Change Document to Accompany the 2013 AIB International Consolidated Standards for Inspection of Beverage Facilities

Regulatory developments, including the passage of US Food and Drug Administration Food Safety Modernization Act (FSMA) and other industry best practices impacting the food industry worldwide, have necessitated a thorough updating process to the AIB International *Consolidated Standards for Inspection*.

The Standards were last updated, with a completely new format, and introduced in 2009. The intent was to achieve improved functionality in the capture of specific data that would assist in pinpointing areas of opportunity within the facility and allow for trending of this data. With the introduction of our Automated Quality Management System in 2011, we again evaluated how the data within the Standards was structured.

For the 2013 updates we have implemented several sets of changes:

1. Changed the way the data is arranged to better capture findings in like areas so that comparisons and data capture can be centralized. To this end, some clause numbers have changed.
2. Items have been grouped differently to provide a more cohesive picture of what is happening in the facility and to make data capture and trending of findings easier.
3. In some cases, criteria were moved to a different category within the Standards to provide a better fit with the evaluation of programs and findings.
4. Made minor changes to headings, or changes to numbering, that are not changes to the criteria evaluated in the previous version of the Standards.

The purpose of the Change Document is to highlight the changes and identify additional criteria and changes to content and to outline expectations during an inspection. Minor changes, referred to in 4 above, will not be described in the document. As always, AIB International wishes to provide transparency behind the reasons for changes to the Beverage Facilities Standards, and the necessary clarification to understand and implement them. By so doing, together we will continue to ensure the ongoing successful implementation of food safety programs worldwide.

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Operational Methods and Personnel Practices

1.1 Rejection of Shipments/Receipt of Dry Goods

1.1.1.3 Critical - The facility maintains **documentation of rejected shipments** ~~and~~ that includes the ~~defect specifications and~~ reasons for rejection.

- *Explanation of the change*: The language was edited to clarify the need to document the reason for rejection of the material.
- *Guidance on evaluation of criteria*: No additional guidance required. Minor edit to criteria text only.

1.1.1.4 Critical - Shuttle vehicles are in **good condition, clean, and free of holes and infestation**.

- *Explanation of the change*: Added requirement to address internally used vehicles typically used to move product to off-site warehouses.
- *Guidance on evaluation of criteria:* The auditor would rate any issues with the shuttle trailer the same as they would any other carrier used to transport product where an issue was identified.

1.2 Rejection of Shipments/Receipt of Perishables

1.2.1.5 Critical - The facility maintains **documentation of rejected shipments** and that includes the ~~defect specifications and~~ reasons for rejection.

- *Explanation of the change*: The language was edited to clarify the need to document the reason for rejection of the material. This is a repeat of 1.1.1.3 because the clauses for rejection of shipments/receipts have been split into two separate clauses- one for dry and one for perishable goods.
- *Guidance on evaluation of criteria:* No additional guidance required. Minor edit to criteria text only.

1.2.1.6 Critical - Shuttle vehicles are in **good condition, clean, and free of holes and infestation**.

- *Explanation of the change*: Added requirement to address internally used vehicles typically used to move product to off-site warehouses.
- *Guidance on evaluation of criteria:* The auditor would rate any issues with the shuttle trailer the same as they would any other carrier used to transport product where an issue was identified.

1.3 Storage Practices

1.3.1.2 Critical - ~~**Receiving**~~ **Dates to facilitate stock rotation are visible** on the ~~bottom unit of the~~ pallet or individual container.

- *Explanation of the change:* The language was edited to take into consideration other methods of stock rotation beyond the use of manually placed receiving dates.
- *Guidance on evaluation of criteria*: No additional guidance required. Minor edit to criteria text only.

1.3.1.6 Critical - ~~**Research and development items,** and infrequently raw materials are stored in a designated area.~~

- *Explanation of the change*: Review of research and development items and infrequently used raw materials is addressed in 1.4.1.4.
- *Guidance on evaluation of criteria*: No additional guidance is required

1.3.2.1 Minor - ~~Receiving~~ Dates used for **stock rotation** are on a **permanent** part of the ~~raw material~~ packaging (e.g., not on the stretch wrap).

- *Explanation of the change:* The language was edited to not just limit this requirement to receiving dates or raw materials only.
- *Guidance on evaluation of criteria*: No additional guidance required. Minor edit to criteria text only.

1.4 Storage Conditions

1.4.1.1 Critical - Storage areas are **clean, well ventilated, and dry**. Raw materials, work-in-process, packaging materials, and finished products are protected from condensate, sewage, dust, dirt, chemicals, or other contaminants.

- *Explanation of the change:* The language was expanded to include work-in-process and finished products.
- *Guidance on evaluation of criteria*: The auditor would rate any issues with work-in-process and finished products based on the risk to product.

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

- *Explanation of the change:* Expanded the scope of the requirement to include protection of raw materials being returned to storage.
- *Guidance on evaluation of criteria*: The auditor would rate any issues regarding protection of raw materials being returned to storage based on risk to product.

1.4.1.3Critical - ~~Artificial and natural~~ **flavors, colors, direct and indirect additives** ~~meet regulatory requirements~~.

- *Explanation of the change*: This requirement was eliminated as letters of guarantee are already required to indicate that these materials are food approved.
- *Guidance on evaluation of criteria*: No additional guidance is required

1.4.1.4 Critical - **Research and Development items** and infrequently used raw materials, ~~and~~ packaging supplies, and finished products are regularly inspected for signs of infestation.

- *Explanation of the change:* Expanded the scope of the requirement to include finished products.
- *Guidance on evaluation of criteria*: The auditor would expand rating of issues with stock rotation to finished products.

1.4.1.6 Critical - **Products returned by customers** are not returned to finished goods storage areas until they are inspected and released for use by authorized personne**l.**

- *Explanation of the change*: Added this requirement to ensure that returned goods are evaluated prior to being restocked in the warehouse.
- *Guidance on evaluation of criteria*: No additional guidance is required

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

- *Explanation of the change:* Added a requirement to ensure that appropriate examination of materials is carried out prior to use of the material.
- *Guidance on evaluation of criteria*: The auditor would rate no more than a minor improvement, if applicable as these materials should have already been subject to incoming materials examination and verification.

