by authorized personnel.

5.25 Water Quality

Water, water sources, and water management strategies are defined to provide clean water that is safe for food contact activities.

Critical Requirements

5.25.1.1 The facility's water supply complies with regulatory requirements.

5.25.1.2 The facility has a safe and/or potable water supply from an approved source.

5.25.1.3 Documentation of the results of water testing is on file.

5.25.1.4 Water, steam, and ice that contacts food and food contact surfaces are regularly monitored to ensure there is no risk to product safety.

5.25.1.5 Water treatment chemicals used in steam or water that comes into direct or indirect contact with food are approved for food contact.

5.25.1.6 Water treatment chemicals are used according to label directions. Results of concentration testing and verification procedures are documented.

5.25.1.7 Regular water samples are taken from underground well water supplies and surface water sites according to local health department codes and government requirements.

Appendix A—Documents to Have Ready for an Inspection

The following is a list of documentation that a Food Safety Professional may ask to review during an inspection. Documentation is listed by Standard. Many facilities find it convenient to gather these documents ahead of time and have them printed in a binder or collected electronically in one central location.

1. Operational Methods and Personnel Practices

1.1 Receipt/Rejection of Dry Goods

- ❑ Rejected shipment records

1.2 Receipt/Rejection of Perishables

- ❑ Temperature check records
- ❑ Rejected shipment records
- ❑ Transport temperature monitoring records

1.4 Storage Conditions

- ❑ Procedures for managing packaging with special handling requirements
- ❑ Failure and corrective actions documentation for packaging with special handling requirements
- ❑ Documentation of disposition decisions for returned products

1.5 Raw Material/Packaging/Finished Product Inventory

- ❑ Inspection documentation for insect-susceptible materials in storage for longer than four weeks

1.7 Carry-over and Rework

- ❑ System to establish maximum storage time, expiration dates, and lot tracking as applicable for carry-over and rework.
- ❑ Records to demonstrate the break and clean process

1.9 Bulk Material Handling

- ❑ Seal verification documentation
- ❑ Tanker wash tags/prior load verification

1.10 Sampling Procedures

- ❑ Sampling procedures

1.11 Processing Aids

- ❑ Food approval and allergen content documentation

1.12 Material Transfer

- ❑ Procedures for transferring and handling food materials, including traceability information

1.13 Material Sifting

- ❑ Records of weekly sifter screen inspections
- ❑ Records of equipment inspections
- ❑ Records of daily tailings log checks, findings, and corrective actions

1.14 Receiving Filters and Strainers

- ❑ Records of strainer inspections, findings, and Corrective Actions

1.15 Foreign Material Control Devices

- ❑ Procedures to operate, monitor, and test foreign material control devices
- ❑ Test records, Corrective Actions, and procedures for foreign material control devices
- ❑ Investigation and Corrective Actions documentation for product rejections

1.18 Allergen Handling

- ❑ Records of label/packaging material verification for production runs

1.20 Single-Service Containers

- ❑ Risk assessment and procedures for reuse of single service containers

1.22 Controlled Temperature Food Safety

- ❑ Temperature limits for food safety
- ❑ Records of temperature monitoring
- ❑ Corrective action procedures for materials affected by controlled temperature failures

1.23 Cross-contamination Prevention

- ❑ Verification of sanitizer concentration and Corrective Actions, if needed

1.24 Cans, Bottles, and Rigid Packaging

- ❑ Preventive maintenance records for monitoring of air/water filtration systems

1.25 Finished Product Transportation

- ❑ Shipping vehicle inspection documentation
- ❑ Security seal or padlock documentation

