

NEXT

GOOD MANUFACTURING PRACTICES FOR THE FOOD INDUSTRY



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NEXT

**MODULE 1:
REGULATORY AND TECHNICAL
OVERVIEW**

**PREVENTIVE CONTROLS FOR
HUMAN FOOD RULE
CONTROLLING FOOD SAFETY
HAZARDS**

**MODULE 2:
PERSONNEL HEALTH AND HYGIENE**

**MODULE 3:
PLANTS AND GROUNDS**

**MODULE 4:
SANITARY OPERATIONS**

**MODULE 5:
SANITARY FACILITIES AND
CONTROLS**

**MODULE 6:
EQUIPMENT AND UTENSILS**

**MODULE 7:
PROCESSES AND CONTROLS**

**MODULE 8:
WAREHOUSING AND DISTRIBUTION**

**MODULE 9:
DEFECT ACTION LEVELS**

BACK

NEXT

MODULE 1:

REGULATORY AND TECHNICAL OVERVIEW

Food Safety and the Food Supply

- Food safety is the assurance that food will not cause illness or injury to the consumer when prepared and/or eaten according to its intended use.
- The food supply is a complex, concentrated, and dynamic chain of activities.
 - Each sector is unique in size, scope, and diversity.
 - Maintaining consumer and costumer trust is challenging.
- Farm-to-table (fork) approach:
 - Integrated, sequential risk reduction strategy to protect public health

Food Laws and Regulations

- Food law is about protecting public health.
 - Adulteration – prevent contaminated products
 - Misbranding – prevent mislabeled products
- Regulatory enforcement and inspection build trust in the food supply and protect the consumer and the brand's reputation.



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Food Laws and Regulations (cont.)

- Two main federal food safety regulatory agencies in the U.S.:
 - U.S. Department of Agriculture
 - Food Safety and Inspection Service (FSIS), Title 9 CFR
 - Food and Drug Administration
 - Center for Food Safety and Applied Nutrition (CFSAN), Title 21 CFR
- Inspections are the chief mechanism for food safety agencies to either remove troubled products or proactively prevent their release into commerce.
 - Prevent contaminated (adulterated) or mislabeled (misbranded) food from reaching the market.

FDA - Facility Registration

The Food, Drug, and Cosmetic Act (FD&C) Act requires that facilities engaged in manufacturing, processing, packing, or holding food for consumption in the U.S be registered with the FDA.

Form Approval: CMB No. 0910-0502, Expiration Date: 8/31/2022, See PPA Statement on page 10

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration DHHS/FDA FOOD FACILITY REGISTRATION (If entering by hand, use blue or black ink only.) Date (mm/dd/yyyy)	FDA USE ONLY
--	---------------------

- Registered Facilities as of 03/01/2025
 - Domestic registrations: 64,694
 - Foreign registrations: 105,783

FDA – Inspection Methods

- The FDA conducts **warrantless** inspections of the premises of regulated industries.
 - “For cause” during a recall or adverse event
 - Surveillance
- FDA inspectors may arrive unannounced and request total access to the facility.
 - Inspectors present credentials and a written **Form 482 – Notice of Inspection**.
 - Inspectors report any significant violations in a **Form 483 – Inspectional Observations**.

FDA - Suspension of Facility Registration

- FDA can suspend a food facility's registration when it determines that:
 - Food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious **Adverse Health Consequences or Death to Humans or Animals (SAHCODHA)**.
- The practical effect of the suspension is to stop a facility's operations.
 - Prohibited from importing food, offering to import food, or introducing food into either intrastate or interstate commerce.

Role of State and Local Governments

- Broader authorities and additional enforcement
 - Licensing requirements
- States have the **inherent power** to seize and destroy food that is unwholesome or unfit.
 - No need for a court or administrative hearing
- **RETAIL FOOD SAFETY:** FDA assists regulatory state, territorial, city, and tribal agencies by providing a model Food Code, scientifically-based guidance, training, program evaluation, and technical assistance.