1.5 Raw Material/Finished Product Inventory

1.5.1.1 Critical - 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.

- *Explanation of the change:* Added work-in-process and finished product to the requirements for stock rotation.
- *Guidance on evaluation of criteria*: The auditor will rate findings as they relate to work-in-process and finished product with relation to the identified risk to the product.

1.5.2.1 Minor - A **system is defined and followed** for identifying and tracking of inspection of insect-susceptible materials (e.g., aged stock inventory, re-palletizing dates, etc.). ~~The **palletizing date** or inspection date is located near the original receiving date.~~

- *Explanation of the change:* Revised the requirement to allow greater flexibility for defining and managing how a facility identifies and tracks inspection of insect-susceptible materials.
- *Guidance on evaluation of criteria*: The auditor will rate this issue based on whether or not the system defined for the facility is followed and ensures examination and tracking of these materials is effective.

1.6 Pallets

1.6.1.2 Critical - When pallets are stored outside, they are **inspected for evidence of contamination** before being brought into the facility for use.

- *Explanation of the change:* Added requirement to ensure that, if pallets are stored outside, they are inspected to prevent the entry of contaminants into the facility.
- *Guidance on evaluation of criteria*: The auditor will randomly review pallets to determine if pallet inspection programs are effective.

1.7 Designated Rework Areas

1.7.1.5 Critical - A **break** in the rework process is defined. Records demonstrate that the break and clean process is followed.

- *Explanation of the change:* The risk level was changed from minor to critical due to changes in regulatory thinking regarding prevention of cross contamination and risk of allergen contamination.
- *Guidance on evaluation of criteria*: If a break and clean cycle is not considered and documented, the auditor would rate the element on the risk to product.

1.9 Bulk Material Handling

Bulk systems and unloading areas are high-activity locations that could introduce external contaminants into the facility. Proper receiving practices ensure protection during unloading and loading.

- *Explanation of the change:* Expanded the italicized text that explains the intent of the requirement to include loading and expand the scope of the requirement.
- *Guidance on evaluation of criteria*: The auditor review of the Standard would also include evaluation and rating of the criteria with relation to bulk material handling during loading.

1.9.1.4 Critical - If present, **security seals** on bulk container hatches or other shipping containers are **checked** against the seal number on the bill of lading to verify that the numbers match during shipping or receiving.

- *Explanation of the change:* Expanded the scope to include both shipping and receiving of bulk containers.
- *Guidance on evaluation of criteria*: The auditor will review this with relation to ensuring that seals are reviewed to adequately identify any tampering with shipped or received materials.

1.9.1.5 Critical - Storage tanks are **waterproof**.

- *Explanation of the change:* Added requirement to ensure that storage vessels for bulk material, especially in an outdoor setting, adequately protect the product stored inside from rain and weather.
- *Guidance on evaluation of criteria:* The auditor will rate this based on risk to the product or actual observation of material contamination.

1.9.1.6 Critical - Conveying tubes or hoses are on **supports off the ground or floor** to prevent contamination or submersion in water.

- *Explanation of the change:* Added requirement to ensure that floors in areas where loading or unloading occurs inside a structure are addressed to prevent contamination.
- *Guidance on evaluation of criteria:* The auditor will rate this based on observation of the effectiveness in preventing contamination of the unloading hoses or lines.

1.9.1.7 Critical - **Pneumatic** systems or **blowers** are provided with air filters.

- *Explanation of the change:* This requirement was added to ensure protection of air that is commingled with product to allow fluidization of materials.
- *Guidance on evaluation of criteria:* The auditor will rate this based on the risk of inclusion of dirt or other foreign material with the air used to fluidize the product or raw material.

1.12 Raw Material Transfer

1.12.1.3 Critical - ~~**Ingredient**~~ **Raw material storage containers** are properly identified to maintain ingredient integrity and traceability.

- *Explanation of the change*: The word was changed to ensure that all raw material storage containers would be included, not just those associated with ingredients.
- *Guidance on evaluation of criteria*: The auditor will evaluate the identification of all raw material containers and the risk associated with any failure to maintain identification of the material to prevent cross contamination, inadvertent use of an unidentified material, or loss of traceability of the material.

1.13 Bulk Material Sifting

1.13.1.9 Critical - 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.

- *Explanation of the change*: The severity of this item was changed from a minor to critical to more adequately assess the significance of the risk associated with damage to this foreign material control device.
- *Guidance on evaluation of criteria*: The auditor will expect that a robust program is defined and carried out to ensure the integrity of the screens and the product.

1.15 Foreign Material Control Devices

1.15.1.3 Critical - Metal detectors or X-ray machines ~~either contain~~ 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 maintains control of the rejected product.

- *Explanation of the change*: Minor edits to the language were made and expansion of the language regarding how reject materials are to be handled were added to this clause to allow more flexibility in how a facility chooses to manage rejected material.
- *Guidance on evaluation of criteria*: The auditor will challenge the program defined by the facility to evaluate that rejected product is adequately controlled to prevent reintroduction of rejected materials into the product stream.

1.17 Ingredient Scoops

1.17.1.2 Critical - Ingredient scoops are **color-coded or identified**, as necessary, to prevent cross contamination from allergens or other non-related materials.

- *Explanation of the change*: Added a requirement for identification or color-coding of scoops based on their use to prevent contamination.
- *Guidance on evaluation of criteria*: The auditor will challenge the program by verifying the system selected for identification is being followed.

1.17.1.3 Critical - Ingredient scoops are clean and in **good condition**.

- *Explanation of the change*: Added a requirement specifically referencing the cleanliness and condition of scoops.
- *Guidance on evaluation of criteria*: The auditor will randomly review scoops to determine if they are clean and in good condition.

1.20 Single-Service Containers

Residue can contaminate any new materials or products added to an old container.

- *Explanation of the change*: This requirement was added to address reuse of single-service containers
- *Guidance on evaluation of criteria*: No additional guidance is required.

1.20.1.1 Critical - Single-service containers are **not reused**.

- *Explanation of the change*: This requirement was added to prevent reuse of containers that were intended to be used only once.
- *Guidance on evaluation of criteria*: No additional guidance is required.

1.20.1.2 Critical - All single-service containers are **crushed, punctured, or otherwise disposed of** so that they cannot be reused.