1.26 Hand Washing Facilities

- ❑ Records of hand sanitizer concentration monitoring

1.27 Washrooms, Showers, Locker Rooms, and Other Welfare Areas

- ❑ Locker inspection and cleaning documentation

1.30 High-Risk Clothing Management

- ❑ Procedures for dressing in visually distinctive clothing

1.31 Personal Items and Jewelry Control

- ❑ Personnel Practices Program
- ❑ Exceptions to Personnel Practices Program

1.32 Health Conditions

- ❑ Personnel health cards, if required
- ❑ Procedures for health conditions notification to management
- ❑ Documentation of testing metal-strip bandages or other detectable protective devices, if used

1.33 Non-Facility Personnel

- ❑ Visitors and Contractors Policy

1.34 Glass Container Breakage

- ❑ Records documenting glass container breakage procedures were followed

1.35 Filling, Capping, and Sealing

- ❑ Documentation of reprocessing or rejection of sealed or filled containers

1.37 Cleaning of Multiple-Service Cans, Bottles and Rigid Packaging

- ❑ Procedures that define washing parameters and monitoring records

1.38 Pasteurized/Thermally Processed Beverages

- ❑ Established critical parameters for pasteurization process
- ❑ Records indicating compliance with critical parameters

1.39 Unpasteurized Beverages

- ❑ Defined methods to reduce spoilage or pathogen development
- ❑ Records indicating compliance with the methods

2. Maintenance for Food Safety

2.9 Air Makeup Units

- ❑ Preventive Maintenance Schedule for fans, blowers, filters, cabinets, and plenums
- ❑ Filter size documentation: 50 microns/MERV 4 or larger

2.12 Lubricants

- ❑ Evidence that lubricants are food-grade

2.16 Equipment Calibration

- ❑ Records of monitoring activities
- ❑ Calibration records

2.17 Compressed Air/Product Contact Gases

- ❑ Micron rating of compressed air filter (5 microns)
- ❑ Purity/filter documentation for other gases for product contact
- ❑ Records of filter inspection and replacement

2.21 Bulk Systems, Unloading, and Loading Areas

Inclement weather procedures, if applicable

2.22 Ammonia Control

- ❑ Inspection records and Corrective Actions

3. Cleaning Practices

3.2 Cleaning Compounds and Sanitizers

- ❑ Food contact surface approval documentation for cleaning compounds and sanitizers
- ❑ Records of testing of sanitizer concentrations
- ❑ Verification procedures for testing sanitizer concentrations, and corrective actions

3.3 Cleaning Tools and Utensils

- ❑ Documentation of color-code or other classifications

3.4 Cleaning Equipment

- ❑ Cleaning of auxiliary equipment

3.5 Daily (Housekeeping) Cleaning

- ❑ Documentation of daily cleaning task assignments, schedules and completion records

3.6 Operational Cleaning

- ❑ Cleaning and verification records for line change-over cleaning and allergen cleaning

3.10 Clean-In-Place (CIP) Systems

- ❑ Documentation of time/temperature/flow rates
- ❑ Documentation of chemical concentration
- ❑ Documentation of cleaning and rinsing verification
- ❑ CIP Operator training records
- ❑ Defined frequency for spray balls, pipes, clamps, couplings, etc. disassembly for cleaning and inspection
- ❑ Documentation of CIP strainer inspection, condition, findings, and corrective actions

3.12 Beverage Facility Equipment

- ❑ Pasteurizer disassembly schedule
- ❑ Gasket inspection defined frequency

4. Integrated Pest Management (IPM)

4.1 Facility Assessment

- ❑ Documentation of the facility assessment
- ❑ Training records for personnel conducting the assessment
- ❑ Documentation of Corrective Actions

4.2 Scope of Service

- ❑ Scope of service records, including all elements as listed in the Standard

4.3 Credentials and Competencies

- ❑ A copy of the certification or registration document for each person who performs pest management activities
- ❑ A copy of the pest management company license, if required
- ❑ A current copy of the certificate of insurance
- ❑ Records to prove that applicators have had training in:
  - GMP
  - Evidence of competency by exam from a recognized organization

