

# Change Document to Accompany the 2017 AIB International Consolidated Standards for Inspection Prerequisite and Food Safety Programs



## Table of Contents

Introduction .....	2
1. Operational Methods and Personnel Practices.....	2
2. Maintenance for Food Safety.....	16
3. Cleaning Practices .....	21
4. Integrated Pest Management.....	27
5. Adequacy of Prerequisite and Food Safety Programs.....	36

## Introduction

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

For the 2017 update, we have implemented several sets of changes:

- AIB reviewed the whole content of the Standard with regard to regulations on a global extent, industry trends, and best practices, so that requirements are streamlined, easily understood, and current.
- New standards have been added and others have been eliminated to ensure that the content is on the leading edge of the industry.
- AIB changed the way data is arranged to better capture findings in like areas so that comparisons and data capture can be centralized. This resulted in the merging and elimination of requirements and, to this end, many standard numbers have changed.
- AIB 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, identify additional criteria and changes to content, and outline expectations during an inspection. Minor changes, referred to in the fourth bullet point above, are not described in the document. As always, AIB International wants to provide transparency regarding the reasons behind the changes to the Prerequisite and Food Safety Standards, and the necessary clarification to understand and implement them. By doing so, together we can continue to ensure the ongoing successful implementation of food safety programs worldwide.

## 1. Operational Methods and Personnel Practices

### 1.1 Rejection of Shipments/Receipt of Dry Goods

**1.1.1.1 Critical** – Damaged, infested, or **dirty transports/containers** or **materials** are rejected.

- Explanation of the change: The scope of the requirement was expanded to include materials. The word “materials” includes but is not limited to raw materials, packaging, work-in-progress, finished products, food contact processing aids, and other as applicable.
- Guidance on evaluation of criteria: Food Safety Professionals will check that the facility rejects damaged, infested, or dirty materials as well as transports and containers.

### 1.2 Rejection of Shipments/Receipt of Perishables

**1.2.1.1 Critical** – Damaged, infested, or **dirty transports/containers** or **materials** are rejected.

- Explanation of the change: The scope of the requirement was expanded to include materials. The word “materials” includes but is not limited to raw

materials, packaging, work-in-progress, finished products, food contact processing aids, and other as applicable.

- *Guidance on evaluation of criteria:* Food Safety Professionals will check that the facility rejects damaged, infested, or dirty materials as well as transports and containers.

**1.2.1.4 Critical – Temperature requirements for perishable or frozen materials are not compromised during the reception process.**

- *Explanation of the change:* New requirement added to ensure that temperature requirements for perishable products are not compromised during reception, inspection, and unloading activities. There should be no product stacking with food safety implications at non-refrigerated docks.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check through observation and inspection that this requirement is met.

**1.2.2.1 Minor – If critical to food safety, continuous temperature monitoring is in place in temperature-controlled vehicles and the facility maintains documentation of temperature during transport.**

- *Explanation of the change:* The requirement was added to address continuous temperature monitoring during transport and the associated records, if this is critical to food safety.
- *Guidance on evaluation of criteria:* Food Safety Professionals will rate no more than a minor improvement if applicable, because this requirement is specific to the type of monitoring. Concerns with actual temperatures are addressed in requirements above.

### 1.3 Storage Practices

**1.3.1.1 Critical – 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.**

- *Explanation of the change:* The requirement was expanded to include food contact processing aids and other as applicable.
- *Guidance on evaluation of criteria:* Food Safety Professionals will expand rating of storage issues to food contact processing aids.

**1.3.1.2 Critical – ~~Dates~~ Systems to facilitate stock rotation are present visible on the pallet or individual container.**

- *Explanation of the change:* The language was modified to take into consideration other systems of stock rotation beyond the use of manually placed dates. The original requirement was outdated in some cases because of computerized systems.
- *Guidance on evaluation of criteria:* Food Safety Professionals will rate any issues with inadequate systems of stock rotation, according to the Critical Rating Guidance.

**1.3.1.3 Critical – ~~Raw~~ Materials are stored off the floor on pallets, slip-sheets, or stands.**

- *Explanation of the change:* The scope of the requirement was expanded to include materials. The word “materials” includes but is not limited to raw materials, packaging, work-in-progress, finished products, food contact processing aids, and other as applicable.

- *Guidance on evaluation of criteria:* Food Safety Professionals will expand rating to packaging, work-in-progress, finished products, food contact processing aids, and other as applicable.

**1.3.1.4 Critical** — ~~Raw materials, packaging, work-in-process and finished products are stored at least 18 in or 45 cm away from walls and ceilings. A clear, unrestricted perimeter is provided at floor-wall junctions to ensure adequate access for cleaning, inspection, and IPM activities.~~

- *Explanation of the change:* The language was modified to clarify the focus of this requirement, which is that access should be provided to perimeter areas to allow for cleaning, inspection, and IPM activities (rather than a specific number of inches or cm).
- *Guidance on evaluation of criteria:* Food Safety Professionals will check that adequate access is provided to perimeter areas to allow for proper cleaning, inspection, and IPM activities.

**1.3.1.5 Critical** — ~~Adequate space is maintained between rows of stored raw materials, packaging, work-in-process, and finished products to allow cleaning and inspection. Procedures are followed to guarantee the proper cleaning, inspection, and monitoring for pest activity in storage areas where an 18 in or 45 cm inspection perimeter cannot be provided.~~ **Adequate spacing is provided between rows to allow for cleaning and inspection.**

- *Explanation of the change:* The language was modified to add clarity to the focus of this requirement, which is that adequate space should be provided so that cleaning and inspection activities are not compromised.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check through observation and inspection the conformity to this requirement.

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

- *Explanation of the change:* Language was added for clarity. Because this requirement may be outdated due to computerized systems in some plants, this only refers to facilities where it is applicable.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**1.3.2.4 Minor** — ~~If an 18 in or 45 cm clearance from walls is impossible due to aisle widths and forklift turning space, a rack system can be installed against the wall. In this case, a bottom rail is installed 18 in or 45 cm off the floor so that no pallets are stored on the floor.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

## 1.4 Storage Conditions

**1.4.1.1 Critical** — Storage areas are **clean, well ventilated, and dry**. ~~Raw~~ **Stored** 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 scope of the requirement was expanded to include materials. The word “materials” includes but is not limited to raw materials, packaging, work-in-progress, finished products, food contact processing aids, and other as applicable.
- *Guidance on evaluation of criteria:* Food Safety Professionals will expand the rating to materials as applicable.

**1.4.1.3 Critical** — All ~~toxic~~ chemicals, including cleaning and maintenance compounds, and **non-product materials**, including equipment and utensils, **are stored in a separate area**.

- *Explanation of the change:* The word “toxic” was removed, meaning that the requirement should apply to all chemicals and should not be limited to toxic chemicals.
- *Guidance on evaluation of criteria:* Food Safety Professionals will rate any issues with storage of chemicals.

**1.4.1.5 Critical** – **Special handling procedures** are followed for packaging materials that pose a product safety risk if mishandled (e.g., ~~aseptic or~~ glass packaging). Failures and Corrective Actions are documented.

- *Explanation of the change:* The word “aseptic” was removed. Packaging materials for aseptic lines are sterilized prior to filling (before sterilization, they are handled like any other packaging material).
- *Guidance on evaluation of criteria:* No additional guidance is required. The language was modified slightly with no change to the meaning or intent of the requirement.

**1.4.1.6 Critical** – **Returned products returned by customers** are not returned to finished goods storage areas **available for use** until they are inspected and **dispositioned** released for use by authorized personnel.

- *Explanation of the change:* The phrase “not returned to finished goods storage areas” was replaced by “not available for use.” The phrase was replaced because, if the facility uses computerized systems, the returned materials might be returned to storage (if there is no segregated storage area available) and remain in a blocked status until they can be dispositioned by authorized personnel. Materials are still inspected as all incoming goods (Standard 1.1 and 1.2 apply).
- *Guidance on evaluation of criteria:* Food Safety Professionals will rate any issues with block and release status of returned materials as applicable.

## 1.5 Raw Material/Finished Product Inventory

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

- *Explanation of the change:* Language was added to specify a minimum frequency for inspections based on the common life cycle of insects.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check records related to such inspections and their frequency (e.g., slow moving stock records, etc.).

**1.5.1.3 Critical** – **Food contact** containers are **covered or inverted** while in storage to protect against contamination from overhead structures.

- *Explanation of the change:* The word “containers” was replaced by “food contact containers,” as the requirement does not apply to garbage or waste containers, etc.
- *Guidance on evaluation of criteria:* Food Safety Professionals will rate any issues with storage of food contact containers.

## 1.6 Pallets

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

- *Explanation of the change:* The requirement was expanded to include that pallets should be used in a way that will not create hazard to materials.

- *Guidance on evaluation of criteria:* Food Safety Professionals will rate issues with pallet condition and use based on risk to materials.

## **1.7 Designated Carry-over and Rework Areas**

- *Explanation of the change:* A merger of Standards 1.7 and 1.18 because both standards involved rework and had similar requirements.

**1.7.1.3 Critical** – There is 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**.

- *Explanation of the change:* The language was modified to add clarity to the intent of this requirement. The previously suggested frequency for reprocessing rework (weekly) was removed and replaced by the requirement for a defined maximum storage time that is not past expiration dates.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check expiration dates and defined maximum storage time for rework materials.

**1.7.1.4 Critical** – Carry-over is **minimal** and used at the first opportunity.

- *Explanation of the change:* Former requirement 1.18.1.2.
- *Guidance on evaluation of criteria:* No guidance is required.

**1.7.1.5 Critical** – Carry-over product, work-in-progress, rework, and raw materials are **properly identified and dated for traceability purposes**. **Expiration dates are included as applicable**.

- *Explanation of the change:* Former requirement 1.18.1.1. The language was modified to add clarity. A new requirement was added for carry-over, work-in-progress, and rework materials to include expiration dates as applicable.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check established expiration dates as applicable.

**1.7.1.6 Critical** – Reworked or blended materials are **lot traceable**.

- *Explanation of the change:* Former requirement 1.18.1.3.
- *Guidance on evaluation of criteria:* No guidance is required.

**1.7.1.7 Critical** – Reworked or blended materials are **strained/sifted prior to use, as applicable, based on a risk assessment**.

- *Explanation of the change:* Former requirement 1.18.1.4. Language was added to allow for a risk based assessment of the need to sieve or filter reworked or blended materials.
- *Guidance on evaluation of criteria:* No additional guidance is required.

## **1.9 Bulk Material Handling**

**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~~ **shipping document** to verify that the numbers match during shipping and receiving.

- *Explanation of the change:* The language was modified to add clarity: Changed “bill of lading” to “shipping document” and removed “if present” to mean that the security seals are required for all bulk material loads.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check security seal numbers on the shipping documents.

**1.9.1.5 Critical** – ~~Storage tanks are waterproof.~~

- *Explanation of the change:* Requirement removed.



- Guidance on evaluation of criteria: No guidance is required.

## 1.10 Sampling Procedures

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

- Explanation of the change: The language was modified to add clarity: The word “aseptic” was replaced by “appropriate.” A requirement was added that sampling should be done in a manner that will not contaminate product.
- Guidance on evaluation of criteria: Food Safety Professionals will rate any issues with potential contamination through sampling procedures.

## 1.12 Raw Material Transfer

**1.12.1.1 Critical** – The facility follows **procedures** for transferring and handling ~~food~~ materials **and includes a system to provide traceability information at all times**.