- *Explanation of the change*: This requirement was added to describe the methodology to be used to prevent use of containers that are intended to be used only once.
- *Guidance on evaluation of criteria*: No additional guidance is required.

1.22 Temperature Sensitive Materials

1.22.1.3 Critical - The facility maintains a **record** of temperature monitoring activities.

- *Explanation of the change*: This requirement was moved from the Maintenance category 2.17.1.5 to the OP category for a better fit.
- *Guidance on evaluation of criteria*: No additional guidance required.

1.22.2.1 Minor - **Continuous recording thermometers** are placed in all rooms or areas where perishable foods are stored and handled.

- *Explanation of the change*: The requirement was added to ensure that there was a continuous record of temperatures of perishable foodstuffs in storage.
- *Guidance on evaluation of criteria*: The auditor will evaluate perishable storage areas to ensure that continuous recording thermometers are provided.

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

- *Explanation of the change*: The requirement was added to ensure that measures were in place to maintain temperatures in areas where perishables are stored.
- *Guidance on evaluation of criteria*: The auditor will evaluate to see what devices are in place to ensure temperatures are maintained in perishable material storage areas.

1.23 Cross Contamination Prevention

1.23.1.2 Critical - Measures are taken to prevent cross contamination by **hazardous ingredients**, such as allergens ~~during~~ in manufacturing, ~~labeling~~ packaging, and ~~holding~~ storage areas.

- *Explanation of the change*: Minor edits were made to the language to better define the areas of control.
- *Guidance on evaluation of criteria*: No additional guidance is required.

1.23.1.4 Critical - Where required, **hand sanitizers, foot baths, or automatic floor sanitizer** sprays are provided to prevent microbiological contamination of product and processing areas.

- *Explanation of the change*: This requirement was added to ensure that sanitizers are used in sensitive operations as a preventive measure for microbiological contamination.
- *Guidance on evaluation of criteria*: No additional guidance is required.

1.23.1.5 Critical - 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.

- *Explanation of the change*: This requirement was added to ensure that adequate monitoring and corrective actions were implemented to ensure that concentration of sanitizers was effectively monitored and maintained.
- *Guidance on evaluation of criteria*: The auditor will ask the facility to test the concentration of the sanitizers and then evaluate the records of testing to ensure that they are completed as defined, meet the defined levels, and that corrective actions are documented when sanitizer levels do not comply with requirements.

1.23.1.6 Critical - 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.

- *Explanation of the change*: This requirement was added for those countries or facilities that use a captive shoe program in lieu of foot sanitizers to prevent cross contamination from foot traffic.
- *Guidance on evaluation of criteria*: In countries where sanitizers or foot baths are not used, the auditor will evaluate how the captive shoe program is implemented and followed.

1.23.1.7 Critical - Measures are taken to prevent cross contamination that can cause **customer complaints**, such as non-organic ingredients in organic foods.

- *Explanation of the change*: The severity was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required

1.25 Can, Bottles, and Rigid Packaging

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

- *Explanation of the change*: This requirement was added to address processes such as bag in the box packaging.
- *Guidance on evaluation of criteria*: No addition guidance is required.

1.25.1.6 Critical - Rigid packaging is **covered or inverted, or overhead structures are maintained** to prevent contamination prior to filling.

- *Explanation of the change*: This requirement was added to ensure rigid packaging is properly guarded from contamination prior to filling.
- *Guidance on evaluation of criteria*: The auditor will evaluate the condition of covers or overhead structures to ensure that packaging materials are adequately protected.

1.26 Finished Product Transportation

1.26.1.6 Critical - ~~Temperatures of **perishable and frozen** products are taken and recorded upon loading.~~ **Staging and loading** of perishable materials does not pose a food safety risk.

- *Explanation of the change*: This requirement was amended to add greater flexibility in how a facility ensures that perishable materials are adequately protected during staging and loading activities.
- *Guidance on evaluation of criteria*: The auditor will challenge the facility by asking them to demonstrate how temperatures of materials are maintained during staging and loading.

1.26.2.3 Minor - Interior light bulbs in finished product transports are **shielded or coated** to prevent breakage.

- *Explanation of the change*: This requirement was added to ensure shielding of light was provided in finished product transports for glass breakage protection.
- *Guidance on evaluation of criteria*: The auditors will randomly review transports for light shielding.

1.26.2.4 Minor - No **odors or other contaminants** are present in transports.

- *Explanation of the change*: This requirement was added for evaluating odors and contaminants in transports prior to loading.
- *Guidance on evaluation of criteria*: Auditors will randomly review transports for evidence of off odors or contaminants.

1.26.2.5 Minor - 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.

- *Explanation of the change*: Added requirement to ensure that transport vehicles that have hauled nonfood items that could provide a potential for product contamination are addressed or that adequate protective barriers are provided in the case that there is commingling in a load.
- *Guidance on evaluation of criteria*: Auditors will randomly review transports for evidence of this and will evaluate if barriers are provided, where applicable.

1.26.2.6 Minor - 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.

- *Explanation of the change*: This requirement was added to ensure that a record of the cold chain was monitored and maintained throughout shipment of the product.
- *Guidance on evaluation of criteria*: The auditor will look for evidence of recording devices or logs documenting that temperatures were maintained during transport.

1.26.2.7 Minor - **Adequate free air circulation** is provided all around the load during perishables transportation. Pallets with slip-sheets or another way to allow adequate air circulation is in place unless the transport has a channeled floor to maintain air circulation.

- *Explanation of the change*: This requirement was added to ensure that adequate air circulation was provided to maintain the temperature of perishable products during shipment.
- *Guidance on evaluation of criteria*: The auditor will randomly evaluate transports to ensure that pallets or floor channels are provided.

1.26.2.8 Minor - If applicable, the vehicle's **refrigeration unit is turned on** and the doors are closed when loading and unloading is not taking place.

- *Explanation of the change*: This requirement was added to ensure adequate precooling and maintenance of the transport temperature when loading or unloading activities are not taking place.
- *Guidance on evaluation of criteria*: The auditor will challenge the facility program to ask them how they ensure that the transport is adequately cooled prior to and during loading to maintain product temperatures.

