

FOOD SAFETY AND THIRD-PARTY AUDIT SCHEMES

OBJECTIVE

Have the basic understanding of:

- Why Food Safety
- Food Safety Terminology (Definition)
- Who Regulates Food Safety
- Auditing Schemes and Their Role in Food Safety.

WHY FOOD SAFETY REGULATION?

➤ 1 in 6 Americans get sick every year from foodborne illness

- 48 million people
- Over 100,000 require hospitalization
- 3,000 die

➤ Primary victims are children, pregnant women

➤ Causes of foodborne illness

- Pathogenic bacteria
- Parasitic protozoa and worms
- Viruses
- Other pathogenic agents (e.g. prions)
- Natural toxins (e.g., from shellfish, mushrooms, marine algae, etc.)

Listeria Outbreak Linked to Ready-to-Eat Foods

For Everyone
JULY 24, 2025

FOOD SAFETY ALERT

Investigation start date: May 10, 2025

Investigation status: Closed

Recall issued: Yes

This outbreak is over and recalled foods are past shelf life. Learn what you can do to protect yourself from getting sick from *Listeria*.

Updates

Locations

Timeline

FAST FACTS

- Cases: 10
- Hospitalizations: 10
- Deaths: 1
- States: 2

Recalled products

Fresh & Ready Foods LLC ready-to-eat products were [recalled](#) on May 10, 2025. Contaminated products are no longer available for sale.

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[Recalled products](#)

[What you should do](#)

DEFINITIONS

- **GMP** - Good manufacturing practices
- **FDA** - Food & Drug Administration
- **USDA** - U. S. Department of Agriculture
- **CFR** – Code of Federal Regulation
- **FSMA** – Food Safety Modernization Act
- **HACCP** - Hazard Analysis Critical Control Point
- **HARPC** - Hazard Analysis Risk-Based Preventive Control

WHO REGULATES FOOD SAFETY IN THE UNITED STATES

➤ FDA:

- Regulates 80% of the food we eat - primarily non-meat items.
- They also regulate drugs, devices, biologics, cosmetics, and veterinary medicines.

➤ USDA:

- Regulates the other 20% of the food---meat, dairy, and poultry.

➤ Local—Health Department

- Perform retail and wholesale food safety audits.
- Promote and oversee public health services.

FEDERAL FOOD, DRUG AND COSMETIC ACT (1938)

THE LAW THAT IS THE FOUNDATION FOR FOOD SAFETY STANDARD

Authorized FDA to regulate the food safety including:

- Food adulteration and misbranding.
- Food labeling requirements.
- Food additives and safety standards.
- Inspection and enforcement authority.

FEDERAL FOOD, DRUG AND COSMETIC ACT (1938)

GMP REGULATION THAT SETS THE PARAMETER FOR FOOD ADULTERATION

CFR – Title 21 Sec 110.5:

A food shall be deemed to be adulterated if it is within the meaning of Section:

- **402 (a) (3)** – that food has been manufactured under such conditions that it is unfit for consumption.
- **402 (a) (4)** – that food has been prepared, packed, **or held under insanitary conditions** whereby it may become contaminated with filth or injurious to health.

INSANITARY CONDITION = ADULTERED FOOD

FOOD SAFETY MODERNIZATION ACT

(Jan 4, 2011) - FSMA

Third party audit program gained more traction after FSMA Act

Why?

FSMA focus on Risk-Assessment and Prevention, a proactive approach to food safety than a reactive approach.

Gave recall authority to FDA even if there no was no reported health impact due to consumption of the product.

FOOD SAFETY MODERNIZATION ACT

(Jan 4, 2011) - FSMA

❖ Preventive Controls

- Facilities should evaluate hazards, monitor and develop **prevention methods** including plan for corrective actions. **Be Proactive – Prevent that react.**

❖ Inspection and Compliance

- **Inspection** is a critical component, and FDA will use its resource in a risk-based manner.