- Explanation of the change: The word “food” was removed to expand the requirement to packaging. The requirement was further expanded to include a system that provides traceability information at all times (identification of materials).
- Guidance on evaluation of criteria: Food Safety Professionals will rate any issues with the facility not following procedures for transferring and handling of materials. Issues with inadequate systems that provide traceability information will also be rated.

**1.12.1.3 Critical** – **Raw material and ingredient storage containers** are properly identified to maintain ~~ingredient~~ **the materials’** integrity and traceability.

- Explanation of the change: The requirement applies to containers for raw materials and ingredients; 1.12.1.1 requires that the procedure includes a system to provide traceability information for materials, while this requirement refers to containers.
- Guidance on evaluation of criteria: No additional guidance is required.

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

- Explanation of the change: Former requirement 1.12.2.4. This minor criteria was elevated to critical and the language was modified to add clarity.
- Guidance on evaluation of criteria: No additional guidance is required.

**1.12.2.4 Critical** – ~~Packaging material is removed from the protective outer package outside of production areas to eliminate potential contamination.~~

- Explanation of the change: The requirement was elevated from minor to critical; see 1.12.1.4.
- Guidance on evaluation of criteria: No guidance is required.

## 1.13 Bulk Material Sifting

- Explanation of the change: The title of the Standard was modified to include sieving of other dry materials, not necessarily received in bulk.

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

- Explanation of the change: The word “objects” was deleted.

- Guidance on evaluation of criteria: No additional guidance is required.

#### **1.14 Bulk Liquid Materials Filters and strainers**

- Explanation of the change: The title of the Standard was modified to include filters and strainers used within the process or for finished product.

##### **1.14.1.3 Critical – Inline filters and strainers are inspected for integrity as part of the CIP process.**

- Explanation of the change: A new requirement was added to address inspection of inline production filters or final product filters where present, performed as part of the CIP process (before or after).
- Guidance on evaluation of criteria: Food Safety Professionals will rate any issues with inspection and integrity of inline filters and strainers.

##### **1.14.1.4 Critical – Strainer mesh sizes are sufficiently restrictive to remove foreign material from liquid ingredient deliveries materials handled.**

- Explanation of the change: The words “ingredient deliveries” were changed to “materials handled” so that the requirement is broader and includes inline filtration, not just bulk liquid reception.
- Guidance on evaluation of criteria: Food Safety Professionals will expand the rating to inline filtration as applicable.

##### **1.14.1.5 Critical – Strainers inspections, used to remove foreign material are inspected, and findings and Corrective Actions are documented and kept on file.**

- Explanation of the change: The language was modified to clarify that the requirement applies to strainers used to remove foreign material (for food safety reasons).
- Guidance on evaluation of criteria: No additional guidance is required.

#### **1.15 Foreign Material Control Devices**

##### **1.15.1.10 Critical – Magnets, where present, are tested for strength on a defined frequency. Deviations from manufacturer requirements or specifications are addressed.**

- Explanation of the change: A new requirement was added to address magnets used as foreign material control devices.
- Guidance on evaluation of criteria: Food Safety Professionals will check that magnets used for food safety purposes are tested for strength on a defined frequency and that testing results are within the manufacturer’s requirements or specifications.

#### **1.16 Waste Material Disposal**

##### **1.16.1.1 Critical – ~~Trash or inedible waste is stored in properly covered, labeled containers.~~ Waste is stored in properly identified containers.**

- Explanation of the change: The requirement was modified: Waste containers need to be properly identified to eliminate issues with improper usage.
- Guidance on evaluation of criteria: Food Safety Professionals will check for potential evidence of misuse of containers and/or containers that have not been properly identified.

##### **1.16.1.2 Critical – ~~Waste containers are emptied at least daily.~~ Waste is managed to prevent pest and microbial issues. Management techniques could include cleaning, covering and emptying containers regularly.**



- *Explanation of the change:* The requirement was modified: Waste and waste containers should be managed in a way to prevent pest and microbial development. This includes emptying, cleaning, and covering containers as needed.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check for evidence of effective waste management, through the lack of pest or microbial development.

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

- *Explanation of the change:* A new requirement was added to address traffic routes for waste disposal.
- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate and rate any potential risks to products or food contact surfaces during removal of waste.

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

- *Explanation of the change:* Former requirement 1.16.1.3. The language was modified to add clarity.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check waste handling activities when possible and will evaluate potential cross-contamination issues.

**1.16.1.6 Critical – Waste disposal meets food regulatory requirements.**

- *Explanation of the change:* The language was modified to add clarity.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**1.17 Ingredient Scoops Containers, Utensils, and Tools**

- *Explanation of the change:* Merging of Standards 1.17 and 1.24.

**1.17.1.1 Critical – All in-use ingredient containers have individual transfer scoops, as needed based on risk assessment, (where needed) to prevent cross-contamination.**

- *Explanation of the change:* The language was modified to add clarity. The use of individual transfer scoops should be risk based.
- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate and rate potential cross-contamination issues caused by scoops.

**1.17.1.2 Critical – Ingredient scoops, tools, and utensils are color-coded or otherwise identified, as necessary, to prevent in a manner that does not allow a cross-contamination risk from allergens or other non-related materials.**

- *Explanation of the change:* The phrase “from allergens or other non-related material” was removed to make the requirement more general as it applies to all cross-contamination issues.
- *Guidance on evaluation of criteria:* Food Safety Professionals will rate issues with the identification of ingredient scoops based on product risk for cross-contamination.

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

- *Explanation of the change:* Covered under requirement 1.17.1.4.
- *Guidance on evaluation of criteria:* No additional guidance is required.

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

- *Explanation of the change:* Former requirement 1.24.1.1.
- *Guidance on evaluation of criteria:* No guidance is required.

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

- *Explanation of the change:* Former requirement 1.24.1.2. The language was modified to add clarity.
- *Guidance on evaluation of criteria:* No guidance is required.

**1.17.1.5 Critical** – Containers are **legibly labeled with contents**.

- *Explanation of the change:* Former requirement 1.24.1.3.
- *Guidance on evaluation of criteria:* No guidance is required.

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

- *Explanation of the change:* Former requirement 1.24.1.4.
- *Guidance on evaluation of criteria:* No guidance is required.

## **1.18 Product Identification**

**1.18.1.1 Critical** – ~~Carry over product, work in progress, rework, and raw materials are properly identified and dated.~~

- *Explanation of the change:* Combined with Standard 1.7.
- *Guidance on evaluation of criteria:* No guidance is required.

**1.18.1.2 Critical** – ~~Carry over is minimal and used at the first opportunity.~~

- *Explanation of the change:* Combined with Standard 1.7.
- *Guidance on evaluation of criteria:* No guidance is required.

**1.18.1.3 Critical** – ~~Reworked or blended materials are lot traceable.~~

- *Explanation of the change:* Combined with Standard 1.7.
- *Guidance on evaluation of criteria:* No guidance is required.

**1.18.1.4 Critical** – ~~Reworked or blended materials are strained/sifted prior to use.~~

- *Explanation of the change:* Combined with Standard 1.7.
- *Guidance on evaluation of criteria:* No guidance is required.

## **1.18 Allergen Handling**

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

- *Explanation of the change:* A new requirement was added to address the identification system for materials containing allergens (i.e., color coded labels, etc.).
- *Guidance on evaluation of criteria:* Food Safety Professionals will check that allergen-containing materials are properly and consistently identified.

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

- *Explanation of the change:* New requirement added to address allergen content for chemicals, processing aids, and other materials as needed.

- *Guidance on evaluation of criteria:* Food Safety Professionals will check that the facility has allergen declarations or another document that includes allergen information for materials such as processing aids, food contact lubricants, handwashing soaps, etc., and that cross-contamination risks are assessed and eliminated.

**1.18.1.3 Critical** – 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.

- *Explanation of the change:* A new requirement was added to address storage practices to eliminate cross-contamination.
- *Guidance on evaluation of criteria:* Food Safety Professionals will rate any allergen storage issues based on risk for product cross-contamination.

**1.18.1.4 Critical** – Product labels are correct for the specific line production run.

- *Explanation of the change:* A new requirement was added: Product packaging and labels should be correct for the specific production batch to eliminate mislabeling issues.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check that the facility has a system in place to verify that product labels are correct for the specific batch of production

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

- *Explanation of the change:* A new requirement was added to address allergen cross-contact issues that might be caused by personal hygiene and outer garments.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check that the facility has a system in place to eliminate allergen cross-contact that may be caused by personal hygiene and use of outer garments.

## **1.22 ~~Temperature Sensitive Materials~~ Controlled Temperature for Food Safety**

- *Explanation of the change:* The language was modified to add clarity.

**1.22.1.2 Critical** – ~~Temperature sensitive materials are stored to maintain the appropriate internal temperatures: 40DegreeF or 4DegreeC or below 140DegreeF or 60DegreeC or above Or in accordance with country specific regulation.~~ 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 food.

- *Explanation of the change:* Requirement removed. A new requirement was added: The facility needs to have temperature limits associated with food safety clearly defined. Process steps that need to be considered as applicable are storage, thawing, tempering, and holding hot food.
- *Guidance on evaluation of criteria:* Food Safety Professionals will rate any issues with temperature requirements associated with food safety not clearly defined or with compromised temperature requirements.

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

- *Explanation of the change:* A new requirement was added: Corrective actions should be defined.

- *Guidance on evaluation of criteria:* Food Safety Professionals will check that the facility has defined corrective actions for materials affected by controlled temperature storage failures based on food safety risk.

**1.22.2.2 Minor** – ~~Freezer and coolers are provided with vinyl strip doors, self-closing devices, or other methods to maintain temperatures.~~ **Temperature monitoring probes are placed at the warmest parts of temperature-controlled storage facilities.**

- *Explanation of the change:* A new requirement was added to address best practices regarding placement of the temperature monitoring probes in controlled temperature storage areas (as related to food safety).
- *Guidance on evaluation of criteria:* Food Safety Professionals will check placement of the temperature monitoring probes.

## **1.23 Cross-contamination Prevention**

**1.23.1.4 Critical** – ~~When required,~~ **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.**

- *Explanation of the change:* The language was modified to add clarity.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**1.23.1.7 Critical** – 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 wrong packaging.**

- *Explanation of the change:* A new requirement was added to address mislabeling issues (i.e., product placed in the wrong packaging).
- *Guidance on evaluation of criteria:* Food Safety Professionals will extend rating to mislabeling issues regarding product placed in the wrong packaging.

## **1.24 Containers and Utensils (Combined with 1.17).**

**1.24.1.1 Critical** – ~~Containers and utensils used to transport, process, hold or store raw materials, work in progress, rework or finished products are constructed, handled and maintained in a way that prevents contamination.~~

- *Explanation of the change:* Combined with 1.17.
- *Guidance on evaluation of criteria:* No guidance is required.

**1.24.1.2 Critical** – ~~Containers for work in progress or finished products are only used for their designated purposes.~~

- *Explanation of the change:* Combined with 1.17.
- *Guidance on evaluation of criteria:* No guidance is required.

**1.24.1.3 Critical** – ~~Containers are legibly labeled with contents.~~

- *Explanation of the change:* Combined with 1.17.
- *Guidance on evaluation of criteria:* No guidance is required.

**1.24.1.4 Critical** – ~~Snap-off blades are not used in production, packaging, or raw material storage areas.~~

- *Explanation of the change:* Combined with 1.17.
- *Guidance on evaluation of criteria:* No guidance is required.

## **1.25 Finished Product Transportation (formerly 1.26)**

**1.25.1.8 Critical** – Temperatures of vehicles, **for temperature-controlled transports**, are **checked and recorded** before loading.