1.27 Hand Washing Facilities

1.27.2.1 Minor - Dispensers for **disposable paper towels** are covered. ~~Hands-free design is desirable.~~

- *Explanation of the change*: The language was edited to provide clarity of what is required for paper towel dispensers.
- *Guidance on evaluation of criteria*: No additional guidance is required.

1.30 Work Clothes, Changing Facilities, and Personnel Areas

1.30.1.8 Critical - Where **protective clothing is required**, it is available at all times when required, and laundered or cleaned in a controlled environment.

- *Explanation of the change*: This requirement was added to address protective clothing availability and cleaning.
- *Guidance on evaluation of criteria*: No additional guidance is required.

1.32 Personal Items and Jewelry Control

1.32.1.1 Critical - 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

- *Explanation of the change*: Body jewelry was added to the list of items.
- *Guidance on evaluation of criteria*: No additional guidance is required.

1.32.2.1 Minor - Personnel in contact with food products ~~avoid~~ are prohibited from wearing **perfume and aftershave**.

- *Explanation of the change*: The text was edited to clarify the requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

1.33 Health Conditions

1.33.1.5 Critical - 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**.

- *Explanation of the change*: The requirement was added to address handling and disposal of food stuffs or product contact surfaces that have come in contact with blood and other bodily fluids.
- *Guidance on evaluation of criteria*: The auditor will ask the facility to provide the program that demonstrates this and any records that show that the procedures were followed, as applicable.

1.33.2.1 Minor - Each lot of metal-strip bandages **is tested in the metal detector**.

- *Explanation of the change*: The word metal-strip was added to better define the bandages for which testing in the metal detector is required.
- *Guidance on evaluation of criteria*: No additional guidance is required.

Maintenance for Food Safety

Outside Grounds and Roof

2.2.1.8 Critical – The **roof and structures** are well maintained.

- *Explanation of the change*: Added requirement specifically addressing the roof and structures.
- *Guidance on evaluation of criteria*: No additional guidance is required.

2.2.2.2 Minor - **Truck bays and garage areas** are maintained to prevent pest attraction or harborage

- *Explanation of the change:* This element was added to include evaluation of garages and truck bays where trucks are serviced that could impact the food safety of the products transported in these vehicles.
- *Guidance of evaluation of criteria:* The auditor will examine these areas as part of the inspection process and rate findings based on identified risk.

2.4 Layout

2.4.1.2 Critical - There is adequate space **to place** equipment and raw materials.

- *Explanation of the change*: The severity of the item was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

2.5 Floors

2.5.1.2 Critical - Wall/floor junctions and corners are **maintained** to facilitate cleaning.

- *Explanation of the change*: The severity of the item was changed from minor to critical. Formerly 2.5.2.2.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: The severity of the item was changed from minor to critical. Formerly 2.5.2.3.
- *Guidance on evaluation of criteria*: No additional guidance is required.

2.5.1.4 Critical – **Floors are designed** to meet the demands of facility operations and withstand cleaning materials and methods.

- *Explanation of the change*: The severity of the item was changed from minor to critical. Formerly 2.5.2.4.
- *Guidance on evaluation of criteria*: No additional guidance is required.

2.5.1.5 Critical – Floors are **impervious**.

- *Explanation of the change*: The severity of the item was changed from minor to critical. Formerly 2.5.2.6.
- *Guidance on evaluation of criteria*: No additional guidance is required.

2.5.1.6 Critical – **Floors are sloped** to direct the flow of water or effluent toward drains.

- *Explanation of the change*: The severity of the item was changed from minor to critical. Formerly 2.5.2.6.
- *Guidance on evaluation of criteria*: No additional guidance is required.

2.7 Walls

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

- *Explanation of the change*: The severity of the item was changed from minor to critical. Formerly 2.5.2.3.
- *Guidance on evaluation of criteria*: No additional guidance is required.

2.7.1.3 Critical – Walls are **designed, constructed, finished and maintained** to:

- Prevent dirt accumulation
- Reduce condensation and mold growth
- Facilitate cleaning
    - *Explanation of the change*: The severity of the item was changed from minor to critical. Formerly 2.5.2.1.
    - *Guidance on evaluation of criteria*: No additional guidance is required.

2.8 Ceilings and Overhead Structures

2.8.1.3 Critical – Ceilings and overheads are **designed, constructed, finished**, and maintained to:

- Prevent dirt accumulation
- Reduce condensation and mold growth
- Facilitate cleaning
    - *Explanation of the change*: The severity of the item was changed from minor to critical. Formerly 2.5.2.1.
    - *Guidance on evaluation of criteria*: No additional guidance is required.

2.8.1.6 Critical - Drips and condensation are **controlled to prevent** establishment of an environment suitable for microbial growth.

- *Explanation of the change:* This element was added to differentiate contamination leading to a microbiological issue, such as mold.
- *Guidance on evaluation of criteria:* No additional guidance is required.

2.10 Air Makeup Units

2.10.1.5 Critical - Filters are capable of removing particles of **50 microns** (Minimum Efficiency Reporting Value [MERV] 4) or larger.

- *Explanation of the change*: Added the equivalent MERV rating to meet the 50 micron requirement for filtering of makeup air.
- *Guidance on evaluation of criteria*: No additional guidance is required.

2.12 Leaks and Lubrications

Leaks, ~~and~~ oil, and lubrication are managed so they do not contaminate food products.

- *Explanation of the change*: Added oil to expand the scope of lubricants evaluated as part of the food safety program.
- *Guidance on evaluation of criteria*: No additional guidance is required.

2.12.1.1 Critical - The facility **prevents, identifies, and eliminates** leaks (oil and lubricants) and excessive lubrication.

- *Explanation of the change*: Expanded the scope of the requirement to include oil.
- *Guidance on evaluation of criteria*: No additional guidance is required.

2.14 Cross Contamination Prevention

2.14.1.4 Critical - **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.

- *Explanation of the change*: Added language to include exhausting to the outdoors to this requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

2.14.1.5 Critical - Cleaning and production areas are segregated with air curtains, partitions, doors, or other exclusionary systems.

- *Explanation of the change*: Changed severity from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

2.15 Equipment and Utensil Construction

2.15.1.1 Critical - All **equipment and utensils** are designed and made of materials that are **easily cleaned and maintained**.

- *Explanation of the change*: Expanded the requirement to include equipment.
- *Guidance on evaluation of criteria*: No additional guidance is required.