4.4 Pesticide Documentation

- ❑ Records of pesticide specimen labels/Technical Data Sheet

4.5 Pesticide Application Documentation

- ❑ Pesticide application records that address the requirements listed in 4.5.1.1 of the AIB International Consolidated Standards
- ❑ Records of the lot number of the pesticide used, or applicator's certificate or registration number, as applicable

4.6 Pesticide Control

- ❑ Inventory of stored pesticides
- ❑ Spill control procedures

4.7 Trend Analysis

- ❑ Records pertaining to pest management activities
- ❑ Service records describing current levels of pest activity
- ❑ Pest-sighting logs or other reporting system
- ❑ Written reports of quarterly (or more frequent) reviews of activity evidence

4.8 Monitoring Device Documentation

- ❑ Site map that lists the locations of all pest-monitoring devices used for targeted pests including temporary monitoring device placement
- ❑ Records of services performed on all pest-monitoring devices

4.11 Insect Light Traps

- ❑ Documentation of the types and quantities of insects captured in the light traps
- ❑ Light change documentation

4.12 Pheromone Monitoring Devices

- ❑ Documentation of the types and quantities of insects captured in the pheromone monitoring devices

5. Adequacy of the Food Safety and Prerequisite Programs

5.1 Accountability

- ❑ A procedure to keep the Prerequisite and Food Safety Programs current and accurate

5.3 Training and Education

- ❑ Written procedures for developing and delivering Prerequisite, Allergen, and Food Defense training
- ❑ Training records for all personnel
- ❑ Criteria for competency requirements to confirm understanding of the information presented

5.4 Self-Inspections

- ❑ Identified observations, corrective actions, root cause analysis and preventive actions (as applicable), specific assignments, actual accomplishments

5.5 Integrated Pest Management (IPM) Program

- ❑ IPM Program
- ❑ Written responsibilities for trained in-house and outside contractors
- ❑ Corrective actions for identified pest issues

5.6 Customer Complaint Program

- ❑ Customer Complaint Program

5.7 Chemical Control Program

- ❑ Chemical Control Program
- ❑ Procedures that address the requirements listed in 5.7.1.2 of the AIB International Consolidated Standards, as applicable

5.8 Microbial Control Program

- ❑ Risk assessment and Microbial Control Program
- ❑ Records of lab analyses and/or environmental sample testing results
- ❑ Hold/release records for pathogen testing
- ❑ Blood/Bodily fluid policy/procedures
- ❑ Validation and verification records of the sterilization process for packaging

5.9 Allergen Control Program

- ❑ Allergen Control Program
- ❑ Procedures that address the requirements listed in 5.9.1.2 of the AIB International Consolidated Standards, as applicable
- ❑ Records of Program updates
- ❑ Records demonstrating conformance and Corrective Actions

5.10 Glass, Brittle Plastics, and Ceramics Program

- ❑ Glass, Brittle Plastics, and Ceramics Program
- ❑ Statements that address essential glass, brittle plastics, and ceramics as they relate to personal belongings
- ❑ Procedures that address handling of glass, brittle plastics, and ceramics breakage
- ❑ A list of essential glass, brittle plastics, and ceramics
- ❑ Scheduled inspections list
- ❑ Procedures to address glass container breakage in manufacturing, packaging, and storage areas

5.11 Cleaning Program

- ❑ Cleaning Program
- ❑ The Master Cleaning Schedule
- ❑ The Housekeeping Schedule
- ❑ The cleaning procedures for equipment, structures, and grounds

5.12 Preventive Maintenance Program

- ❑ Preventive Maintenance Program
- ❑ Work order system
- ❑ Procedures for:
  - Post-maintenance cleaning
  - Notification of production, sanitation, and/or QA personnel
  - Parts and tools reconciliation
  - Evaluation and sign-off
- ❑ Records of compliance
- ❑ Preventive Maintenance Schedule for back siphonage and backflow prevention units
- ❑ Temporary repairs procedures