- *Explanation of the change:* Former requirement 1.26.1.8. The language was modified to add clarity.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**1.25.1.10 Critical** – Prior to loading, **all shipping vehicles and products are inspected** for cleanliness, **damage, or** ~~and structural~~ defects that could jeopardize the product.

- *Explanation of the change:* Former requirement 1.26.1.10. The language was modified to include inspection of products prior to loading (in case they have been damaged while in storage in the warehouse).
- *Guidance on evaluation of criteria:* Food Safety Professionals will check that the facility inspects shipping vehicles and product for damage, cleanliness, and signs of infestation prior to loading.

**1.25.1.12 Critical** – **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.

- *Explanation of the change:* Former requirement 1.26.1.12. The language was modified to include risk based inspection and cleaning frequency for trucks.
- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate and rate issues with poor cleanliness and condition of the trucks, and issues with the frequency of inspection and cleaning activities not being defined.

**1.25.1.13 Critical** – 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:* Former requirement 1.26.2.6. The minor requirement was elevated to critical.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check that the facility maintains records of temperature checks during transport.

**1.25.1.14 Critical** – **Security seals or padlocks** are provided, and their use is documented as per facility or customer requirements.

- *Explanation of the change:* Former requirement 1.26.2.2. The minor requirement was elevated to critical.
- *Guidance on evaluation of criteria:* No additional guidance is required.

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

- *Explanation of the change:* Former requirement 1.26.2.5. The minor requirement was elevated to critical.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**1.26.2.1 Minor** – ~~Common carriers or customers are encouraged to maintain their delivery vehicles in sanitary condition, and in good repair.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

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

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**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 taking place.~~



- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

## **1.26 Hand Washing Facilities** (formerly 1.27)

**1.26.1.3 Critical** – **Hand sanitizing stations** are provided, ~~as where~~ appropriate, based on risk assessment.

- *Explanation of the change:* Former requirement 1.27.1.3. The language was modified to include risk based assessment of hand sanitizing station locations.
- *Guidance on evaluation of criteria:* Food Safety Professionals will rate issues related to absence of hand sanitizing stations in areas critical to food safety.

**1.26.1.5 Critical** – **“Wash hands”** signs appear above sinks and entries to production areas, ~~where appropriate.~~

- *Explanation of the change:* Former requirement 1.27.1.5. The language was modified to add clarity. “Wash hands” signs are required at all hand washing areas and at production entries.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**1.27.2.1 Minor** – ~~Dispensers for disposable paper towels are covered.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

## **1.27 Washrooms, Showers, and Locker Rooms** (formerly 1.28)

**1.28.1.2 Critical** – ~~No pests or mold are present~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

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

- *Explanation of the change:* Former requirement 1.28.1.3. The language was modified to include all items that might pose a risk to food safety. This could include personnel practices such as storing ingredient scoops and other tools or utensils in lockers, etc.
- *Guidance on evaluation of criteria:* Food Safety Professionals will extend rating to include mishandling or inappropriate storage of items, which might pose a risk to food safety.

**1.27.2.1 Minor** – Company-owned **personnel lockers are inspected** on a defined frequency ~~as allowed by national or local regulations.~~

- *Explanation of the change:* Former requirement 1.28.2.1. The language was modified to add the phrase “as allowed by national or local regulations” to address regions where the facility is not allowed to inspect personnel lockers for privacy reasons.
- *Guidance on evaluation of criteria:* No additional guidance is required.

## **1.28 Personal Hygiene** (formerly 1.29)

**1.28.1.3 Critical** – Personnel are ~~encouraged~~ **required** to practice **good personal hygiene** at all times.

- *Explanation of the change:* Former requirement 1.29.1.3. The language was modified to add clarity.
- *Guidance on evaluation of criteria:* No additional guidance is required.



### **1.30 High-Risk Clothing Management** (formerly 1.31)

**1.31.2.1 Minor** – ~~Personal clothing above the knee is completely covered by work clothes (e.g., smocks).~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

### **1.32 Health Conditions** (formerly 1.33)

**1.32.1.1 Critical** – No person with **exposed** boils, sores, infected wounds, or any other **infections or communicable disease** is permitted to contact food ~~as defined by regulations.~~

- *Explanation of the change:* Former requirement 1.33.1.1. The word “exposed” was added for clarity.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**1.32.2.1 Minor** – ~~Each lot of metal strip bandages is~~ **tested in the metal detector** **verified as being detectable with the facility's foreign material detection device.**

- *Explanation of the change:* Former requirement 1.33.2.1. The language was modified to include that each lot of bandages is verified as to detectability by the foreign material detection device present in the facility (i.e., X-ray instead of metal detector).
- *Guidance on evaluation of criteria:* Food Safety Professionals will check facility practices regarding testing bandages at the foreign material detection device.

### **1.33 Non-Facility Personnel** (formerly 1.34)

**1.33.1.1 Critical** – 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
- *Explanation of the change:* Former requirement 1.34.1.1. The language was modified to add the requirement that non-facility personnel should comply with company policies.
- *Guidance on evaluation of criteria:* No additional guidance is required.

### **1.35 Glass Container Breakage** (formerly 1.36)

**1.35.1.2 Critical** – Records are current and document that **procedures for glass breakage** clean-up in storage, handling, production, and packaging areas are **effectively** followed.

- *Explanation of the change:* Former requirement 1.36.1.2. The word “effectively” was added to mean that if glass breakage procedures are followed and completed, no broken glass will be present.
- *Guidance on evaluation of criteria:* Food Safety Professionals will rate any observations of broken glass still present in the area after glass breakage procedures have been completed.

### **1.37 Examination of Materials** (formerly 1.38)

**1.37.1.1 Critical** – ~~Materials that cannot be sifted or filtered, such as~~ fruits, nuts, coconut, and ~~other similar materials products,~~ are **visually examined** ~~before~~ **prior to** use.

- *Explanation of the change:* Former requirement 1.38.1.2. The language was modified to add clarity. The requirement applies to materials and ingredients that cannot be sifted or filtered.
- *Guidance on evaluation of criteria:* No additional guidance is required.

## 2. Maintenance for Food Safety

### 2.1 Facility Location

**2.1.2.2 Critical** – ~~Effective measures are in place to prevent product contamination from neighboring properties. These measures are periodically reviewed.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

### 2.2 Outside Grounds and Roof

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

- *Explanation of the change:* Language was added to provide clarity.
- *Guidance on evaluation of criteria:* Food Safety Professionals will rate observations of unsanitary conditions of the outside grounds related to litter and waste removal.

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

- *Explanation of the change:* The language was modified to include any vegetation that could provide pest harborage or access to the building.
- *Guidance on evaluation of criteria:* Food Safety Professionals will rate any issues with vegetation such as trees, shrubs, and weeds near the building that could increase pest ingress possibilities.

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

- *Explanation of the change:* The requirement was expanded to include outside grounds.
- *Guidance on evaluation of criteria:* Food Safety Professionals will rate any issues with the roof, building structures, and outside grounds maintenance.

**2.2.2.1 Minor** – ~~Outdoor equipment storage is minimal.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

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

- *Explanation of the change:* The requirement was expanded to include cleanliness issues that could cause pest attraction in truck bays and garage areas.
- *Guidance on evaluation of criteria:* Food Safety Professionals will look for evidence of maintenance and cleanliness issues that could cause pest attraction at truck bays and garage areas.

## 2.3 ~~Security Equipment~~

- *Explanation of the change:* The standard was removed because it is not directly linked to food safety (food defense issues should be rated under 5.15 Food Defense and physical observations should be evaluated according to the vulnerability assessment).

### 2.3.2.1 ~~Minor – Physical security measures that require maintenance or design can include:~~

- ~~Perimeter fences~~
- Surveillance cameras
- Locked doors
- Security guard stations
- Controlled access
- Controlled bulk storage areas
- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

## 2.3 Layout (formerly 2.4)

### 2.3.1.1 **Critical** – Space is maintained **between** equipment and structures to enable ~~cleaning~~ dismantling and maintenance activities.

- *Explanation of the change:* Former requirement 2.4.1.1. The language was modified to include dismantling and maintenance activities.
- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate the space between equipment to allow access for dismantling and maintenance activities related to food safety.

### 2.3.1.2 **Critical** – ~~There is adequate space to place equipment and raw materials.~~ Adequate space is provided between equipment or structures to **allow access** for cleaning, inspection, and IPM activities.

- *Explanation of the change:* The original requirement is addressed in 2.4.1.1 and 1.19.2.3. A new requirement was added to address layouts that, in some cases, include structures with narrow voids between adjacent areas (e.g., office space in production or warehouses).
- *Guidance on evaluation of criteria:* Food Safety Professionals will rate the presence of narrow void between equipment and/or structures and evaluate access provided for cleaning, inspection, and IPM activities.

## 2.4 Floors (formerly 2.5)

### 2.4.1.1 **Critical** – Floors are ~~made of materials that are~~ **impervious and** easily cleaned ~~and kept in good repair.~~

- *Explanation of the change:* Former requirement 2.5.1.1. The language was modified to include that floors should be impervious (not permitting penetration, incapable of being damaged and affected) and easily cleaned.
- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate and rate issues with floor damage as related to food safety.

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

- *Explanation of the change:* Former requirement 2.5.1.4. The requirement was expanded to include that floor construction should be durable, as applicable and possible, to withstand the operation environment.
- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate the floor's maintenance condition and ability to withstand the operation environment and cleaning activities.

**2.5.1.5 Critical** – Floors are ~~impervious~~.

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**2.6 Walls** (formerly 2.7)

**2.6.1.3 Critical** – 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)**
- *Explanation of the change:* Former requirement 2.7.1.3. The requirement was expanded to include that walls should be durable to withstand operation environment.
- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate the maintenance condition of walls and their ability to withstand operation environment, as related to food safety issues.

**2.7 Ceilings and Overhead Structures** (formerly 2.8)

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

- Prevent dirt accumulation
- Reduce condensation and mold/**microbial** growth
- Facilitate cleaning
- *Explanation of the change:* Former requirement 2.8.1.3. Language was added to expand the requirement as related to microbial issues and to add clarity.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**2.7.1.5 Critical** – Fixtures, ducts, pipes, and overhead structures are installed and maintained so that **drips, leaks, and condensation do not contaminate** foods, raw materials, or food contact surfaces.

- *Explanation of the change:* Former requirement 2.8.1.5. The requirement was expanded to include issues with product leaks and other leaks.
- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate overhead structures with regards to leaks, drips, and condensation issues that could affect food safety.

**2.8 Glass, Brittle Plastics, and Ceramics Control** (formerly 2.9)

**2.9.1.4 Critical** – ~~Glass that cannot be fully protected is addressed in the Glass, Brittle Plastics, and Ceramics Program.~~

- *Explanation of the change:* Requirement removed. The requirement was included under requirement 2.8.1.4.

**2.8.1.2 Critical** – Light bulbs, fixtures, windows, mirrors, skylights, and other glass suspended over product zones, product areas, **and material storage areas** ~~ingredients, or packaging supplies~~ are of the **safety type** or are otherwise protected to prevent breakage.

- *Explanation of the change:* Former requirement 2.9.1.2. The requirement was expanded to include lighting in finished goods storage areas.
- *Guidance on evaluation of criteria:* Unprotected lighting should be evaluated based on risk of product contamination, including inadvertent transfer of broken glass from storage areas to exposed product areas.

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

- *Explanation of the change:* Former requirement 2.9.1.5. The language was generalized to include all issues related with essential glass, brittle plastics, and ceramics present in the facility.
- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate and rate observations related to essential glass, brittle plastics, and ceramics present in areas where product contamination is likely.