Food Safety Modernization Act (FSMA)

- Regulatory reform of the food section of the 1938 FD&C Act
 - FDA-registered facilities
- Shift in food safety controls from reactive to proactive:
 - Requiring science-based preventive controls at food facilities and on farms.
 - Strengthening FDA inspection, record-keeping, and mandatory-recall authority.
 - Holding importers responsible for verifying that foreign suppliers meet U.S. food safety standards.
- Ten final rules

FSMA Final Rules

1. Produce Safety (21 CFR Part 112)
2. Pre-Harvest Agricultural Water (21 CFR Part 112, Subpart E)
3. Preventive Controls for Human Foods (21 CFR Part 117)
4. Preventive Controls for Animal Food (21 CFR Part 507)
5. Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR 121)
6. Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (21 CFR Part 1, Subpart L)
7. Accredited Third-Party Certification (21 CFR Part 1, Subpart M)
8. Sanitary Transportation of Human and Animal Food (21 CFR Part 112, Subpart O)
9. Laboratory Accreditation for Analyses of Foods (21 CFR Part 1, Subpart R)
10. Food Traceability (21 CFR Part 1, Subpart S)

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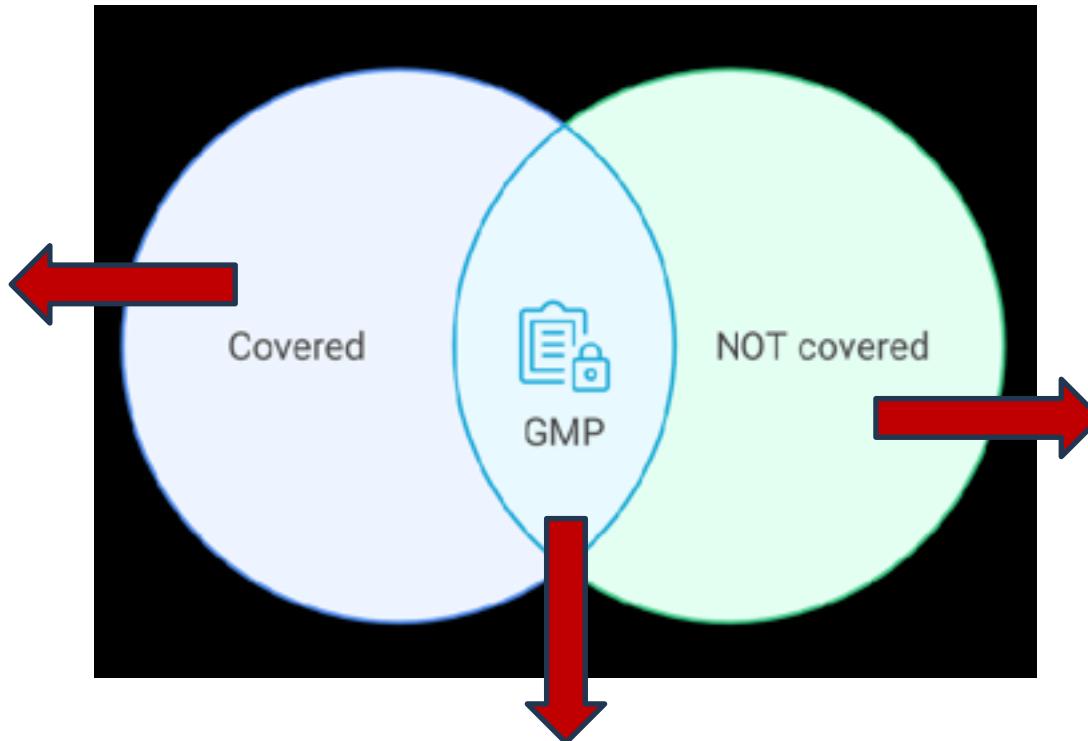
PREVENTIVE CONTROLS FOR HUMAN FOOD RULE

Who is Covered by the PCHF Rule?