5.13 Receiving and Shipping Program

- ❑ Receiving and Shipping procedures
- ❑ Procedures for tractor, trailer, lorry, and rail deliveries
- ❑ Procedures for bulk material vehicle inspection
- ❑ Procedures for the handling of LTL vehicles
- ❑ Documented inspection results
- ❑ Distribution records
  - Records of temperatures of perishable items upon loading
  - Records of temperatures of pre-cooled vehicles for temperature-sensitive materials
- ❑ Transportation breakdown procedures

5.14 Regulatory Affairs and Inspections Program

- ❑ Regulatory Affairs and Inspections Program

5.15 Food Defense Program

- ❑ Vulnerability Assessment and mitigation measures
- ❑ Food Defense Plan
- ❑ Food Defense training records

5.16 Regulated Food Defense Program

- ❑ Vulnerability Assessment and mitigation measures
- ❑ Food Defense Plan
- ❑ Monitoring records
- ❑ Food Defense training records
- ❑ FDQI training credentials

5.17 Traceability Program

- ❑ Traceability Program
- ❑ Records of lot numbers or grower information for raw materials, rework, ingredients, work-in-process, finished product, processing aids, food contact packaging, etc.
- ❑ Records of finished product coding
- ❑ Results of program testing twice annually, including elements as described at requirement 5.17.1.4 and 5.17.1.6

5.18 Recall/Withdrawal Program

- ❑ Recall/Withdrawal Program with information detailed in requirement 5.18.1.3
- ❑ Distribution records to the initial point of distribution by specific lot

5.19 Non-Conforming Product Program

- ❑ Non-Conforming Product Program
- ❑ Procedures that address non-conforming product investigation, corrective actions, handling, and disposal

- ❑ Disposition records for recall materials
- ❑ Documentation for damaged or destroyed materials and adjusted inventories
- ❑ Records of destruction/reprocessing for products with positive pathogen testing results

5.20 Approved Supplier Program

- ❑ Approved Supplier Program
- ❑ Approved Supplier Program procedures including list of approved and non-approved suppliers, Food Fraud risk assessment, evaluation of suppliers, actions when audit/monitoring has not occurred, standards of performance for ongoing assessment, Supply Chain Control Program, imports if applicable
- ❑ Records of supplier performance monitoring
- ❑ Documentation of the methods and frequency for supplier performance monitoring
- ❑ Documentation for sifting of bag and box materials and straining for liquid ingredients

5.21 Regulated Processing Records

- ❑ Procedures for all regulated process steps
- ❑ Qualified personnel training records
- ❑ Process records

5.22 HACCP

- ❑ Written HACCP plan including 12 tasks as defined by FAO and associated records
- ❑ Records demonstrating compliance with plan
- ❑ Records of program review
- ❑ HACCP training records for qualified personnel

5.23 HARPC

- ❑ Written food safety plan with all elements included in requirement 5.23.1.3
- ❑ PCQI training records
- ❑ Records of program review

5.24 Positive Hold and Release Procedures

- ❑ Positive hold and release procedures
- ❑ Records of compliance with release procedures

5.25 Water Quality

- ❑ Results of water sample testing or documents proving potability
- ❑ Evidence that boiler chemicals are approved for food contact
- ❑ Records of testing for water, steam and ice that contact food and food contact surfaces

Appendix B—Appeal Process

If there is a concern about an inspection experience or scoring:

1. Contact Customer Service:
    - **North America** + 1-785-537-4750 or 1-800-633-5137
    - **Latin America** + 52-442-135-0912 or 1-800-300-5608
    - **Japan** + 81-3-5659-5081
    - **Europe** + 44 0-1372 365-788
    - **China** + 86 021-60959606
    - info@aibinternational.com
2. The Customer Liaison will gather information about the concern and forward it to our Quality Assurance Team for review.
3. The Quality Assurance Representative will gather information, assess the concern, and determine the course of action.
    - The client will be contacted to further define the concern and to assist with the investigation.
    - The client should provide further information in the form of pictures and additional explanation with no logo or letterhead, so the anonymity of the review process is preserved.
    - Findings rated as Minor Issues Noted will not be accepted for appeal.
4. The Quality Assurance Representative will then assess the concern and determine the course of action. This may include either a Technical Review or a Blind Review.
    - A Technical Review is conducted before the report is issued.
    - A Blind Review is conducted after the report is issued and must be requested within 30 days of completion of the GMP inspection.
5. The response to either a Technical Review or a Blind Review will be issued and is binding on both parties. If a Technical Review is conducted, there will be no Blind Review conducted. Once the result of the review is issued, the report will be sent out.

6. For Technical Reviews and Blind Reviews:
    - The report is placed on hold when a Technical Review is requested.
    - Blind Reviews are conducted after the report is issued. If changes are made based on the results of the review, the report will be reissued.
7. The report is sent for review:
    - The Company Name, Location, Participant Names, Category Scores, Total Scores, and the Name of the Food Safety Professional will be removed from the initial inspection report.
    - Five independent parties will review the report impartially, and with no outside influences.
    - A consensus of opinion will be gathered by the Quality Assurance Team and reported back to the client.

8. In the event of an unsuccessful appeal, AIB International reserves the right to charge the client for the investigation.

Appendix C—Glossary

Acceptance with Restrictions—Non-conforming product is accepted within a limited scope of use.

Adenosine Triphosphate Testing (ATP)—ATP is found in all animal, plant, bacterial, yeast, and mold cells. It occurs in food and in microbial contamination. The ATP test uses bioluminescence to detect the presence of ATP left on a surface after cleaning to validate the removal of product that could contribute to microbiological contamination on product contact surfaces.

Adulteration—To make imperfect by adding extraneous, improper, or inferior ingredients.

Air Makeup Unit—Equipment that tempers outside air and introduces it into a building to eliminate negative pressure and provide positive operating pressure within a facility.

Air Return Duct—Ductwork that takes air from inside the facility and returns it to the main air handling or makeup unit.

Aseptic—Free of pathogenic microorganisms.

Aseptic Packaging—The process through which food products and packaging are sterilized separately and then combined and sealed in a sterilized atmosphere.

Audit—A systematic evaluation of food facility documentation to determine if programs and related activities achieve planned expectations.

Auditor—A person who conducts an audit.

Avicide—A pesticide that targets birds.

Back Siphonage—The flowing back of used, contaminated, or polluted water from a plumbing fixture or vessel into the pipe which feeds it; caused by reduced pressure in the pipe.

Bioluminescence—Emission of visible light by living organisms, such as fireflies, fish, fungi, bacteria, or others.

Body Jewelry—Adornments to the face or body that are seemingly suspended on the skin with no visible piercings or other attachment point. These are typically suspended on the body or face through the implantation

of a magnet below the skin to hold the jewelry in place.

Brittle Plastics—Non-polycarbonate-based plastics such as acrylic or Plexiglas, Perspex, Lucite, etc.

Bulk Materials—Materials that are delivered or shipped via means of a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, hopper bin, or any other vehicle in which food is shipped in large quantities, with the food coming into direct contact with the vehicle.

Captive Shoe Program—Footwear that is specifically designated to be kept and worn in one area to prevent cross-contamination.

Carry-over Product—Product from one production run that is carried over into the next production run.

Catch Pan—A shallow or open container placed under a gearbox to collect any leakage to prevent product contamination.

Category—The AIB International Consolidated Standards for Inspection are divided into five categories: Operational Methods and Personnel Practices, Maintenance for Food Safety, Cleaning Practices, Integrated Pest Management, and Adequacy of Prerequisite and Food Safety Programs.