## **2.9 Air Makeup Units** (formerly 2.10)

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

- *Explanation of the change:* Former requirement 2.10.2.1. This minor requirement was elevated to critical and expanded to include that dust extraction should be adequate for the process and equipment/structures should be maintained.
- *Guidance on evaluation of criteria:* No additional guidance is required.

## **2.13 Cross-contamination Prevention** (formerly 2.14)

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

- *Explanation of the change:* Former requirement 2.14.1.1. The language was modified to add clarity.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**2.13.1.3 Critical** – Areas for **washing and cleaning** are located away from production activities, ~~where~~ **as appropriate based on risk**.

- *Explanation of the change:* Former requirement 2.14.1.3. The language was modified to add clarity to the intent of this requirement.
- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate and rate observations related to the location of washing and cleaning areas based on risk of product contamination.

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

- *Explanation of the change:* Former requirement 2.14.1.5. The language was modified to add clarity. Segregation items and exclusionary systems should be sanitary.
- *Guidance on evaluation of criteria:* No additional guidance is required.

## **2.15 Temporary Repair Materials** (formerly 2.16)

**2.15.1.1 Critical** – 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.

- *Explanation of the change:* Former requirement 2.16.1.1. The requirement was expanded to include control of deteriorating temporary repairs in case this happens before a permanent solution can be installed.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**2.15.1.3 Critical** – The facility maintains a **record of work orders** or repair requests, which include progress and status.

- *Explanation of the change:* Former requirement 2.16.1.3. The requirement was expanded to include progress and status (e.g., pending or completed) of the work orders. The language of the requirement was modified to address work orders with no follow up, which are observed in many cases.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check the progress and status information of the work order records.

**2.15.1.4 Critical** – The facility follows **temporary repair procedures**, which include a list of materials approved for use as temporary repairs.

- *Explanation of the change:* Former requirement 2.16.1.4. A new requirement was added that the facility should define materials allowed for use in temporary repairs (e.g., product packaging should not be allowed for temporary repairs).
- *Guidance on evaluation of criteria:* Food Safety Professionals will check the procedure and list of materials approved for use as temporary repairs with regards to food safety concerns.

## **2.16 Temperature Measuring Devices** ~~Equipment Calibration~~ (formerly 2.17)

- *Explanation of the change:* The scope of this standard was expanded to include calibration of all equipment as necessary to food safety (not only temperature measuring devices).

**2.16.1.3 Critical** – Temperature and other measuring devices critical to product safety are monitored on a frequent basis frequency, as defined by risk assessment.

- *Explanation of the change:* Former requirement 2.17.1.3. The requirement was expanded to include monitoring of other devices critical to food safety as well as thermometers, as applicable.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check monitoring of all devices critical to food safety as applicable based on risk.

**2.16.1.4 Critical** – The facility uses **monitoring systems** that trigger alarms when temperatures exceed set deviations from critical limits occur.

- *Explanation of the change:* Former requirement 2.17.1.4. The language was modified to address all critical limit deviations as applicable.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**2.16.1.5 Critical** – **Thermometers are located** inside coolers, freezers, and other temperature-controlled storage areas. **Monitoring systems are in place.**

- *Explanation of the change:* Former requirement 2.17.1.5. Language was added to include the requirement for temperature monitoring systems to be in place (continuous or manual monitoring).



- *Guidance on evaluation of criteria:* Food Safety Professionals will review temperature monitoring records.

**2.16.1.6 Critical** – **Devices critical to food safety** i.e. pH-meters, manometers, metal detectors and x-ray machines, are routinely calibrated.

- *Explanation of the change:* A new requirement was added to address calibration of all devices critical to food safety as applicable.
- *Guidance on evaluation of criteria:* Food Safety Professionals will review calibration certificates and records as applicable.

## **2.19 Parts Storage** (formerly 2.20)

**2.19.1.3 Critical** – Only **clean repair parts and equipment** are stored in parts storage areas.

- *Explanation of the change:* Former requirement 2.20.2.1. The minor requirement was elevated to critical.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**2.19.2.1 Minor** – **Small items such as nuts, bolts, washers and other, are properly stored to prevent contamination of product or damage to equipment.**

- *Explanation of the change:* A new requirement was added to address storage for small items that may cause product contamination issues.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check that small items are properly stored to prevent food safety issues.

## **2.20 Hand Washing Facilities Design** (formerly 2.21)

**2.20.1.4 Critical** – **Hands-free hand washing equipment is and paper dispensers are** provided in production areas where essential to product safety.

- *Explanation of the change:* Former requirement 2.21.1.4. The scope of the requirement was expanded to include paper dispensers, which need to be hands-free.
- *Guidance on evaluation of criteria:* No additional guidance is required.

# **3. Cleaning Practices**

## **3.2 ~~Food Contact~~ Cleaning Compounds and Sanitizers**

- *Explanation of the change:* The scope of the requirement was expanded to add clarity and address chemical residues as well.

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

- *Explanation of the change:* The word “surface” was added to increase accuracy.
- *Guidance on evaluation of criteria:* No additional guidance is required.

## **3.3 ~~Equipment and~~ Cleaning Tools and Utensils**

- *Explanation of the change:* The standard was divided into two for clarity and uniformity purposes. This standard refers to cleaning tools and utensils and the next standard addresses cleaning equipment issues.

**3.3.1.1 Critical** – **Cleaning equipment and tools and utensils are available for use.**

- *Explanation of the change:* The word “equipment” was removed as a subsequent requirement addresses this.
- *Guidance on evaluation of criteria:* No additional guidance is required.

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

- *Explanation of the change:* The word “equipment” was replaced by “tools and utensils” as a subsequent requirement addresses equipment. The requirement was expanded to include packaging.
- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate the maintenance condition of cleaning tools and utensils with regards to food and/or packaging contamination issues.

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

- *Explanation of the change:* The word “tools” was added for uniformity purposes and to include all relevant items.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**3.3.1.4 Critical** – **Tools and utensils** used to **clean restrooms or floor drains** are never used for any other cleaning purposes.

- *Explanation of the change:* The word “tools” was added for uniformity purposes and to include all relevant items.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**3.3.1.5 Critical** – All cleaning **tools and utensils** are **cleaned and properly stored** after use. Proper storage includes segregation to ensure that cross-contamination does not occur.

- *Explanation of the change:* The word “tools” was added for uniformity purposes and to include all relevant items.
- *Guidance on evaluation of criteria:* No additional guidance is required.

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

- *Explanation of the change:* The word “tools” was added for uniformity purposes and to include all relevant items.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**3.3.1.8 Critical** – **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 product.

- *Explanation of the change:* The word “tools” was added for uniformity purposes and to include all relevant items.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**3.3.1.9 Critical** – **Separate and distinct tools and utensils are used to clean food contact surfaces between different allergens or non-allergens.**

- *Explanation of the change:* A new requirement was added to address the use of different tools and utensils when it comes to allergen cleaning to avoid cross-contamination issues.
- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate and rate observations related to the use of tools and utensils during allergen cleaning that pose a risk of cross-contamination.

**3.3.2.1 Minor** – ~~Air hoses with restricted head pressure are used only to clean inaccessible equipment.~~

- *Explanation of the change:* Requirement removed and replaced by 3.4.1.2.
- *Guidance on evaluation of criteria:* No guidance is required.

**3.3.2.2 Minor** – Air hoses used for cleaning when the facility is **not in operation** in order to prevent potential product contamination.

- *Explanation of the change:* Requirement removed and replaced by 3.4.1.2.
- *Guidance on evaluation of criteria:* No guidance is required.

**3.3.2.3 Minor** – Forklifts, pallet jacks, and similar equipment are **cleaned and the cleaning is tracked** on the Master Cleaning Schedule or Preventive Maintenance Schedule.

- *Explanation of the change:* Requirement removed and replaced by 3.4.1.6.
- *Guidance on evaluation of criteria:* No guidance is required.

### 3.4 Cleaning Equipment

- *Explanation of the change:* The standards were divided for clarity and uniformity purposes. This standard refers to cleaning equipment requirements.

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

- *Explanation of the change:* Former requirement 3.3.1.9. The scope of the requirement was expanded to include packaging. Food contact packaging should be handled as an ingredient.
- *Guidance on evaluation of criteria:* No additional guidance is required.

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

- *Explanation of the change:* New requirement added to address the use of compressed air for cleaning.
- *Guidance on evaluation of criteria:* Food Safety Professionals will rate any issues of cross-contamination or other bad practices related to compressed air used for cleaning.

**3.4.1.6 Critical** – **Auxiliary equipment** (e.g. forklifts, pallet jacks, aerial lifts, and similar equipment) are cleaned and well maintained.

- *Explanation of the change:* A new requirement was added to address the cleaning of auxiliary equipment, which is commonly omitted from the cleaning schedule and, at times, the equipment is used in product areas and over product zones. The auxiliary equipment may also be an insect and rodent harborage area (similar to former requirement 3.3.2.3, which was elevated to critical with modified language).
- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate the cleaning and maintenance condition of auxiliary equipment and review associated records.

### 3.5 Daily (Housekeeping) Cleaning

**3.5.1.2 Critical** – Daily cleaning tasks **are clearly assigned** ~~to the appropriate department and completed.~~

- *Explanation of the change:* Former requirement 3.4.1.2. The scope of the requirement was expanded to include completion of assigned tasks.

- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate and rate observations related to daily housekeeping tasks not assigned or not being completed.

### 3.6 Operational Cleaning

- *Explanation of the change:* A new standard was added to address daily product zone cleaning.

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

- *Explanation of the change:* A new requirement was added: Operational cleaning tasks should be performed at a frequency and in a way that will keep production zones clean during working hours.
- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate operational cleaning issues as noted during the inspection.

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

- *Explanation of the change:* A new requirement was added to address line change-over cleaning tasks and verification of cleaning process.
- *Guidance on evaluation of criteria:* Food Safety Professionals will inspect production lines and equipment with regards to cleanliness, previous product debris, and chemical residues as applicable and include associated records.

#### 3.6.1.3 Critical – Allergen cleaning is completed, verified, and documented.

- *Explanation of the change:* A new requirement was added to address cleaning when allergens are involved.
- *Guidance on evaluation of criteria:* Food Safety Professionals will review line change-over cleaning records and verification documentation for allergen cleaning.

### 3.7 Periodic Cleaning Tasks / Product Zone Cleaning

- *Explanation of the change:* The language was modified to add accuracy and distinguish from operational cleaning (this is the down-time deep cleaning conducted on the lines).

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

- *Explanation of the change:* Language was added to include the requirement that procedures are being followed.
- *Guidance on evaluation of criteria:* Food Safety Professionals will observe cleanliness of equipment, review cleaning procedures and check completion records.

#### 3.7.1.3 Critical – Periodic cleaning tasks are assigned and completed.

- *Explanation of the change:* Language was added to include the requirement that assigned periodic cleaning tasks are completed as well.
- *Guidance on evaluation of criteria:* Food Safety Professionals will observe cleanliness of equipment and review cleaning records.

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

- *Explanation of the change:* The words “vent grids” were removed because they are addressed in new requirement 3.7.1.6.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**3.7.1.6 Critical – Ventilation, air extracting ducts and vent grids are dismantled and cleaned on a defined frequency to prevent contamination issues.**

- *Explanation of the change:* A new requirement was added to cover ventilation, air extracting ducts, vent grids, and other similar structures that are often overlooked or cleaned superficially and may cause contamination issues due to dirt, dust, debris, condensation, or insect development. (A superficial cleaning might address easy-to-access parts rather than dismantling and effectively cleaning the equipment to prevent insect development.)
- *Guidance on evaluation of criteria:* Food Safety Professionals will inspect and evaluate cleaning condition of ventilation and other equipment and will review associated cleaning records.