FDA-registered food facilities that

- **manufacture,**
- **process,**
- **pack, or**
- **hold**

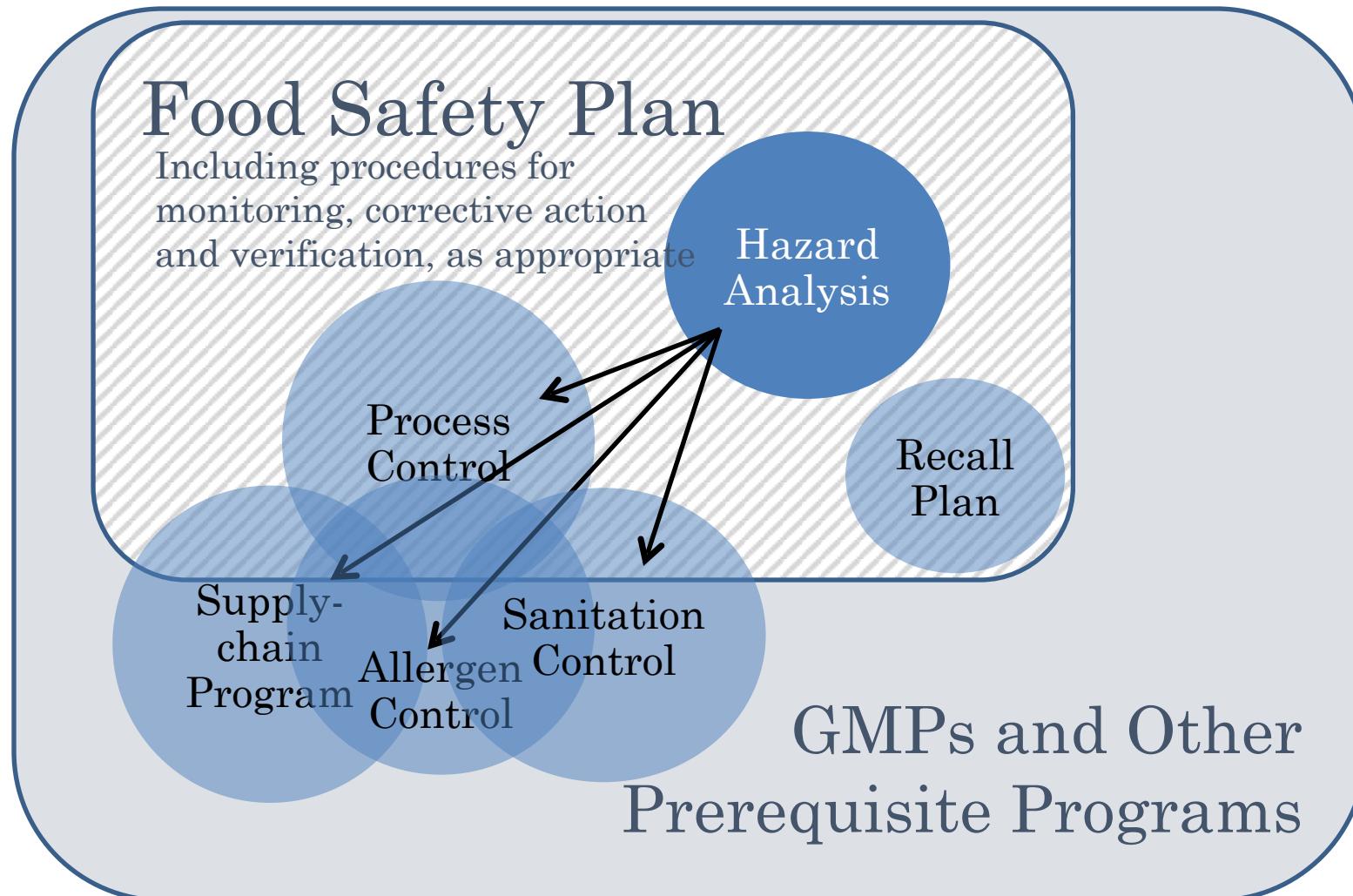
foods for human consumption.



- Farms
- Juice HACCP
- Seafood HACCP
- Low Acid foods
- Acidified foods
- Retail
- Food service

Minimum expectations to produce safe and wholesome foods

Preventive Controls for Human Food (cont.)