❖ Imported Food Safety

- FDA has ability to regulate imported products through verification (**audit**)

❖ Response

- FDA has mandatory recall authority

❖ Enhanced Partnership

- Recognizes collaboration among food safety agencies – federal, state, local, tribal and foreign agencies

FOOD SAFETY MODERNIZATION ACT

(Jan 4, 2011) - FSMA

- FDA will accept only their auditor's report or US based customer's inspection to ensure they are following FSMA
 - ❖ **Will accept 3rd party reports to ensure compliance with FSMA**
- FDA – will not accept GFSI recognized schemes but consider those facilities as low risk. What this means is that GFSI audited facilities (BRC, SQF, ISO 22000, Primus GFS) will be low on their radar compared to other high-risk facilities.
- GFSI is working on an addendum with FDA, which FDA might accept in future for auditing requirements.

WHO ARE THIRD PARTY AUDITORS?

Accredited Independent Bodies that conduct food safety audits using a systemic approach to evaluate and certify whether the facility is complying with all applicable food safety standards.

THIRD PARTY AUDITING BODIES

➤ North American Standard:

- ASI – American Sanitation Institute
- AIB – American Institute of Baking
- NSF (National Sanitation Foundation) International.
- Silliker

➤ Global Food Safety Initiative (GFSI):

- BRC – British Retail Consortium
- SQF – Safe Quality Food
- FSSC 22000 – Food Safety System Certification 22000
- Primus GFS

IMPORTANCE OF THIRD-PARTY AUDITING SCHEMES

- 3rd Party audit **VALIDATE** that the facility is meeting the overall food safety regulatory requirements which includes sanitation and pest control.
- Programs are based on HACCP (before FSMA) OR HARPC (after FSMA)
 - ❖ HACCP: Hazard Analysis Critical Control Point
 - Coordinated by HACCP Manager
 - ❖ HARPC: Hazard Analysis Risk-Based Preventive Control
 - Coordinated by PCQI (Preventive Control Qualified Individual)

THIRD PARTY AUDITING SCHEMES

NPMA 3rd Party Audit Scheme

— 1 —

August 2023

	AIB – American Institute of Baking	BRC Global Standards for Food	"FSSC 22000 – Food Safety System Certification"	NPMA – National Pest Management Association	NSF–Cook & Thurber	Primus GFS	Mérieux NutrSciences Certification LLC	SQF – Safe Quality Food	YUM Brands
EXTERIOR RODENT CONTROL									
Device Types	Not specified.	Not specified. Adhere to local, state, and federal regulations.	Must be described in program. Detectors and traps shall be of robust, tamper-resistant construction. They shall be appropriate for the target pest.	Based on history and assessment of potential for infestation. Bait stations or multiple-catch traps.	Not Specified. Bait stations must be identified, locked and secured in place. Secured means not easily removed and/ or are not removable by general public.	Bait stations or live traps. Bait secured within station.	Exterior stations must be secured in place next to building, closed, and a key or a tool (e.g. allen wrench) is required to open.	"Not Specified. Based on a risk assessment and resultant validated pest management plan so that the proper device, location and placement is implemented. Verification should be used to ensure type is working for pest prevention."	Must be effectively maintained, no loose or granular rodenticide is approved for use. Bait stations shall be used outside the facility.
Tamper Resistant	Bait stations must be tamper resistant, positioned, anchored in place, locked, and labeled.	Compliance with EPA PRN 94-7 tier 1 bait station sufficient.	Detectors and traps shall be of robust, tamper-resistant construction. They shall be appropriate for the target pest.	Compliance with EPA PRN 94-7 tier 1 bait station sufficient.	Compliance with EPA PRN 94-7 tier 1 bait station sufficient.	Bait stations should be locked and tamper resistant in some way (e.g., locks, screws, etc.). Bait stations should be secured to prevent removal.	Bait stations must be secured in place and tamper resistant. Bait must be anchored inside the station.	Not specified.	Not specified, but expected in food service facilities; required in distribution and packaging facilities.
Device Spacing	"Placement of exterior rodent monitoring devices (including remotely monitored devices) is based on the detailed facility survey and activity history as required by county or local regulatory requirements. In absence of an assessment devices are placed in intervals of 50 to 100 feet."	Appropriately located and maintained to prevent contamination risk to product.	"Pest-monitoring programs shall include the placing of detectors and traps in key locations to identify pest activity;"	"Based on professional judgment and history and assessment of potential for infestation. In the absence of historical data, initial spacing of 50 to 100 feet."	"If Pest Control Operator (PCO) has not provided direction, spacing should be 50 feet or 15.25 meters".	The distance between devices should be determined based on the activity and the needs of the operation. As a reference, the following guideline can be used to locate exterior equipment: 50-100ft per v. 3.2 standards.	25-50 feet but based upon risk.	They should be located and operated to prevent contamination risk to product, packaging containers, or processing equipments.	"Food service facilities: The number and placement of traps shall be effective to control pests and mitigate risk of entry into facility; Packaging and distribution facilities: max 50 ft except where public access".
Doors	External doors, windows, or other openings are close-fitting or otherwise pest-proofed to less than 6 mm or 1/4 inch. Windows, doors,	Maintained in good condition. Doors and dock levellers shall be close fitting or adequately proofed. External doors to open product areas	External doors, windows, or ventilation openings shall be designed to minimize the potential for entry of pests.	Devices should be placed on either side of doors that lead to the exterior.	Must be made based upon habitat and potential access.	Doors, windows, louvers, and screens should be maintained, doors should fit tightly with a maximum allowable gap of 1/8 inch (3 mm). Doors to	Adequate screening or other protection is provided for defense against pests. Doors and windows should be closed or screened with no	All external windows, ventilation openings, doors, and other openings shall be effectively sealed when close and proofed against dust,	Devices are located in such a manner as to not contaminate product, packaging materials or equipment. Must be placed to achieve