**3.7.1.11 Critical – Idle lines and equipment that is not regularly used are kept clean to eliminate pest and microbial issues.**

- *Explanation of the change:* A new requirement was added to address the cleanliness of idle lines that may be present in production areas (because the lines cannot be removed).
- *Guidance on evaluation of criteria:* Food Safety Professionals will inspect idle lines for cleanliness and pest attraction/harborage issues.

### **3.8 Maintenance Cleaning**

- *Explanation of the change:* A new standard was added that includes existing requirements moved from Product Zone Cleaning to a separate requirement to add clarity and avoid misinterpretation. Maintenance cleaning is a separate task that needs to be completed every time maintenance work is done and is not necessarily part of the periodic cleaning activities on the product zone areas.

**3.8.1.1 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 **after maintenance tasks are complete** (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:* Former 3.5.1.11. The phrase “after maintenance tasks are complete” was added to increase accuracy.
- *Guidance on evaluation of criteria:* No additional guidance is required.

### **3.9 Non-Product Zone and Support Area Cleaning**

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

- *Explanation of the change:* The language was modified to include packaging, as food contact packaging should be handled as an ingredient. “Raw materials” was replaced by “materials” to expand the requirement to include work-in-progress, other ingredients, processing aids, and other materials as applicable.

- *Guidance on evaluation of criteria:* Food Safety Professionals will expand rating to all storage areas and warehouses present.

### 3.10 Clean in Place (CIP) Systems

**3.10.1.2 Critical** – ~~Minimum~~ Requirements for **time/temperature and flow rate** are established, **monitored**, and documented.

- *Explanation of the change:* Language was added for clarity and to include monitoring for time/temperature and flow rate parameters.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check established requirements for time/temperature and flow rate parameters in CIP systems as applicable and review monitoring records.

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

- *Explanation of the change:* The phrase “on a defined frequency” was added to require a specified frequency for this cleaning task.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check cleaning frequencies, instructions, and records for spray balls, pipes, clamps, couplings, and connections as applicable.

**3.10.1.10 Critical** – **Effective cleaning is verified and documented.**

- *Explanation of the change:* A new requirement was added to address verification of cleaning tasks and documented results.
- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate cleaning condition of equipment as possible, and will review cleaning verification records.

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

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

**3.10.1.13 Critical** – **Filters and strainers are opened, inspected, and cleaned on a regular basis.**

- *Explanation of the change:* A new critical requirement was added to address the inspection of filters and strainers present in the CIP system (as it is a critical requirement that they are present).
- *Guidance on evaluation of criteria:* Food Safety Professionals will inspect the filters and strainers as possible and will review inspection records.

### 3.11 Clean out of Place (COP) Systems

- *Explanation of the change:* A new standard was added to address Clean Out of Place (COP) practices.

**3.11.1.1 Critical** – **Reuse of COP solutions does not pose a risk to product safety.**

- *Explanation of the change:* A new requirement was added to address the reuse of cleaning chemical solutions.
- *Guidance on evaluation of criteria:* Food Safety Professionals will rate the reuse of cleaning chemical (COP) solutions with respect to cross-contamination issues.

**3.11.1.2 Critical** – **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.**



- *Explanation of the change:* A new requirement was added to address the cleaning of tanks used for soaking, disinfection, etc., in clean-out-of-place systems.
- *Guidance on evaluation of criteria:* Food Safety Professionals will review the cleaning records for clean-out-of-place tanks.

## 4. Integrated Pest Management

### 4.1 Integrated Pest Management (IPM) Program

**4.1.1.4 Critical** – 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.**

- *Explanation of the change:* The minor requirement was elevated to critical. Language was added to require an in-house technically responsible person. Experience has indicated that it is critical for in-house personnel to follow the outsourced IPM Program.
- *Guidance on evaluation of criteria:* No additional guidance is required.

### 4.2 Facility Assessment

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

- *Explanation of the change:* The language was modified to include that assessment needs to be completed by trained personnel, with minimum training requirements Pest Biology and applicable IPM regulations. The frequency was changed from “annual” to “at least annually.”
- *Guidance on evaluation of criteria:* Food Safety Professionals will review the facility assessment and training records for personnel conducting it.

**4.2.1.2 Critical** – The assessment evaluates all areas **inside and outside** the facility, **and includes:**

- **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
- *Explanation of the change:* The language was modified to add clarity and increase accuracy. In many facilities the assessment is only a physical inspection mentioning pest-proofing issues that does not go into detail or actual assessment and evaluation of the pest management program. This change outlines the minimum elements that need to be considered during the assessment.

- *Guidance on evaluation of criteria:* Food Safety Professionals will review the facility assessment and evaluate its depth with regards to elements described in this requirement.

**4.2.1.4 Critical** – ~~Assessments are conducted by internal or external trained IPM personnel.~~

- *Explanation of the change:* Requirement removed. The requirement is covered under 4.2.1.1.
- *Guidance on evaluation of criteria:* No guidance is required.

**4.3 Other Guidelines**

**4.3.1.1 Critical** – ~~IPM Programs established under alternative guidelines (such as organic, green, or sustainable) demonstrate effective pest management through the lack of evidence of pest management issues, and by meeting the criteria in the IPM section of this Standard.~~

- *Explanation of the change:* Removed Standard 4.3 because the alternative guidelines (such as for organic, green, etc.) are not directly linked with food safety, and thus are not necessarily within the scope of this standard.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**4.3 Signed Contracts Scope of Service** (formerly 4.4)

- *A clearly defined scope of service details all applicable pest management activities and responsibilities and serves as the foundation for an effective IPM Program.*
- *Explanation of the change:* The language in the title was modified to add clarity.

**4.3.1.1 Critical** – The facility has a signed contract that defined scope of service includes:

- Both the facility and the IPM company name
- IPM Facility contact person both for the facility and the contractor
- Frequency of services
- Description of ~~contracted~~ contracted services and how they will be completed
- Term of 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
- *Explanation of the change:* Former requirement 4.4.1.1. The language was modified to correct a typo and for accuracy. The detailed elements need to be clearly defined, though not necessarily in the signed contract (in many cases they are in an addendum or other document detailing the scope of service). A contact person for both sides needs to be appointed.
- *Guidance on evaluation of criteria:* Food Safety Professionals will review the scope of service document.

**4.4 Credentials and Competencies** (formerly 4.5)

**4.4.1.3 Critical** – ~~Persons conducting IPM services have documented~~ Applicators provide verification of GMP Training.

- *Explanation of the change:* The language was modified to add clarity with no change to the meaning or intent of the requirement.
- *Guidance on evaluation of criteria:* No additional guidance is required.

#### **4.5 Pesticide Documentation** (formerly 4.6)

**4.6.1.1 Critical** – ~~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:* Requirement removed. Chemical safety data sheets are not directly related to food safety. They mainly concern occupational safety, and thus are not within scope of this standard.
- *Guidance on evaluation of criteria:* No additional guidance is required.

#### **4.6 Pesticide Application Documentation** (formerly 4.7)

**4.6.1.1 Critical** – Documented **pesticide application activities** include:

- Product name of materials applied
- The EPA, PMRA, or product registration number 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
- *Explanation of the change:* Former requirement 4.7.1.1. Language was added to include the printed name of the applicator.
- *Guidance on evaluation of criteria:* No additional guidance is required.

#### **4.7 Pesticide Control** (formerly 4.8)

**4.7.1.6 Critical** – The facility maintains a complete **inventory of all stored pesticides**.

- *Explanation of the change:* Former requirement 4.8.1.6. The language was modified to add clarity. The requirement applies to stored pesticides on site at the facility.
- *Guidance on evaluation of criteria:* No additional guidance is required.

#### **4.8 Trend Analysis** (formerly 4.9)

**4.8.1.2 Critical** – The **pest-sighting log or reporting system** provides information about the response taken by pest management personnel.

- *Explanation of the change:* Former requirement 4.9.1.2. The language was modified to add “reporting system” for facilities that might not use a pest-sighting log and have another reporting system (e.g., computerized).
- *Guidance on evaluation of criteria:* No additional guidance is required.

**4.8.1.4 Critical** – The **pest-sighting log** ~~has a designated location~~ **or reporting system is available to facility personnel.**

- *Explanation of the change:* Former requirement 4.9.1.4. The language was modified to include engagement of facility personnel.

- *Guidance on evaluation of criteria:* Food Safety Professionals will review the pest-sighting log or pest reporting system.

**4.8.1.5 Critical** – Information gathered through the pest-sighting log or reporting system includes:

- Date
- Time
- Type of pests observed
- Location
- Actions taken
- Names of reporting personnel
- *Explanation of the change:* Former requirement 4.9.1.5. The language was modified to include another reporting system (if a pest-sighting log is not used) and to require information about the location of the sighting.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**4.8.1.6 Critical** – ~~Pest management personnel review the log each quarter to identify trends in pest activity.~~ **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.

- *Explanation of the change:* Former requirement 4.9.1.6. The language was modified to make the requirement more accurate and current. There have been cases where the log is used for facility personnel, while contractor's findings are documented in service records, and there is no merging of the two to get accurate information on pests seen. Also, based on activity levels, monthly trending may be more appropriate.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check that trend analysis records include all current information on activity evidence and pest sightings, and that follow up is performed.

**4.8.1.7 Critical** – ~~Corrective Actions are documented~~ for identified issues **are applied and documented as complete.**

- *Explanation of the change:* Former requirement 4.9.1.7. The language was modified to make the requirement more accurate and include closing of Corrective Actions. Evaluation of Corrective Actions also needs to be completed for EU countries.
- *Guidance on evaluation of criteria:* Food Safety Professionals will review Corrective Action records and follow-up activities.

#### **4.9 Monitoring Device Documentation (formerly 4.10)**

**4.9.1.2 Critical** – A current and accurate **site map** that lists the locations of all ~~pest~~ monitoring devices used ~~in rodent and insect control~~ **for target pests** is on file.

- *Explanation of the change:* Former requirement 4.10.1.2. The language was modified to increase accuracy.
- *Guidance on evaluation of criteria:* No additional guidance is required.

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

- *Explanation of the change:* Former requirement 4.10.1.3. The language was modified to add flexibility. In some cases, a separate map gets lost or forgotten and traps are left uncontrolled. The plant can choose to map temporary traps in the total site map or separately. A requirement was added that unneeded temporary devices are accounted for and removed.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check site maps for permanent and temporary devices.

**4.9.1.4 Critical** – ~~The facility~~ **Records of all services** performed on all pest-monitoring devices **are available**.

- *Explanation of the change:* Former requirement 4.10.1.4. The language was modified for accuracy. All observations and services performed on all pest-monitoring devices need to be documented (not documenting by exception, only when a finding is identified).
- *Guidance on evaluation of criteria:* No additional guidance is required.

**4.10.1.5 Critical** – Services for monitoring devices are ~~documented with recording mechanisms~~, such as punch-cards, bar codes, or ledgers, and may be maintained in hard copy or electronic format.

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**4.9.1.5 Critical** – Service records for monitoring devices ~~match documentation on file in the facility~~ **IPM Program requirements**.

- *Explanation of the change:* Former requirement 4.10.1.6. The language was modified to expand the requirement so that service records meet IPM Program requirements.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check service records for monitoring devices.