Prerequisite Programs (PRP)

- Procedures that provide the basic environmental and operating conditions necessary to produce safe foods.
 - Good Manufacturing Practices
 - Calibration programs
 - Preventive maintenance
 - Supplier controls and specifications
 - Many others!
- Part of, but managed separately from the food safety plan
 - Developed, implemented, and monitored *before* putting a food safety plan in place.

Foundation for an *effective* food safety plan

Good Manufacturing Practices

- **Minimum sanitary and processing requirements for producing safe and wholesome food.**
 - GMP are a set of guidelines to be carried out by a plant to ensure that food is produced under sanitary conditions.
- Important part of regulatory control over the safety of the nation's food supply.
- Applicable to all FDA-regulated food facilities.
- Incompliance = *potential* adulteration
- Adulteration has a regulatory consequence.

Regulatory Changes

21 CFR 110

1. 110.10 Personnel
2. 110.20 Plant and grounds.
3. 110.35 Sanitary operations.
4. 110.37 Sanitary facilities and controls.
5. 110.40 Equipment and utensils.
6. 110.80 Processes and controls.
7. 110.93 Warehousing and distribution.
8. 110.110 Natural or unavoidable defects in food for human use that present no health hazard.

21 CFR 117

1. 117.10 Personnel
2. 117.20 Plant and Grounds
3. 117.35 Sanitary Operations
4. 117.37 Sanitary Facilities and Controls
5. 117.40 Equipment and Utensils
6. 117.80 Processes and Controls
7. 117.93 Warehousing and Distribution
8. 117.95 Holding and distribution of human food by-products for use as animal food
9. 117.110 Defect Action Levels

Updated GMP: Current Good Manufacturing Practices (cGMP)

- 21 CFR 117 Subpart B
- Allergen cross contact is now addressed.
- Education and training are now binding.
 - Management is required to ensure that all employees are qualified to perform their assigned duties.
 - Employees must have training to manufacture, process, pack, or hold food that is clean and safe.
 - Individuals must receive training in the principles of food hygiene and food safety.

21 CFR 117 Subpart B: cGMP Provisions

- Personnel
- Plant and grounds
- Sanitary operations
- Sanitary facilities and controls
- Equipment and utensils
- Processes and controls
- Warehousing and distribution
- Holding and distribution of human food by-products for use as animal food
- Defect action levels