2.17 Temperature Measuring Devices

2.17.1.5 Critical - **Thermometers are located** inside coolers, freezers, and other temperature-controlled storage areas.

- *Explanation of the change*: Changed severity from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

2.18 Compressed Air/Product Contact Gases

2.18.1.3 Critical - **Other gases** used in product contact are of **suitable purity** to protect the finished material or are **filtered** to remove contaminants.

- *Explanation of the change*: Added requirement to address other gas~~s~~es that may be used for food contact purposes.
- *Guidance on evaluation of criteria*: In the absence of a filter, appropriate purity and food contact approval documentation will be on file for other food contact gas~~s~~es.

2.18.1.4 Critical - **Records of filter inspectio**n and replacement are maintained

- *Explanation of the change:* This requirement was added to ensure inspection and replacement frequencies were defined to ensure product integrity.
- *Guidance on evaluation of criteria.* No additional guidance is required.

2.19 Transporting Equipment

2.19.1.2 Critical - ~~Forklifts, pallet jacks, and similar equipment are listed on the **Preventive Maintenance** and/or Master Cleaning Schedules for cleaning and follow up.~~

- *Explanation of the change*: This requirement was removed because it is already captured in the Cleaning Practices section of the Standards.
- *Guidance on evaluation of criteria*: No additional guidance is required.

2.20.1.2 Critical - **Used and soiled conveyor belts** are discarded and not stored for future use.

- *Explanation of the change*: Added this requirement to ensure that old, soiled or damaged belts are not stored for future use for food contact purposes where there would be potential for product contamination.
- *Guidance on evaluation of criteria*: No additional guidance is required

2.21 Hand Washing Facilities Design

2.21.1.4 Critical - **Hands-free** hand washing equipment is ~~desirable~~ provided in production areas, where essential to product safety ~~required~~.

- *Explanation of the change*: The text of the requirement was edited to clarify the intent of this requirement.
- *Guidance on evaluation of criteria*: The expectation is that hands are clean at all times. The intent of the requirement is to ensure that hands-free hand washing equipment is provided where a microbiologically sensitive product (meat, RTE, dairy, eggs etc.) is produced to reduce the potential for recontamination of the hands.

2.22 Bulk Systems and Unloading Areas

2.22.1.1 Critical - Bulk systems and unloading areas are **installed and maintained to prevent ingredient contamination** (e.g., roof, covering, canopy, umbrella, inclement weather procedures, etc.).

- *Explanation of the change*: The text was edited to specify the various types of ingredient contamination prevention measures used.
- *Guidance on evaluation of criteria*: No additional guidance is required.

Cleaning Practices

3.2 Food Contact Cleaning Compounds and Sanitizers

3.2.1.2 Critical - **Sanitizer concentrations** are tested to make sure they are consistent with the product label. ~~This includes Clean In Place (CIP) systems.~~

- *Explanation of the change*: CIP systems were eliminated from this requirement and added as a new, separate requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

3.3 Equipment and Tools

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

- *Explanation of the change*: The text was edited to expand the criteria to address water uses in all areas and not just wet production areas.
- *Guidance on evaluation of criteria*: No additional guidance is required.

3.3.1.10 Critical - **Designated ladders** and cleaning equipment are used in contact with interior product contact surfaces and bulk transport vessels (e.g., rail cars, tankers).

- *Explanation of the change*: This new requirement was added to ensure that ladders and equipment used in product zones of bulk vessels and transports are specifically designated for use in these areas.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: This new requirement addresses storage of ladders and equipment used to clean and access bulk storage vessels and transports.
- *Guidance on evaluation of criteria*: No additional guidance is required.

3.3.1.12 Critical - Suitable **clothing, head coverings, and foot coverings** are worn when entering rail cars or other vessels for cleaning, repair, or other purposes to prevent contamination of internal product contact surfaces with hair or foreign material.

- *Explanation of the change*: This requirement was added to ensure that protective clothing is worn by personnel entering bulk vessels or transports.
- *Guidance on evaluation of criteria*: No additional guidance is required.

3.5 Product Zone Cleaning

3.5.1.1 Critical - ~~Periodic~~ Cleaning tasks **comply with applicable ~~safety laws, regulations, and~~ equipment cleaning procedures**.

- *Explanation of the change*: The requirement has been edited to broaden the scope to meet the applicable procedures for equipment cleaning.
- *Guidance on evaluation of criteria*: No additional guidance is required.

3.5.1.4 Critical - **Equipment guards, trims, and panels** are removed and replaced ~~according to local and national regulations~~ to inspect and clean the interior of all equipment.

- *Explanation of the change*: The requirement has been edited to broaden the scope to meet the applicable procedures for equipment cleaning where dismantling of equipment may occur.
- *Guidance on evaluation of criteria*: No additional guidance is required.

3.5.1.6 Critical - Food contact surfaces, product zones, and equipment that require sanitizing are **cleaned and sanitized.** ~~to destroy pathogenic microorganisms and remove contaminants.~~

- *Explanation of the change*: The requirement has been edited to broaden the scope to meet the applicable procedures for equipment that requires both cleaning and a sanitizing step in the process.
- *Guidance on evaluation of criteria*: No additional guidance is required.

3.5.1.7 Critical - Equipment and utensils that do no require sanitizing are cleaned~~ and sanitized~~ on a **predetermined schedule.** ~~to prevent microbiological contamination.~~

- *Explanation of the change*: The requirement has been edited to broaden the scope to meet the applicable procedures and schedules for cleaning of equipment that does not include a requirement for sanitizing of the product contact surface.
- *Guidance on evaluation of criteria*: No additional guidance is required.

3.5.1.11 Critical - 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 that could contaminate product and accounting for these materials.

- *Explanation of the change*: Three similar requirements from the 2009 version of the Standard were combined into one cohesive requirement. Requirements 3.6.1.1, 3.6.1.3 and 3.6.1.4 were combined into one single requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

3.5.1.12 Critical - 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 scheduled frequency.

- *Explanation of the change*: New requirements were added to address ice making, storage, and transport equipment cleaning practices.
- *Guidance on evaluation of criteria*: No additional guidance is required.