AIB Food Safety Scheme Categories

- ALL schemes have parameter grouped into categories to meet food safety standards.

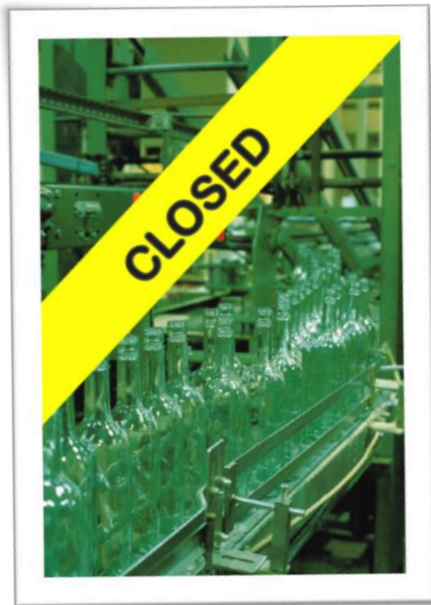
AIB

- **FIVE Categories in AIB Program**

- Operational Method and Personnel Practices
- Maintenance for Food Safety
- Cleaning Practices
- Integrated Pest Management
 - Includes maintaining a Logbook to maintain required documents
- Adequacy of Prerequisite and Food Safety Programs

- IPM accounts for 20% (200 points out of 1000) of the total score

AUDIT IMPACT



➤ Automatic Failures!!!

- Birds or excreta on stock
- Significant insect infestations
- Rodent activity (live, droppings, gnaw marks, etc.)
- Pesticide misapplication

➤ Customer and revenue loss

➤ Re-Audits



TYPE OF THIRD-PARTY AUDITED ACCOUNTS

Food Processing

Packaging Plants

Box manufacturing plants

Pharmaceutical

Distribution Centers and Warehouses

HOW TO BE FULLY AUDIT-READY AND ACHIEVE A PERFECT SCORE IN A THIRD-PARTY INSPECTION

❑ Inspection

- ❖ Inspect all areas not just monitoring devices.

❑ Service

- ❖ Monitoring devices documentation must include the total number of pest caught and action taken.

❑ Documentation

- ❖ Service report should include inspection findings (Condition, Avenue and Source) and service details including corrective actions taken.

➤ **IT IS CRITICAL COMPONENT OF OUR SERVICE, customer doing well in their audit depends on our documentations.....**

Documentation

□ LOGBOOK Presentation