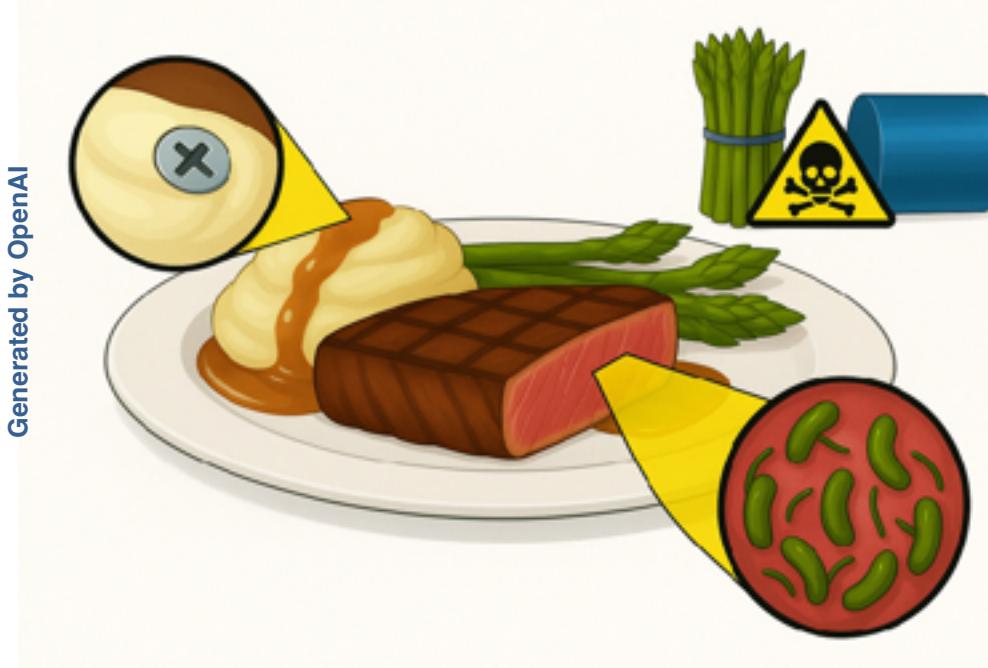
The screenshot shows the homepage of the Code of Federal Regulations (eCFR) system. At the top, there is a logo for the National Archives and a seal. The title "Code of Federal Regulations" is prominently displayed, followed by the subtitle "A point in time eCFR system". Below this, a blue bar indicates "Title 21". A message box states "Displaying title 21, up to date as of 4/10/2025. Title 21 was last amended 3/31/2025." with a link to "view historical versions". A search bar allows users to "Enter a search term or CFR reference (eg. Title or 1 CFR 1.1)". Below the search bar, the breadcrumb navigation shows "Title 21 / Chapter I / Subchapter B / Part 117 / Subpart B". Navigation links for "Previous" and "Next" are also present. On the left, a sidebar provides links for "Table of Contents", "Details", "Print/PDF", and "Display Options". The main content area includes sections for "ECFR CONTENT" (with a link to "View table of contents for this page"), "ENHANCED CONTENT" (with a link to "View table of contents for this page"), and an "EDITORIAL NOTE ON PART 117" (noting nomenclature changes appear at 81 FR 49896, July 29, 2016). The subpart is identified as "Subpart B—Current Good Manufacturing Practice".

FDA – Inspection Frequency

- Current Good Manufacturing Practices
 - 1 to 3 days
- Modified-qualified Facility
- Modified Warehouse with Unexposed Packaged Food
- Limited scope
 - 1 to 3 days
- Full Preventive Controls
 - Around 5 days
- Compliance Directed PC – directed or comprehensive

Food Safety Hazard

A biological, chemical or physical agent that is reasonably foreseeable to cause illness or injury in the absence of its control.



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Hazard vs. Risk

HAZARD

Biological, chemical, or physical agent capable of causing illness or injury in the consumer in the absence of their control

CONTROL, REDUCE, ELIMINATE

RISK

A probability function of the incidence of occurrence of a hazard and the severity of the illness/injury caused by that hazard

MINIMIZE

Physical Hazards

- Glass
- Needles
- Metal
- Rocks
- Seeds
- Wood
- Others



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Common Sources of Physical Hazards

TABLE 2. FDA Quick Reference Guide for Common Sources of Physical Hazards

TABLE 2. FD

Source

Ingredient-rel:

Facility-related
related (proce:
environment, i
pests)

People-related
behaviors)

Source	Metal, Ferrous and Nonferrous	Plastic, Ceramic, and Glass	Other
Ingredient-related	<ul style="list-style-type: none"> Farm field debris Precut, ground, injected, sliced Items where metal was not properly controlled by supplier 	<ul style="list-style-type: none"> Farm field debris Packaging materials 	<ul style="list-style-type: none"> Pits or pit fragments Shells
Facility-related and process-related (processing/production environment, equipment, and pests)	<ul style="list-style-type: none"> Equipment Grinders, slicers, knives Sieves, screens, wire mesh belts Mixing paddles Metal cans (shavings, lids) Pumps Cook kettles with swept surface paddles Drop buckets 	<ul style="list-style-type: none"> Equipment (inspection belts, small wares, buckets) Facility (glass light fixtures, glass windows in doors, plastic strip curtains) Glass containers Scoops Mixing paddles 	<ul style="list-style-type: none"> Incomplete removal of pits or pit fragments, shells Poor design (particle size of food inappropriate for consumer; choking hazard)
People-related (actions or behaviors)	<ul style="list-style-type: none"> Jewelry Hair pins Thermometers Writing utensils 	<ul style="list-style-type: none"> Buttons Zipper pulls 	<ul style="list-style-type: none"> N/A

* Writing utensils
<https://www.food-safety.com/articles/8501-controlling-foreign-object-hazards-in-food#figure1>

IS FILTH A
PHYSICAL HAZARD?