3.5.1.13 Critical - Pipelines, mixing, and holding tanks can be **flushed, cleaned, and sanitized**, as needed.

- *Explanation of the change*: This new requirement was added to ensure that the ability to adequately clean and sanitize vessels and pipelines was addressed.
- *Guidance on evaluation of criteria*: No additional guidance is required.

3.6 Non-Product Zone and Support Area Cleaning

Cleaning of non-product zones and support areas eliminate product residues that may allow insect development, mold, or other contaminants that could affect the product or impact production.

- *Explanation of the change*: A new Standard was created to address cleaning of non-product contact zones and support areas that may impact the food safety of products produced at the site.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: The requirement has been edited to broaden the scope to meet the applicable procedures for equipment cleaning where dismantling of equipment may occur.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: This requirement was added to ensure that issues in non-production areas that could impact the production or storage of raw materials or finished products were captured in the scope of the inspection.
- *Guidance on evaluation of criteria*: No additional guidance is required.

3.6.1.4 Critical - Non-production areas **used for the storage** of equipment, raw materials, finished products, or product contact utensils are cleaned and maintained to prevent contamination of product, raw materials, or equipment.

- *Explanation of the change*: This new requirement was added to address storage areas for items such as equipment and raw materials that may impact product safety.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: This new requirement addresses cleaning of dock leveler pits to prevent product accumulations and potential for pest development or attraction.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: This requirement was added to ensure that cleaning of the structures used for storage is addressed as part of the cleaning program.
- *Guidance on evaluation of criteria*: No additional guidance is required.

3.6.1.7 Critical - **Recoup and salvage areas** are cleaned on a frequency to control spillage and damaged product to prevent development of sanitation issues that could lead to product contamination or pest activity.

- *Explanation of the change*: This requirement was added to ensure that areas used to recoup compromised products are addressed as part of the cleaning requirements.
- *Guidance on evaluation of criteria*: No additional guidance is required.

3.6.1.8 Critical - **Refrigeration equipment** (e.g., condensers, fans, etc.) are cleaned on a defined frequency to prevent microbial and dirt accumulation.

- *Explanation of the change*: This requirement was added to address cleaning of refrigeration equipment.
- *Guidance on evaluation of criteria*: No additional guidance is required.

3.6.1.9 Critical - **Drains** are routinely **cleaned and sanitized** to prevent microbial and pest development.

- *Explanation of the change*: This requirement was added to address cleaning of drains.
- *Guidance on evaluation of criteria*: No additional guidance is required.

3.7 Clean In Place (CIP) Systems

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

- *Explanation of the change*: This requirement was added to ensure that a strainer was provided to prevent foreign material from entering the system and clogging spray balls or from adhering to food contact equipment surfaces.
- *Guidance on evaluation of criteria*: No additional guidance is required.

Integrated Pest Management

4.6 Pesticide Documentation

4.6.1.1 Critical - ~~**Material Safety Data Sheets (MSDS)**~~ **Chemical Safety Data Sheets** or equivalent are on file for all pesticides used in the facility by in-house personnel or contractors. Documentation is available for review on request as hard copy or electronic files.

- *Explanation of the change*: The text was edited to reflect the change in naming convention from Material Safety Data Sheet to Chemical Safety Data Sheets.
- *Guidance on evaluation of criteria*: No additional guidance is required.

4.8 Pesticide Control

4.8.1.2 Critical - **Pesticides are ~~applied~~**~~, and if required,~~ **stored** according to label directions.

- *Explanation of the change*: The requirement text was edited to address pesticide storage.
- *Guidance on evaluation of criteria*: No additional guidance is required.

4.8.1.5 Critical - ~~Pesticides **are approved** by the designated facility representative before application, and are incorporated into the Chemical Control Program.~~

- *Explanation of the change*: This requirement was removed, as it was a duplication of requirement 4.7.1.1.
- *Guidance on evaluation of criteria*: No additional guidance is required.

4.9 Trend Analysis

4.9.1.2 Critical - ~~When used,~~ The **pest-sighting log** provides information about the response taken by pest management personnel.

- *Explanation of the change*: The requirement was updated to clarify the language regarding the use of the pest-sighting log.
- *Guidance on evaluation of criteria*: The auditor will be evaluating the program to ensure that a pest-sighting log is in place.

4.9.1.4 Critical – The **pest-sighting log** has a designated location.

- *Explanation of the change*: The severity was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

4.9.1.5 Critical - The **pest-sighting log includes**:

• Date
• Time
• Type of pests observed
• Actions taken
• Names of reporting personnel

- *Explanation of the change*: The severity was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

4.9.1.6 Critical - Pest management personnel **review the log each quarter** to identify trends in pest activity. A report of findings is submitted to designated facility personnel.

- *Explanation of the change*: The severity was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

4.9.1.7 Critical - **Corrective Actions** are documented for identified issues.

- *Explanation of the change*: The severity was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

4.11 Exterior Rodent Monitoring Devices

4.11.2.1 Minor - Monitoring devices are placed at intervals of 50-100 ft. or 15-30 m. Areas of high rodent activity ~~may~~ should have a higher concentration of devices.

- *Explanation of the change*: Minor edits were provided to the text to further clarify this requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

4.12 Interior Rodent Monitoring Devices

4.12.1.6 Critical - Facilities in countries that prohibit the use of mechanical traps may consider the use of **alternative devices** on a case-by-case basis. These devices may include:

• Gassing (e.g., CO2) traps
• Live ~~cage~~ catch traps
• See-saw tubes
• Electrocution traps
• Extended trigger traps that send alert e-mails or text messages

- *Explanation of the change*: Minor edits were made to better clarify the requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

4.13 Insect Light Traps

4.13.1.6 Critical – Insect light traps are used to **monitor flying insect activity** at locations that are likely to allow access to the facility.

- *Explanation of the change*: Changed severity from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

4.13.1.7 Critical - The facility **documents the types and quantities of insects** found in 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 pests, etc.) and quantities captured (specific or relative numbers [i.e. high, medium, low]) to evaluate the risks and determine the appropriate control measures to be taken.

- *Explanation of the change*: Changed severity from minor to critical and added edits to the text to ensure that data is evaluated to address any pest control issues based on insect findings in these devices.
- *Guidance on evaluation of criteria*: No additional guidance is required.