#### **4.10 Exterior Rodent Monitoring Devices (formerly 4.11)**

**4.10.1.1 Critical** – ~~Based on the detailed facility survey, exterior monitoring devices are placed along the foundation walls on the exterior of the facility.~~ **The placement of exterior rodent monitoring 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 50–100 ft. or 15–30 m.

- *Explanation of the change:* Former requirement 4.11.1.1 combined with 4.11.2.1. Placement of exterior monitoring devices should be based on the facility survey and take into consideration historical data and sightings, identified pest species, assessment of environment, and previous corrective actions. The placement should target harborage and nesting areas to eliminate presence. If the placement of devices cannot be based on the assessment, interval guidelines provided are based on the “Norway Rat” and “Roof Rat” sections of *Rodent Control: A Practical Guide for Pest Management Professional*, by Robert M. Corrigan.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check placement of the external monitoring devices.

**4.10.1.2 Critical** – All exterior monitoring devices are inspected **at least monthly** ~~There devices are checked or more often when if~~ activity levels **dictate** increase.

- *Explanation of the change:* Former requirement 4.11.1.2. The language was modified slightly with no change to the meaning or intent of the requirement.

- *Guidance on evaluation of criteria:* No guidance is required.

**4.10.1.3 Critical** – Exterior ~~bait stations~~ **monitoring devices** ~~that containing~~ **rodenticides are locked** with single-use plastic ties, padlocks, or devices provided by the manufacturer, such as key systems.

- *Explanation of the change:* Former requirement 4.11.1.3. The words “exterior bait stations” were changed to “monitoring devices” to be more accurate and in line with the requirement title.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**4.10.1.4 Critical** – Exterior ~~bait stations~~ **rodent monitoring devices** ~~are~~ **tamper resistant** and are positioned, anchored in place, locked, and labeled.

- *Explanation of the change:* Former requirement 4.11.1.4. The words “exterior bait stations” were changed to “monitoring devices” to be more accurate and in line with the requirement title.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**4.10.1.7 Critical** – 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.

- *Explanation of the change:* A new requirement was added: The frequency of inspection of mechanical traps used for exterior monitoring should be defined by the plant based on risk assessment and history of activity, ensuring the effectiveness of the pest management program.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**4.10.1.8 Critical** – Where prohibited by regulations, **rodenticides are not used** for regular monitoring.

- *Explanation of the change:* A new requirement was added: According to new EU Standard, rodenticides are used to treat infestations and only non-toxic bait or mechanical devices are used for regular monitoring. (This requirement is not applicable to the US and other regions.)
- *Guidance on evaluation of criteria:* No additional guidance is required.

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

- *Explanation of the change:* Requirement removed (incorporated into 4.11.1.1).
- *Guidance on evaluation of criteria:* No guidance is required.

**4.10.2.1 Minor** – Evidence of **non-target wildlife** feeding at the exterior monitoring locations, where rodenticides are used, is evaluated and addressed as required by regulations.

- *Explanation of the change:* A new requirement was added to address bait being consumed by non-target animals.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check records, evaluation of activity (wildlife damage), and response as required by regulations.

## **4.11 Interior Rodent Monitoring Devices** (formerly 4.12)

**4.11.1.1 Critical** – ~~Toxic and non-toxic commercial baits (blocks, liquids, etc.) are~~ **is not used** for interior monitoring.



- *Explanation of the change:* Former requirement 4.12.1.1. Non-toxic monitoring/tracking bait allowed for proactive IPM Programs (as seen in following requirement 4.12.1.7).
- *Guidance on evaluation of criteria:* No additional guidance is required.

**4.11.1.2 Critical** – Based on the detailed facility survey, interior monitoring devices are placed in **sensitive areas** specific to the rodent species, and other areas of **pest 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 20–40 ft. or 6–12 m along exterior walls, and are strategically placed in sensitive areas toward the interior of the facility.**
- *Explanation of the change:* Former requirement 4.12.1.2. The placement of interior monitoring devices should be based on the facility survey and take into consideration historical data and sightings, identified pest species, assessment of environment, previous corrective actions, and they should consider sensitive areas such as the examples provided. If the placement of devices cannot be based on the assessment, interval guidelines provided are based on the “House Mouse” section of *Rodent Control: A Practical Guide for Pest Management Professional*, by Robert M. Corrigan.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check placement of the interior rodent monitoring devices.

**4.11.1.4 Critical** – 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.**

- *Explanation of the change:* Former requirement 4.12.1.4. Due to new technology devices that do not require very frequent inspections and other reasons, the facility may choose based on their assessment (and absence of pest sightings) a frequency of inspections other than weekly if the consistent performance of monitoring equipment and efficiency of the IPM Program can be demonstrated.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check the frequency of internal monitoring device inspections, service records, pest-sighting logs, and trend reports to assess effectiveness of the program. Effectiveness includes timely removal of rodents to prevent attraction of secondary pests, mechanically functioning devices, and cleanliness of devices to prevent attraction for insects.

**4.11.1.7 Critical** – **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.

- *Explanation of the change:* A new requirement was added that non-toxic monitoring/tracking bait may be used to provide a roadmap of where the pests have been going in the plant. This bait may be used in a proactive way.
- *Guidance on evaluation of criteria:* Food Safety Professionals will evaluate the program and use of non-toxic monitoring/tracking bait in a proactive way.

**4.12.2.1 Minor** – ~~Monitoring devices are placed at intervals of 20-40 ft or 6-12 m along exterior walls, and are strategically placed in sensitive areas toward the interior of the facility.~~

- *Explanation of the change:* Requirement removed (incorporated into 4.12.1.2)
- *Guidance on evaluation of criteria:* No guidance is required.

#### **4.12 Insect Light Traps** (formerly 4.13)

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

- *Explanation of the change:* Former requirement 4.13.1.1. Language was added to clarify that the use of insect light traps should be based on the facility assessment and is not necessarily required by this standard. The requirement applies if insect light traps are used on site.
- *Guidance on evaluation of criteria:* The lack of installed insect light traps will be assessed by Food Safety Professionals, through the demonstrated absence of flying insects.

**4.12.1.2 Critical** – Insect light traps are installed in a way that does **not attract insects** to the facility **or open food**.

- *Explanation of the change:* Former requirement 4.13.1.2. The language was modified slightly.
- *Guidance on evaluation of criteria:* No guidance is required.

**4.12.1.3 Critical** – **Service checks** are performed on all units on a weekly basis during the active season and 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 tube breakage
- *Explanation of the change:* Former requirement 4.13.1.3. The language was modified to clarify the intent of the requirement: More frequent service checks are required if activity rates are high and less frequent if they are low.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check frequency of service checks for insect trap lights service records, trends, etc.

**4.12.1.4 Critical** – **Shatter-resistant lights** are used in all units **located in raw materials and production areas**. **Other lights are** ~~or otherwise explained~~ **managed** in the facility's Glass, Brittle Plastics, and Ceramics Program.

- *Explanation of the change:* Former requirement 4.13.1.4. The language was modified to add clarity as to the requirement for shatter resistant lights.

- *Guidance on evaluation of criteria:* Food Safety Professionals will check the use of shatter resistant lights in raw material and production areas and that the facility manages and inspects other type (non-shatter resistant) used in other areas in the Glass, Brittle Plastics, and Ceramics Program.

**4.12.1.5 Critical** – All services provided to light traps are **documented**. ~~Service records are kept in the device and on file with the pest management documentation.~~

- *Explanation of the change:* Former requirement 4.13.1.5. Part of requirement was deleted because it was obsolete.
- *Guidance on evaluation of criteria:* No guidance is required.

**4.12.1.6 Critical** – Insect light traps are used to **monitor flying insect activity** at locations ~~that are likely to allow access to the facility~~ **identified by the annual IPM assessment**.

- *Explanation of the change:* Former requirement 4.13.1.6. Use and placement of insect light traps should be based on the facility assessment considering historical data of at least 12 months, identified species, environment, previously applied corrective actions, etc.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check use and placement of insect light traps devices.

**4.12.2.1 Minor** – Insect light trap **tubes are changed** at least annually at the beginning of the active season **or based on manufacturer's recommendations**.

- *Explanation of the change:* Former requirement 4.13.2.1. Language was added to allow for new technology lights that might have other requirements.
- *Guidance on evaluation of criteria:* No additional guidance is required.

#### **4.13 Pheromone Monitoring Devices** (formerly 4.14)

**4.13.1.1 Critical** – **When used**, pheromone monitoring devices, **appropriate to the pest species** are **installed, maintained, and replaced** according to label requirements **and the annual IPM assessment**.

- *Explanation of the change:* Former requirement 4.14.1.1. The requirement was modified to include lures that need to be appropriate to the pest species identified. Devices and lures should be maintained and replaced as needed (recommended by label).
- *Guidance on evaluation of criteria:* No additional guidance is required.

#### **4.14 Bird Control** (formerly 4.15)

**4.15.1.3 Critical** – ~~Avicides are used according to label directions and local regulations.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

#### **4.16 Pest Habitat Identified Pest Activity** (formerly 4.17)

- *Explanation of the change:* The title language was modified for accuracy. This Standard will include observations related to pest habitat, including resident pests (if present), environment assessment, and occasional intruders.

## 5. Adequacy of Prerequisite and Food Safety Programs

### 5.1 Written Policy

- *Explanation of the change:* The standard was removed to help with time management of the audits and keep them inspection based. The intent of the requirement may be covered in the accountability section.

**5.1.1.1 Critical** – ~~There is a written Policy Statement that outlines the facility's commitment to produce safe, legal products for consumers.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.1.2.1 Minor** – ~~Senior management signs the Policy Statement.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

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

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.1.2.3 Minor** – ~~Senior management regularly reviews the Policy Statement.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No 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:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

### 5.1 Accountability (formerly 5.2)

**5.2.1.2 Critical** – ~~The facility has a current and accurate organizational chart that shows who is responsible for ensuring compliance to regulatory laws and guidelines.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.1.1.2 Critical** – The facility has a documented procedures to keep the Prerequisite and Food Safety Programs **current and accurate**, which includes 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
- *Explanation of the change:* Former requirement 5.2.1.3. Language was added to include the requirement for accountability and compliance to applicable regulations concerning food safety.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check the documented procedures and accountability.

**5.1.1.3 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. **Companies define written procedures to identify new food safety regulations. Facilities register with appropriate Government Agencies** based on site location and countries of export.

- *Explanation of the change:* Former requirement 5.2.1.4. The language was modified to include the previous requirement while adding former requirement 5.17.1.1 (registration with FDA and other Government Agencies as applicable).
- *Guidance on evaluation of criteria:* Food Safety Professionals will check the written procedures for keeping current with regulations and registrations as applicable.

**5.1.1.4 Critical – Procedures define:**

- **Job description 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:* Former requirement 5.4.1.1 was simplified to only include responsibilities, alternates, and deputies instead of job descriptions.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check procedures that define responsibilities for key food safety roles and alternates/deputies.

**5.2 Support** (formerly 5.3)

**5.2.1.1 Critical** – ~~All departments directly involved in implementing Prerequisite and Food Safety Programs have budget and labor support to maintain the proper and timely acquisition of appropriate tools, materials, equipment, monitoring devices, chemicals, or other support.~~ **Adequate resources are provided to support effective implementation of the Prerequisite and Food Safety Program.**

- *Explanation of the change:* Former requirement 5.3.1.1. The language was modified with no change to the meaning or intent of the requirement.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.4 Written Procedures**

- *Explanation of the change:* Removed standard. Key parts have been included under new requirement 5.1.1.4.