Chemical Hazards

- Allergens
- Antibiotics
- Cleaners and sanitizers
- Controlled ingredients
- Heavy metals
- Mycotoxins
- Pesticides
- Radioactive substances
- Others

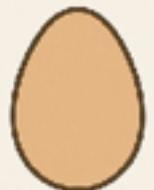


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Chemical Hazards (cont.)

- Toxic substances that may render a food unsafe for consumption.
 - Naturally occurring in the product or ingredient
 - Intentionally added during production or processing
 - Unintentionally added during production or processing
- Chemicals that are used properly do not present a high risk; however, they can cause severe health effects or even death if misused.
- **Food grade does not equal food safe.**

BIG 9 ALLERGENS



Eggs



Fish



Milk



Peanuts



Sesame



Soybeans



Shellfish



Tree nuts



Wheat

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The Big Nine Allergenic Food Groups in the U.S.

- Hives
- Nausea
- Abdominal pain
- Blood pressure drop
- Loss of consciousness
- Anaphylactic shock
- Death

Biological Hazards

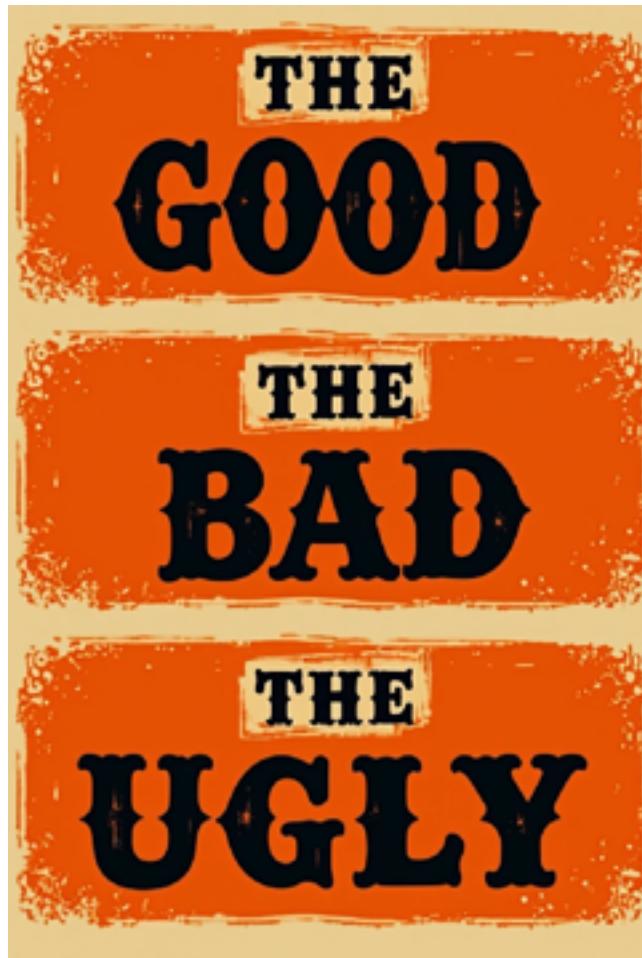
- Bacteria
- Viruses
- Parasites
 - Protozoa
 - Tapeworms and roundworms
- Fungi
 - Yeasts and molds
- Others



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Biological Hazards (cont.)