4.14 Pheromone Monitoring Devices

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

- *Explanation of the change*: The explanation of the Standard was edited to add those types of facilities where use of pheromone monitoring is required.
- *Guidance on evaluation of criteria*: No additional guidance is required.

4.17 Pest Habitat

4.17.1.2 Critical – Implementation of an effective pest management program is **demonstrated through the lack of identified pest activity**. Specifically, pest activity whose identification and control is managed as part of the IPM Program.

- *Explanation of the change*: Added the requirement to easily capture identified pest activity for which the identification and control would be managed as part of the IPM program.
- *Guidance on evaluation of criteria*: No additional guidance is required.

Adequacy of Prerequisite and Food Safety Programs

5.1 Written Policy

5.1.2.1 Minor - Senior management **signs** the Policy Statement.

- *Explanation of the change*: The severity was reduced from critical to minor.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.1.2.2 Minor - The Policy Statement is **regularly communicated** throughout the facility.

- *Explanation of the change*: The severity was reduced from critical to minor.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.1.2.3 Minor - **Senior management regularly reviews** the Policy Statement.

- *Explanation of the change*: The severity was reduced from critical to minor.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.1.2.4 Minor - Supervisory staff and key personnel are trained to **understand and implement** the Policy Statement.

- *Explanation of the change*: The severity was reduced from critical to minor.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.2 Accountability

5.2.1.4 Critical - Facilities **define written procedures to meet legislative requirements** as defined by country or export requirements (e.g., allergen labeling and control, Reportable Food Registry, Food Safety Modernization Act, etc.). The facility is aware of the program and its role in implementing the requirements.

- *Explanation of the change*: This requirement was added to ensure that any new requirements regarding legislative or regulatory changes are identified and the role of the facility in its implementation or reporting is understood.
- *Guidance on evaluation of criteria*: The auditor will request procedures written and designed to meet legislative or regulatory requirement to verify that the site is aware of their location when they are needed and to ensure that plant personnel responsibilities are clearly defined.

5.4 Written Procedures

5.4.1.1 Critical - ~~The facility has **written procedures** that define step-by-step processes to ensure the safety of facility products. The~~ pProcedures ~~further~~ define:

• **Job Descriptions** that identify responsibilities related to Prerequisite and Food Safety Programs
• **Alternates/Deputies** that are designated to cover for the absence of key personnel.

- *Explanation of the change*: Edited the text to eliminate redundancy with review of programs included as part of the written procedure audits.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.4.1.2 Critical - ~~Management **regularly reviews** written procedures to ensure continued effectiveness and suitability.~~

- *Explanation of the change*: This requirement was eliminated as this would be reviewed as part of the written procedure audits.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.4.1.2 Critical - The written procedures are **readily available** to facility personnel.

- *Explanation of the change*: Changed severity from minor to critical. This was formerly 5.4.2.2 in the previous Standard.
- *Guidance on evaluation of criteria*: No additional guidance is required

5.4.2.1 Minor - ~~The written procedures address~~ **~~all requirements in the AIB International Consolidated Standards for Inspection~~.**

- *Explanation of the change*: This requirement was eliminated as this would be reviewed as part of the written procedure audits.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.5 Training and Education

5.5.1.3 Critical - The training includes **~~exit criteria~~ established means for verification** of competency ~~requirements used to confirm~~ of the information presented (e.g. testing, supervisor verification, verbal responses, etc.).

- *Explanation of the change*: The text was edited to further clarify this requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.6 Self-Inspection

5.6.1.5 Critical - The Food Safety Committee and the responsible key personnel set ~~time~~ **deadlines** for Corrective Action implementation.

- *Explanation of the change*: Minor edits were made to the text to clarify the requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: This requirement was added to ensure that adequate access was provided to thoroughly examine equipment and structures.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.7 Written Procedure Audits

5.7.1.1 Critical - The **scope and frequency** of the audit is based on risk assessment or importance of activity. Audits are conducted at least annually and assess execution of the program.

- *Explanation of the change*: Minor edits were added to the text to further clarify the intent of this requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.7.1.5 Critical - Responsible key personnel set **~~time~~ deadlines** for Corrective Action implementation.

- *Explanation of the change*: Minor edits were provided to the text to further clarify the intent of this requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.9 Chemical Control Program

5.9.1.2 Critical - Procedures address**, as applicable**:

• Chemical approval
• Purchase authority
• Controlled and segregated storage
• Handling
• Labels/Labeling
• Identification of where and how the chemicals are to be used
• Concentration verification
• Training and education
• Actual usage
• Inventory control
• Chemical disposal
• Container disposal
• Spill containment and control
• Chemical Safety Data Sheet archiving
• Contractor chemicals

- *Explanation of the change*: Minor edits were made to further clarify the requirement text.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.10 Microbial Control Program

5.10.1.1 Critical - ~~If needed,~~ The facility has completed a risk assessment and a **written** Microbial Control Program that addresses microbiological analysis ~~in the~~ for raw materials, finished product, production, and packaging ~~environment~~ as dictated by the assessment.

- *Explanation of the change*: The requirement was expanded to require the facility to complete a risk assessment to determine what, if any, microbial control or monitoring program is required.
- *Guidance on evaluation of criteria*: The auditor will ask the facility to at least demonstrate that the risk assessment was completed and current.

5.10.1.5 Critical - Contract labs maintain appropriate **accreditation** to carry out the analyses performed.

- *Explanation of the change*: This requirement has been added to require proof of the competency of the lab providing the testing results.
- *Guidance on evaluation of criteria*: The auditor will ask to see the current accreditation documents for any contract labs providing testing results.

5.10.1.6 Critical - 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.

- *Explanation of the change*: This requirement was added to address the hold and release program for products undergoing pathogen testing to ensure that they are not prematurely released.
- *Guidance on evaluation of criteria*: The auditor will select a product(s) for which pathogen testing is being or has been completed. They will challenge the system by evaluating if the product was placed on hold and then will look at the date of the return of results and the release of the product for use based on this.

5.10.1.7 Critical - Products that **test positive for pathogens are appropriately reprocessed or destroyed**. Documentation of the disposition of these materials is maintained.

- *Explanation of the change*: This requirement was added to address the disposition of materials that test positive for pathogens.
- *Guidance on evaluation of criteria*: The auditor will look at the disposition records for any materials that were tested and had positive pathogen results returned to ensure appropriate disposition of these materials.