Category Score—The numerical score for each of the following categories: Operational Methods and Personnel Practices, Maintenance for Food Safety, Cleaning Practices, Integrated Pest Management, and Adequacy of Prerequisite and Food Safety Programs.

Category Score Range—The numerical range within which a category will be scored. The five category score ranges align with the five risk assessment categories: No Issues Observed (200), Minor Issues Noted (180–195), Improvement Needed (160–175), Serious (140–-155), or Unsatisfactory (≤135).

Clean in Place (CIP)—The removal of soil from product contact surfaces in a stationary position by circulating, spraying, or flowing chemical solutions and water rinses onto and over surfaces to be cleaned.

Clean Out of Place (COP)—The manual cleaning of dismantled parts of equipment.

Cleaning Types—

Deep—Cleaning that typically requires skilled personnel and involves the disassembly of equipment or entry into equipment housings for safe removal of food residues to

eliminate the potential for cross-contamination and prevent mold, microbiological, or insect development.

Operational—Cleaning of production lines and equipment within operational hours i.e., line change-over cleaning.

Housekeeping—Cleaning of exterior surface areas to keep a facility neat and clean.

Maintenance—Cleaning that requires specialized assistance from skilled maintenance personnel to remove food residues, maintenance chemicals, foreign material, or contamination resulting from maintenance activities.

Personnel Areas—Cleaning of bathrooms, locker rooms, break areas, or other similar areas.

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Competency—A range of skill, knowledge, or ability.

Contamination—The act or process of making something harmful or unsuitable. The presence of extraneous, especially infectious, material that renders a substance or preparation impure or harmful.

Corrective Action—A change implemented to address an identified weakness.

Critical Control Points (CCPs)—A point, step, or procedure at which controls can be applied and a food safety hazard can be prevented, eliminated, or reduced to an acceptable level.

Cross-contact - Cross-contact occurs when an allergen is transferred to another food or surface.

Cross-Contamination – Cross-contamination occurs when harmful bacteria are transferred to a food from another food or surface.

Damaged Product/Salvage Area—A specific area set aside to accumulate, sort, and repackage or discard damaged products.

Deflector Plate—An angled piece of metal or plastic with a lip on either side that is placed under a bearing or gearbox to divert lubrication or other leakage away from the product or food contact surface to prevent contamination.

Environmental Protection Agency (EPA)—The US government agency tasked with developing and enforcing regulations that implement environmental laws enacted by Congress. This includes, but is not limited to, regulations such as: pesticide laws and registration, The Clean Water Act, and drinking water requirements.

Essential Glass—Glass in a facility that is unavoidable or that cannot be replaced with another material.

FAO—Food and Agriculture Organization of the United Nations

Findings—Notes made by a Food Safety Professional that are indexed to a Standard or related requirement. There may be multiple findings in an observation.

Floor/Wall Junction—The point at which the floor and wall meet.

Food Facility—Any facility that manufactures, processes, packs, or holds food for human consumption.

Food Grade—A material or product that will not transfer nonfood chemicals into the food and contains no chemicals that would be hazardous to human health.

Food Safety Modernization Act (FSMA)—The act signed into law on January 4, 2011, that aims to ensure the safety of the US food supply by shifting the focus from responding to contamination to preventing it.

Food Safety Plan—A plan which identifies, evaluates, and proactively controls hazards which are significant for food safety.

Food Safety Professional – An individual who has been trained to conduct inspections of a facility against the AIB International Consolidated Standards.

Foreign Supplier Verification Program—The import requirement of FSMA that deals with verification of the safety of food offered for import into the United States. Importers that fail to comply with this program are prohibited from importing food into the United States.

Good Manufacturing Practice (GMP)—A food manufacturing practice that, when followed, protects food from contamination. Sometimes a "c" is placed in front of the abbreviation, GMP, to indicate that the practice is current.

Hazard Analysis Critical Control Points (HACCP)—A food safety plan that identifies, evaluates and controls hazards significant to food safety.