**5.4.1.1 Critical – Procedures 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:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

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

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

### 5.3 Training and Education (formerly 5.5)

**5.3.1.1 Critical** – There are **written procedures** for developing and delivering Prerequisite and Food Safety (HACCP) and Food Defense training and education to all personnel. Procedures include training as required by regulations.

- *Explanation of the change:* Former requirement 5.5.1.1. The language was modified to include the requirement for food defense training and HACCP training (former requirements 5.17.1.3 and 5.25.1.3, respectively). A requirement was added to address training as required by regulations (e.g., Qualified Individual).
- *Guidance on evaluation of criteria:* Food Safety Professionals will check training schedules, participation records, and employee personal training files.

**5.3.1.4 Critical** – 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.

- *Explanation of the change:* Former requirement 5.5.1.4. Language was added to include training according to job function and the new requirement regarding training according to level of responsibility.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check training procedures, plans, schedules, and personal files as necessary.

### 5.4 Self-Inspections (formerly 5.6)

**5.4.1.3 Critical** – 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
- *Explanation of the change:* Former requirement 5.6.1.3. A requirement was added for the facility to conduct a root cause analysis for significant food safety hazards and apply preventive actions to eliminate the risk of future recurrence.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check self-inspection records with respect to applicable elements as detailed above.

**5.4.1.5 Critical** – The Food Safety Committee and the responsible key personnel set **deadlines** for Corrective Action implementation **and Preventive Action as applicable**.

- *Explanation of the change:* Former requirement 5.6.1.5. Language was added to include responsibilities and timelines for preventive actions when there are such.
- *Guidance on evaluation of criteria:* Food Safety Professionals will check corrective and preventive action records.

**5.4.1.6 Critical** – The results of the Corrective **and Preventive** Actions are **verified** to ensure satisfactory completion.

- *Explanation of the change:* Former requirement 5.6.1.6. The language was modified to include preventive actions as applicable.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**5.4.2.2 Minor – Follow-up inspections** ensure that **findings are addressed** ~~observations are corrected.~~



- *Explanation of the change:* Former requirement 5.6.2.2. The language was modified with no change to the meaning or intent of the requirement.
- *Guidance on evaluation of criteria:* No guidance is required.

## **5.5 Written Procedure Audits (formerly 5.7)**

**5.7.1.2 Critical** – ~~The audits are carried out by competent auditors that are independent of the area of operation being evaluated.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.7.1.3 Critical** – ~~The auditor documents the results of the audit. The documentation includes:~~

- ~~Identified observations~~
- ~~Corrective Actions~~
- ~~Specific assignments~~
- ~~Actual accomplishments.~~
- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.7.1.4 Critical** – ~~Results of the audit are brought to the attention of the personnel responsible for the activity being audited.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

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

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.7.1.6 Critical** – ~~The results of Corrective Actions are verified to ensure satisfactory completion.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

## **5.6 Customer Compliant Program (formerly 5.8)**

**5.8.1.2 Critical** – ~~The Customer Complaint Program includes a procedure for quick distribution of complaint information to all departments responsible for implementing Prerequisite and Food Safety Programs.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.8.1.3 Critical** – ~~Actions appropriate to the seriousness and frequency of the complaints are carried out promptly and effectively.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

## **5.7 Chemical Control Program (formerly 5.9)**

**5.7.1.2 Critical** – **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
- ~~Spill containment and control~~
- ~~Chemical Safety Data Sheet archiving~~
- Contractor chemicals
- **Allergen declarations**
- *Explanation of the change:* Former requirement 5.9.1.2. The language was modified to make the requirement more relevant to food safety and it includes two additions. Chemical safety data sheets are no longer required as they are more relevant to occupational safety; Technical Data sheets are required instead as they are more relevant to food safety. The updated requirement also includes a program to prevent cross-contamination and Allergen declarations for chemicals.
- *Guidance on evaluation of criteria:* Food Safety Professionals will review the chemical control program with respect to the elements detailed in this standard.

## **5.8 Microbial Control Program** (formerly 5.10)

**5.8.1.2 Critical** – 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**
- *Explanation of the change:* Former requirement 5.10.1.2. The language was modified to include regulatory requirements for monitoring and preventive actions as applicable.
- *Guidance on evaluation of criteria:* Food Safety Professionals will review the microbial control program risk assessment, monitoring activities, and related records.

**5.8.1.7 Critical** – 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.

- *Explanation of the change:* Former requirement 5.10.1.7. The language was modified to add clarity. There are specific pathogens or countries, where the

legal limit is not absence of the bacteria. In this case, a test result for the specific pathogen might be positive and below the set legal limit and no further action will be required.

- *Guidance on evaluation of criteria:* No additional guidance is required.

## **5.9 Allergen Control Program** (formerly 5.11)

**5.9.1.1 Critical** – ~~The facility has a written~~ An Allergen Control Program **is in place** that addresses allergens ~~specific to country~~ **as handled in the facility, and as required by** regulations **in the country of manufacture and country of export.**

- *Explanation of the change:* The scope of the requirement was expanded to include allergens present in the plant and regulatory requirements of different countries (e.g., country of use).
- *Guidance on evaluation of criteria:* No additional guidance is required.

### **5.9.1.2 Critical – 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
- *Explanation of the change:* Former requirement 5.11.1.2. A new requirement was added for validation of the allergen control program and related procedures. Validation, as applicable, will be conducted on a defined frequency (e.g., yearly) or if there are changes made to procedures that will affect the efficacy of the program.
- *Guidance on evaluation of criteria:* No additional guidance is required.

### **5.9.1.3 Critical** – The Program is **updated** when there are changes in:

- Ingredients
- Processing aids
- Ingredient suppliers
- Products
- Processes
- Labeling
- Applicable regulations
- *Explanation of the change:* Former requirement 5.11.1.3. The requirement was expanded to update the program if there are changes in applicable regulations (e.g., changes in the regulated allergens in a country).
- *Guidance on evaluation of criteria:* No additional guidance is required.

## **5.10 Glass, Brittle Plastics, and Ceramics Program (formerly 5.12)**

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

- *Explanation of the change:* Former requirement 5.12.1.1. Language was added for clarity with no change to the meaning or intent of the requirement. Brittle plastics referred to here are of the acrylic category.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**5.10.1.2 Critical** – The ~~written Glass, Brittle Plastics, and Ceramics~~ program includes the following **policy statements**:

- No glass, brittle plastics, or ceramics are to be used in ~~the facility~~ **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.
- *Explanation of the change:* Former requirement 5.12.1.2. The language was modified to increase accuracy. The former requirement stated “no glass, brittle plastics or ceramics are to be used in the facility,” which is not accurate because the requirement did not apply to office areas where contamination is not possible.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**5.10.1.3 Critical** – **Procedures address:**

- Handling, breakage (including stored glass, brittle plastics, or 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
- *Explanation of the change:* Former requirement 5.12.1.3. The language was modified to increase accuracy (as above).
- *Guidance on evaluation of criteria:* No additional guidance is required.

## **5.12 Preventive Maintenance Program (formerly 5.14)**

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

- *Explanation of the change:* Former requirement 5.14.1.1. The word “adulteration” was changed to “contamination” because adulteration is often used to mean intentional contamination.
- *Guidance on evaluation of criteria:* No additional guidance is required.

## **5.14 Regulatory Affairs and Inspections Program (formerly 5.16)**

**5.14.1.1 Critical** – 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
- *Explanation of the change:* Former requirement 5.16.2.1. The minor requirement was elevated to critical.

- Guidance on evaluation of criteria: No additional guidance is required.

### **5.15 Food Defense Program (formerly 5.17)**

**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 U.S.A.~~

- Explanation of the change: This is now covered under requirement 5.1.1.3.
- Guidance on evaluation of criteria: No additional guidance is required.

**5.15.1.1 Critical** – ~~The facility conducts a Vulnerability Assessment and documents the results. Acceptable Vulnerability Assessments may include:~~

- ~~Operational Risk Management (ORM)~~
- ~~Threat Evaluation Assessment and Management (TEAM)~~
- ~~CARVER + Shock~~
- ~~Internal assessment form~~
- ~~C-TPAT~~

The facility has a written **Vulnerability Assessment**, which is conducted by person(s) trained in Food Defense. Vulnerability assessment is reviewed on a frequency based on regulation or at least annually.

- Explanation of the change: Former requirement 5.17.1.2. The language was modified to increase the accuracy and timeliness of the requirement. The vulnerability assessment needs to be conducted by trained personnel and reviewed at least annually (or as required by regulations).
- Guidance on evaluation of criteria: Food Safety Professionals will review food defense training records for personnel conducting the vulnerability assessment. The assessment will also be reviewed and evaluated.

**5.15.2.1 Minor** – ~~The written Food Defense Plan Program considers the vulnerability assessment and includes information related to:~~ **mitigation measures based on the Vulnerability Assessment.**

- ~~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: Former requirement 5.17.1.3. The language was modified to require the facility to put in place measures to mitigate identified vulnerabilities.
- Guidance on evaluation of criteria: Food Safety Professionals will review and evaluate measures taken to mitigate identified vulnerabilities.

### **5.16 Traceability Program (formerly 5.18)**

**5.16.1.2 Critical** – The facility identifies and documents **lot numbers and traceability information** for:

- Raw materials

- Rework
- Food contact packaging materials
- Work-in-progress
- Finished product
- Distribution to the customer, ~~where appropriate~~
- Processing aids
- *Explanation of the change:* The language was modified to increase accuracy in case something other than a lot number is used for traceability (e.g., line, date and time of production might be used to identify work in progress).
- *Guidance on evaluation of criteria:* No additional guidance is required.

**5.16.1.4 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
- Corrective actions and process improvements where gaps in the program have been identified
- *Explanation of the change:* Former requirement 5.19.1.3. A requirement was added for the facility to put in place Corrective Actions and improve the process as needed when gaps have been identified during the testing process.
- *Guidance on evaluation of criteria:* Food Safety Professionals will review traceability testing records and evaluate results, success rate, timings, and process improvements.

**5.16.2.1 Minor** – The facility maintains **country of origin information** for materials as required by regulations.

- *Explanation of the change:* A new requirement was added to address country of origin for raw materials if required by law (for example, by new EU labeling regulations, US regulations, etc.).
- *Guidance on evaluation of criteria:* No additional guidance is required.

**5.17 Recall/Withdrawal Program** (formerly 5.19)

**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:* Requirement removed regarding “actual tests results.” Testing in this case is more related to traceability, as in current requirement 5.16.1.4.
- *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:* Requirement removed. Testing was moved to traceability (5.16), implied under 5.16.1.4.
- *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:* Requirement removed. Testing was moved to traceability (5.16), and is still included under 5.16.1.4.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**5.17.1.3 Critical** – The written **Recall/Withdrawal Program** includes 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**
- ~~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:* Former requirement 5.19.1.6. A requirement was added that the recall program consider the type of crisis (food safety or food defense) and handle each accordingly.
- *Guidance on evaluation of criteria:* Food Safety Professionals will review and evaluate the recall/withdrawal program records.

**5.18 Non-conforming Product Program** (formerly 5.20)

**5.18.1.2 Critical** – **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**
- *Explanation of the change:* Former requirement 5.20.1.2. A requirement was added that the procedures define authorized personnel to decide about product disposition (release, reprocess, or destroy).
- *Guidance on evaluation of criteria:* Food Safety Professionals will review non-conforming product procedures with respect to the above mentioned elements.