5.15 Receiving Program

5.15.1.5 Critical - Procedures for **bulk material deliveries** include steps 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 load out~~ 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

- *Explanation of the change*: Minor edits were made to clarify the requirement and to include considerations for unloading in inclement weather.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.15.1.9 Critical - The facility has **written procedures** for mycotoxin and pathogen-susceptible raw materials.

- *Explanation of the change*: The severity of the requirement was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.17 Food Defense Program

5.17.1.1 Critical - The facility maintains evidence of FDA **registration under the Bioterrorism Act** and re-registers at the frequency defined by the FDA. This requirement applies only if the facility manufactures, processes, packs, holds and distributes, or exports food for human or animal consumption in the USA.

- *Explanation of the change*: Additional text was added that indicates that re-reregistration per the FDA defined frequency is required.
- *Guidance on evaluation of criteria*: The auditor will ask the facility to demonstrate that the registration frequency was met.

5.17.1.3 Critical - The **written** Food Defense Program considers the Vulnerability Assessment and includes information related to:

• A trained Coordinator
• Food Defense Team members and contact information
• Key regulatory agency representatives and contact information
• First responders and contact information
• Annual documented Food Defense training and education
• Annual Food Defense Program review

- *Explanation of the change*: The severity of the requirement was changed from minor to critical and development of a formal Food Defense Program based on the findings in the vulnerability assessment were added.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.19 Recall/Withdraw Program

5.19.1.3 Critical - 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

- *Explanation of the change*: The severity of the requirement was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.19.1.4 Critical - Testing supports the recall to the **first level of distribution** outside of the control of the facility.

- *Explanation of the change*: The severity of the requirement was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.19.1.5 Critical - One of the recall tests includes **traceability** of the ingredient or food contact packaging material.

- *Explanation of the change*: The severity of the requirement was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.19.1.6 Critical - The written **Recall or Withdrawal Program** includes information related to:
• Recall/Crisis Management team contact information: corporate, emergency, and after hours
• Roles and responsibilities for team members
• Location of the Traceability Program
• Key regulatory agency representative emergency contact information
• Supplier (including food contact packaging) and customer emergency contact information
• Sample recall/withdrawal notification letters

- *Explanation of the change*: The severity of the requirement was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.21 Approved Supplier Program

5.21.1.3 Critical - **Methods and frequency** of supplier performance monitoring is based on risk to the facility.

- *Explanation of the change*: The severity of the requirement was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.21.1.4 Critical - **Laboratories** used for analyses are independently accredited by a competent body. Labs can be internal or external.

- *Explanation of the change*: The severity of the requirement was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.21.1.5 Critical - Facilities that manufacture or ship products to the USA include f**oreign supplier verification and import requirements** as part of the approval program.

- *Explanation of the change*: This requirement was added to ensure that foreign supplier verification is incorporated into the supplier approval programs to meet FSMA requirements.
- *Guidance on evaluation of criteria*: The auditor will challenge the program by asking the facility to demonstrate how foreign material supplier verification and import requirements are addressed at the facility.

5.22 Specification Program

5.22.1.3 Critical - **Documentation** from the supplier states that bag or box materials were sifted or liquid ingredients were strained prior to packaging. In the case that sifting or 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.

- *Explanation of the change*: The requirement was moved from the Operational Methods section and edited to include foreign material control requirements for liquids or documentation of the device used if not a sifter or strainer. The severity was changed from minor to critical.
- *Guidance on evaluation of criteria*: The auditor will randomly select several raw materials and request the documentation stating the foreign material control device used by the supplier.

5.24 High-Risk Processing Record Program

The High-Risk Processing Record Program provides a written approach for documenting records and implementing procedures for changing processing parameters. This Program supports food safety practices in facilities with a microbiological kill step. Examples include, but are not limited to: cooked meat products, pasteurized products, thermal processing, nut roasting, etc.

- *Explanation of the change*: Examples of high-risk processing were added to the italicized text explaining the intent of the requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.24.1.15 Critical - Documentation of the **validation of the kill step** is on file and demonstrates the efficacy of the process.

- *Explanation of the change*: This requirement was added to ensure that validation is conducted to ensure that the defined kill step is effective.
- *Guidance on evaluation of criteria*: The auditor will request documentation that demonstrates that the defined kill step has been validated.

5.24.1.16 Critical - The facility has a procedure to ensure **obsolete documentation** is removed, and if appropriate, replaced with a revised version.

- *Explanation of the change*: The severity of the requirement was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

5.25 HACCP Program

5.25.1.6 Critical - The facility follows the **Seven Principles** of HACCP:

1. The facility has conducted and documented a Hazard Analysis for each raw material and process step. In the case of facilities producing or exporting to the USA or other countries with regulations, regulatory (FDA) requirements for HARPC (Hazard Analysis and Risk Based Preventive Controls) will be evaluated taking into consideration the defined hazard categories or country-defined requirements.
2. Based on the Hazard Analysis, the Critical Control Points (CCPs) are identified, and the procedures for controlling the hazards are described.
3. The Critical Limits for the CCPs are scientifically established and recorded.
4. The facility has established procedures for Monitoring the HACCP Program that includes identification of frequency of activities and responsible person(s).
5. The facility has established procedures for Deviation from the HACCP Program that include identification of short- and long-term Corrective Actions.
6. The facility has established procedures for Verification of the HACCP Program that include identification of frequency of activities and responsible person(s).
7. The facility has legible documented records of monitoring, deviation, and verification activities.

- *Explanation of the change*: Language was added to this requirement to ensure that the Hazard Analysis meets new regulatory guidelines that are country dependent.
- *Guidance on evaluation of criteria*: The auditor will, using the USA as an example, evaluate the Hazard Analysis to ensure that the 12 defined hazards were incorporated.

5.26 Specialized Testing

5.26.1.2 Critical - **Where required by country**, the facility maintains current records of raw material testing, which may include but are not limited to:

• Pesticide residues
• Genetically Modified Organisms (GMO)
• Heavy metals
• Radioactivity
• Allergens
• Mycotoxins

- *Explanation of the change*: Additional examples of raw material testing were added to this requirement. The severity was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.