Hazard Analysis Risk-Based Preventive Controls (HARPC) —A food safety plan which identifies, evaluates, and proactively controls hazards which are significant for food safety.

HVAC — Heating, Ventilation, and Air Conditioning.

High-Risk Operation—Operation that involves high risk food: any ready-to-eat food that will support the growth of pathogenic bacteria easily and does not require any further heat treatment or cooking.

Imminent—Likely to occur at any moment.

Impervious - Not allowing fluid to pass through.

Infestation—The presence of live or dead life cycle stages of insects in a host product, the evidence of insect presence, or the establishment of an active breeding population.

Initial Category Score—This is the first score assigned based on severity. The total number of single and separate observations may bring the initial category score down.

Inspection—A thorough physical review of a food facility to assess what is actually happening in a facility at a moment in time.

Inspector—A person who inspects a facility for compliance to regulatory standards.

Integrated Pest Management (IPM)—An effective and environmentally sensitive approach to pest management that relies on a combination of common-sense practices. The information in combination with available pest control methods is used to manage pest damage by the most economical means and with the least possible hazard to the people, property, and environment.

Kill Step—The relationship of temperature (e.g., cooked product), temperature and time (e.g., pasteurization), or temperature, pressure, and time (e.g., canning) that effectively destroys pathogens within a cooked food product. The temperature, and/or pressure, and/or time requirements, for processing are science-based.

Less Than Load (LTL)—A shipment that contains materials that will be delivered to multiple sites.

Materials—Includes but is not limited to raw materials, packaging, work-in-process, finished products, food contact processing aids, and other as applicable.

Minimum Efficiency Reporting Value (MERV)—The measurement scale developed by the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) to rate the effectiveness of air filters.

Multiple Observations—Findings (single or multiple) noted under more than one

Standard clause and related requirements. For example: All findings noted in 1.1 Rejection of Shipments/Receipt of Dry Goods and 1.3 Storage Practices will be counted as two observations. An observation will be counted for each Standard involved.

Non-toxic—Not toxic; a non-toxic substance is not considered a food but would not cause injury or death if consumed.

Pasteurize—To expose a food product to an elevated temperature or pressure for a defined period of time to destroy certain microorganisms that can produce disease or cause spoilage. The result is partial sterilization to destroy disease-causing or other undesirable organisms.

Pathogen—An agent that causes disease, especially a living microorganism such as a bacterium or a fungus.

Perishable—Food with limited shelf life that is likely to decay rapidly if not refrigerated.

Pest Harborage—Any condition or structural defect that provides a place for pests to live and reproduce.

Pesticide—A chemical used to kill harmful animals or plants. Pesticides are used especially in agriculture and around areas where humans live. Some are harmful to humans, either from direct contact or as residue on food, or they are harmful to the environment because of their high toxicity, such as DDT (which is now banned in many countries). Pesticides include fungicides, herbicides, insecticides, and rodenticides.

PMRA: Pest Management Regulatory Agency (Canada).

pH—The numerical measure of acidity or alkalinity of a solution. Numbers decrease for acidity and increase for alkalinity. A neutral solution has a pH measure of 7.

Pheromone—A chemical secreted by an animal, especially an insect, that influences the behavior or development of others of the same species, and often functions as an attractant of the opposite sex.

Pheromone Trap—A trap that uses a pheromone to attract insects to a glue board so that the insects are captured. Pheromone traps are used to determine the presence and quantity of insects in order to identify activity or infestation in a facility.

Plenums—A space, usually above a ceiling or below a floor, that can serve as a receiving chamber for heated or cooled air to be distributed to inhabited areas.

Policy—Statements that reflect decisions made by management. Policies are frequently strategic statements from facility leadership that demonstrate the direction of the organization and prove senior management support.

Potable—Fit to drink. In food safety, this usually refers to water.