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- Foods are complex and dynamic microbial ecosystems.
- Microbes can be introduced at any point during the food production chain.
 - Ingredients and supplies
 - Processing environment
 - Personnel
 - Air, compressed gases, dust
 - Pests
 - Others

BACK

NEXT

CONTROLLING FOOD SAFETY HAZARDS

Food Safety Risk Management

TABLE 20. Qualitative risk analysis matrix: level of risk

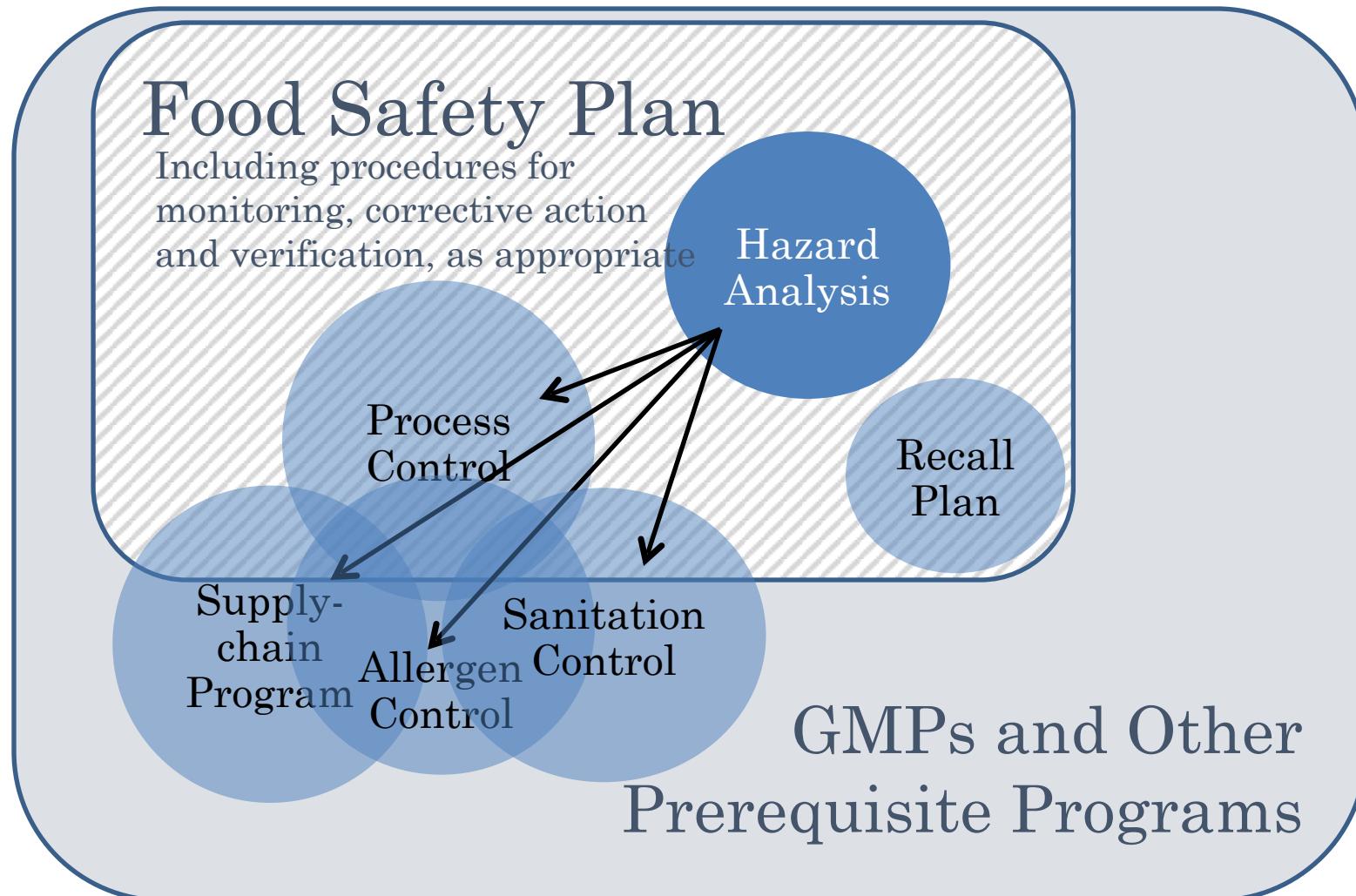
Likelihood	Consequences				
	1 Insignificant	2 Minor	3 Moderate	4 Major	5 Catastrophic
A (almost certain)	Moderate	High	Very high	Very high	Very high
B (likely)	Moderate	High	High	Very high	Very high
C (possible)	Low	Moderate	High	Very high	Very high
D (unlikely)	Low	Low	Moderate	High	Very high
E (rare)	Low	Low	Moderate	High	High