**5.19 Approved Supplier Program** (formerly 5.21)

**5.19.1.2 Critical** – **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 inspection 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**
- *Explanation of the change:* Former requirement 5.21.1.2. Two requirements were added: (1) The facility should assess economically motivated adulteration risks (food fraud) during the supplier approval process and (2) A supply chain control program should be in place (as required by regulations).
- *Guidance on evaluation of criteria:* Food Safety Professionals will review and evaluate the supplier approval program and associated records, including the vulnerability assessment for economically motivated adulteration and the supply chain program, as applicable.

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

- *Explanation of the change:* Requirement removed. FSMA requirements are included in separate module.
- *Guidance on evaluation of criteria:* No additional guidance is required.

## **5.20 Specification Program** (formerly 5.22)

**5.20.1.2 Critical** – The specifications and procedures include adequate and **accurate information** related to:

- **Food Safety Information**
- Compliance with regulation
- Agreements between relevant parties
- Defined review frequencies
- *Explanation of the change:* Specifications should include food safety information (e.g., storage and handling, cooking instructions, allergen contents, etc.).
- *Guidance on evaluation of criteria:* No additional guidance is required.

## **5.21 Letters of Guarantee or Certifications** (formerly 5.23)

**5.23.2.1 Critical** – Letters of Guarantee or Certifications provide an indication of compliance to Defect Action Levels (DALs) for raw materials, packaging, and finished goods (U.S.A. only).

- *Explanation of the change:* Requirement removed. The requirement was only applicable to the US, and FSMA requirements are included in a separate module.
- *Guidance on evaluation of criteria:* No additional guidance is required.

## **5.22 High Risk Regulated Processing Records Program** (formerly 5.24)

- *Explanation of the change:* Former Standard 5.24: High Risk Processing Record Program could be confusing as there was a different approach depending on the region (a US approach based on regulatory requirements). The new standard applies to regulated processing records and applies only to countries that have such regulations.

**5.22.1.1 Critical** – The facility has **identified all applicable regulated process steps** as **written High Risk Processing Record Program**.

- *Explanation of the change:* A new requirement was added that the facility has identified all regulated process steps in their process, if there are such regulations.

- *Guidance on evaluation of criteria:* Food Safety Professionals will review records of regulated process steps to ensure they have been followed accordingly.

**5.22.1.2 Critical** – The facility maintains ~~processing records~~. **Written procedures are in place for all regulated process steps.**

- *Explanation of the change:* A new requirement was added that the facility has written procedures in place for all regulated process steps.
- *Guidance on evaluation of criteria:* Food Safety Professionals will review written procedures.

**5.22.1.3 Critical** – The records are ~~legible, genuine, in good condition, and contain sufficient information to comply with government regulations~~. **Records demonstrate compliance with regulated process steps.**

- *Explanation of the change:* A new requirement was added that records demonstrate compliance with applicable regulations (also including retention of records requirements).
- *Guidance on evaluation of criteria:* Food Safety Professionals will review records for compliance.

**5.22.1.4 Critical** – The facility has ~~procedures for collection, review, maintenance, storage, and retrieval of records~~. **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
- *Explanation of the change:* Former requirement 5.24.1.6.
- *Guidance on evaluation of criteria:* No guidance is required.

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

- *Explanation of the change:* Former requirement 5.24.1.5. The language was modified to add clarity regarding establishing the appropriate amount of time for record retention.
- *Guidance on evaluation of criteria:* Food Safety Professionals will review records and verify retention time.

**5.24.1.6 Critical** – ~~Only qualified personnel who have defined responsibility for Program compliance authorize the following:~~

- ~~Amendments to records~~
- Corrective Actions
- Verification of Corrective Actions
- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.24.1.7 Critical** – ~~Procedures are legible, unambiguous, and sufficiently detailed to enable personnel to associate the procedure with the corresponding process.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.24.1.8 Critical** – ~~Current and accurate, authorized versions of Programs are available to personnel.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.24.1.9 Critical** – ~~When changes are made to product formulation, processing methods, equipment, or packaging, the following actions are completed to ensure product safety:~~

- Re-establish processing characteristics
- Validate product data
- Justify reasons for change or amendments to the documents critical to product safety
- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.24.1.10 Critical** – ~~The procedures ensure:~~

- ~~The processes and equipment used to produce consistently safe products with the desired characteristics~~
- Coverage of all processes critical to product safety
- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.24.1.11 Critical** – ~~In the case of equipment failure or process deviation, procedures are in place to establish the food safety status of the product prior to release.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.24.1.12 Critical** – ~~Written procedures are in place to investigate the cause of the nonconformity to standards, specifications, and procedures critical to product safety and legality.~~

- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.24.1.13 Critical** – ~~Corrective Action documentation:~~

- ~~Is completed in a timely manner to prevent further occurrence~~
- Is approved by personnel with the defined responsibility and accountability for the activity
- Provides verification of completion of the Corrective Action
- Documents the person responsible and accountable for completion
- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.24.1.14 Critical** – ~~When the facility undertakes or subcontracts analyses, the procedures address:~~

- ~~Using appropriate procedures and facilities~~
- Ensuring the reliability of test results
- Employing qualified and/or trained personnel
- *Explanation of the change:* Requirement removed.
- *Guidance on evaluation of criteria:* No 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:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**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:* Requirement removed.
- *Guidance on evaluation of criteria:* No guidance is required.

**5.23 HACCP Program Food Safety Plan** (formerly 5.25)

- *Explanation of the change:* The title was modified to be more current, to include different systems depending on the region (e.g., HACCP, Preventive Controls Program, and others, as applicable), and to be in line with GFSI Standards Schemes' terminology.

**5.25.1.1 Critical** – ~~Specific Prerequisite Programs are in place and functioning:~~

- GMPs
- Personnel Practices
- Customer Complaint
- Chemical Control
- Cleaning
- Preventive Maintenance
- Transportation and Storage
- Integrated Pest Management
- Receiving
- Traceability
- Recall/Withdrawal
- Allergen Control
- Approved Supplier
- *Explanation of the change:* Requirement removed. All of these prerequisite programs are already required in this Standard (categories 1–4).
- *Guidance on evaluation of criteria:* No additional guidance is required.

**5.23.1.1 Critical** – ~~The facility has a written HACCP Program that has been signed by senior management~~ **identified all applicable regulatory requirements for food safety plans.**

- *Explanation of the change:* A new requirement was added: The facility needs to have identified all applicable regulatory requirements regarding its food safety plan.
- *Guidance on evaluation of criteria:* Food Safety Professionals will review records for identified regulatory requirements as applicable.

**5.23.1.2 Critical** – **Written food safety plans are in place where required by regulation.**

~~The facility has a HACCP team with members from multiple functions of the facility. The team has the following characteristics:~~

- ~~The team members have been trained~~
- ~~The HACCP Coordinator has documented HACCP training.~~
- *Explanation of the change:* The former requirement (5.25.1.3) about HACCP team was removed because a different approach might apply depending on the region (food safety team, HACCP team, qualified individual, and other). A food safety plan needs to be in place and should comply with applicable regulations.
- *Guidance on evaluation of criteria:* Food Safety Professionals will review and evaluate the food safety system.

**5.23.1.4 Critical** – The facility has **Finished Product Profiles** for each product type produced.

- *Explanation of the change:* Requirement removed (included under 5.23.1.3).
- *Guidance on evaluation of criteria:* No guidance is required.

**5.23.1.5 Critical** – The facility has a **Process Flow Diagram** for each product type produced.

- *Explanation of the change:* Requirement removed (included under 5.23.1.3).
- *Guidance on evaluation of criteria:* No guidance is required.

**5.23.1.3 Critical** – The facility follows the **Seven Principles of HACCP** For products that aren't 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 12 tasks as defined by FAO:

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 Risk Based Preventive Controls) will be evaluated taking into consideration the defined hazard categories or country defined requirements. **Establish a HACCP Team.**
2. Based on the Hazard Analysis, the **Critical Control Points (CCPs)** are identified, and the procedures for controlling the hazards are described. **Describe the product.**
3. The **Critical Limits** for the CCPs are scientifically established and recorded. **Identify the product's intended use.**
4. The facility has established procedures for **Monitoring** the HACCP Program that include identification of frequency of activities and responsible person(s). **Draw up the commodity flow diagram.**
5. The facility has established procedures for **Deviation** from the HACCP Program that include identification of short term and long term Corrective Actions. **Onsite confirmation of the flow diagram.**
6. The facility has established procedures for **Verification** of the HACCP Program that include identification of frequency of activities and responsible person(s). **Identify and analyze hazards.**
7. The facility has legible ~~documented records~~ of monitoring, deviation, and verification activities. **Determine the critical control points.**
8. Establish critical limits for each CCP.
9. Establish a monitoring procedure.
10. Establish corrective action for identified deviation.
11. Verify the HACCP Plan.
12. Keep records

- *Explanation of the change:* Former requirement 5.25.1.6. If no other regulation is in place, the facility is required to have a HACCP plan based on Codex Alimentarius requirements that will include all contents (12 steps) as defined by FAO.
- *Guidance on evaluation of criteria:* Food Safety Professionals will review and evaluate the HACCP plan.

**5.25.1.7 Critical** – The facility conducts and documents **training** on the HACCP Program. The training targets:

- Responsibility for management
- Awareness for non-management personnel



- Job-specific procedures for personnel working at a designated Critical Control Point (CCP)
- *Explanation of the change:* Requirement removed. The requirement is currently included under Training – 5.3 (5.3.1.1 and 5.3.1.4).
- *Guidance on evaluation of criteria:* No additional guidance is required.

**5.23.1.4 Critical** –Records demonstrate **compliance** to food safety plans.

- *Explanation of the change:* A new requirement was added that the food safety plan is implemented and followed and records demonstrate compliance.
- *Guidance on evaluation of criteria:* Food Safety Professionals will review food safety plan records.

**5.23.1.5 Critical** –~~The Critical Control Points (CCPs) identified are controlled and monitored within the HACCP Master Plan.~~ **Only qualified personnel who have defined responsibility for program compliance authorize the following:**

- **Amendments to records**
- Corrective Actions
- Verification of Corrective Actions
- *Explanation of the change:* Former requirement 5.25.1.8. The requirement is currently included under 5.23.1.3. The new requirement is based on previous 5.24.1.6, as applicable to the food safety plan.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**5.23.1.6 Critical** –~~The facility conducts a review of the HACCP Program annually or as changes occur (e.g. products or process): Records are available Records are kept one year or two times the shelf life of the product, whichever is longer or as defined by regulatory requirements.~~ **Food Safety plans 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.**

- *Explanation of the change:* Former requirement 5.25.1.9. The language was modified with no change to the meaning or intent of the requirement regarding the program review.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**5.25.1.10 Critical** –~~Facilities that must comply with regulatory HACCP meet the defined requirements.~~

- *Explanation of the change:* Requirement removed (included under 5.22).
- *Guidance on evaluation of criteria:* No guidance is required.

**5.25 Release Procedures** (formerly 5.27)

**5.25.1.1 Critical** – The facility **defines and** follows **release procedures**.

- *Explanation of the change:* Former requirement 5.27.1.1. The language was modified slightly to include that the facility needs defined release procedures that are being followed.
- *Guidance on evaluation of criteria:* Food Safety Professionals will review and evaluate release procedures and associated records.

**5.26 Design Standards** (formerly 5.28)

**5.26.1.1 Critical** – The facility has ~~design standards that apply to~~ **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**, and pest infestations, and ~~make cleaning changes to facilitate~~ **cleaning efforts**.

- Explanation of the change: Former requirement 5.28.1.1. The facility needs to follow sanitary design principles.
- Guidance on evaluation of criteria: No additional guidance is required.