Practices—Physical evidence that a Program is being followed in a facility. For example, if a Food Safety Professional sees that a facility keeps chemicals segregated and secure, this is proof that a facility is implementing a Chemical Control Program through practice.

Prerequisite Programs—Food facility programs that lay the foundation for food safety and HACCP/HARPC and create the environment required for producing clean and safe food.

Preventive Control—Risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive Maintenance Program—A schedule of planned maintenance activities.

Prior Load Verification—Documentation indicating that the same material was shipped in a bulk vessel to demonstrate that no cross-contamination of non-like materials shipped in the same vessel occurred. This is typically done when a wash or dry-cleaning step is not conducted between loads.

Procedures—Step-by-step instructions on how to execute a task in a Program. For example, in a facility's Chemical Control Program, there may be a procedure on how to clean up a chemical spill.

Processing Aid— Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.

Product Area—The area close enough to the product zone that, if an issue were found there, would impact the safety of the product zone.

Product Zone—All food contact surfaces, and all unprotected areas directly above food contact surfaces. The product zone includes areas directly above

exposed raw materials, work-in-process, or finished product.

Program—A collection of documentation related to the management of an element in a facility that impacts food safety. For example, a Chemical Control Program documents everything related to the control of chemicals in a food facility. This might include procedures, policies, personnel responsible, lists of approved chemicals, storage requirements, documentation requirements, or other documents.

Recall—The voluntary removal of a product from the marketplace when the product is either in violation of regulations or regulatory agencies could take legal action against the product.

Regrading—The process by which product that does not meet specification, or is deemed substandard, is reassessed and diverted to another use for which it can meet a defined specification or be used for another purpose.

Rejection—To refuse to accept non-conforming product.

Rework—Clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and is suitable for use as food.

Risk Assessment—A systemic process of organizing information to support a risk decision to be made within a risk management process. It consists of the identification of hazards and the analysis and evaluation of risks associated with expose to those hazards.

Security Seal—A closure to prove no tampering of contents has occurred.

Sensitive—Readily affected or vulnerable. In this document, sensitive is used to describe foods that are affected by temperature and areas of a facility that are vulnerable to pests or contamination.

Severity—The level of risk within a risk assessment category (e.g., how severe is an observation within the risk category of Improvement Needed?).

Single Observation—Findings (single or multiple) noted under a single Standard clause and related requirements. Example: All findings noted in Standard clause 1.6 Pallets or in any of its requirements (1.6.1.1, 1.6.1.2, 1.6.1.3, 1.6.1.2) will be evaluated as one observation.

Single-Service Container—A container that is designed to be used once and discarded.

Socks—Typically a cloth material enclosure provided on the top of a silo, mixer, or tanker transport to allow airflow to occur while protecting the interior product and product contact surfaces from contamination.

Total Score—The total of all category scores.

Toxic—Capable of causing injury or death, especially by chemical means; poisonous.

Traceability—The identification of any suspect ingredient or finished product and its initial shipment location. While related to recall, traceability is a separate program.

Transportation Breakdown Procedures—Procedures to ensure the safety of food (refrigerated, frozen, or ambient food products) in the event of a vehicle breakdown or cooling unit malfunction during product transportation.

Validation—Process validation means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

Verification—To establish whether a Program or procedure is being followed or not.

Wash Certificates/Tags—A certificate stating that a trailer or vessel was appropriately cleaned and/or sanitized prior to loading to prevent contamination of the product contained within. Wash certificates may contain information related to the date the cleaning occurred, the party performing the cleaning, wash temperatures, or any other relevant information.

Withdrawal—The voluntary removal or correction of a product in the marketplace that involves a minor infraction that does not warrant legal action.

Work-in-Process—Products that are in-between machines, processes, or activities, and are awaiting further processing.

Standards Index

1 Operational Methods and Personnel Practices

2 Maintenance for Food Safety

3 Cleaning Practice

4 Integrated Pest Managemen

5 Adequacy of Prerequisite and Food Safety Programs