FAO (2021). *Microbiological risk assessment - Guidance for food*. Microbiological Risk Assessment Series No. 36. Rome. <https://doi.org/10.4060/cb5006en>

**Pre-Requisite
Programs for low- and
moderate-risk hazards**

**Preventive Controls for
high- and very high-
risk hazards**

Preventive Controls for Human Food



SANITATION PREVENTIVE CONTROLS

SANITATION

Cleaning

Removes soil using soap or detergents



Sanitizing

Kills bacteria



Dry Cleaning

Removes soil without water



Disinfecting

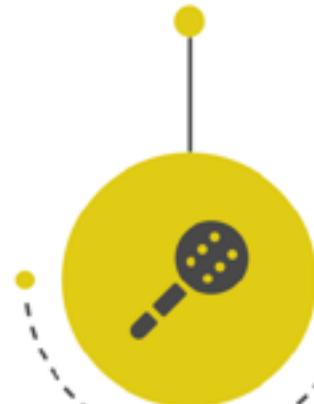
Kills viruses and bacteria

ALLERGEN PREVENTIVE CONTROLS

<https://arpn.unl.edu/sites/unl.edu.jans.foodscience.farrp/files/media/file/2008%20English%20Components%20an%20Effective%20Allergen%20Control%20Plan.pdf>

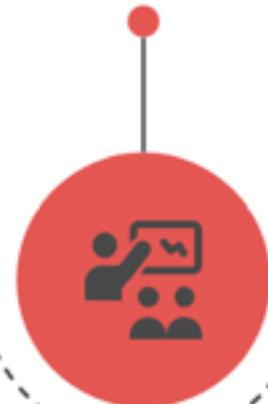
Identification of Allergens

List all allergens present in products



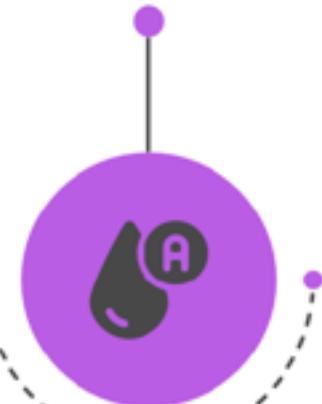
Employee Training

Provide comprehensive training on allergen awareness and handling



Labeling

Ensure labels accurately reflect allergen content, complying with regulations like FALCPA



Supplier Management

Ensure suppliers have documented allergen control plans and notify of any changes



Cleaning

Establish protocols to prevent cross-contact during production



PROCESS PREVENTIVE CONTROLS

Thermal Processes



Process
Preventive
Controls

High Pressure Processing



Dehydration and Drying



Pickling and Fermentation



Foreign Material Detection

SUPPLY CHAIN PREVENTIVE CONTROLS

Verification of controls used by suppliers to control hazards in raw materials or other ingredients before receipt by a manufacturer/processor.

- **Certificate of Analysis** (CoA): A document, provided by the supplier of a food prior to or upon receipt of the food, that documents certain characteristics and attributes of the food.
- **Letter of Guarantee** (LOG): a document that provides details for food safety management systems that are used in the areas of food processing, handling, and storage.

Other Ways to Manage Food Safety Hazards

- Cleaning and sanitizing
- **Good Manufacturing Practices**
- Pest control programs
- Preventive maintenance
- Separation of ingredients and/or processes
- Supplier programs – equipment, industrial chemicals, ingredients, packaging material
- Visual inspection of ingredients and packaging material
- Many others

BACK

NEXT

MODULE 2:

PERSONNEL HEALTH AND HYGIENE

Personnel Health and Hygiene

- Food safety hazards may be introduced by the food workers.
 - Biological hazards – infectious agents
 - Chemical hazards – allergens
 - Physical hazards – jewelry and other personal items
- Prevent potential adulteration and/or misbranding
 - Adulteration: biological, chemical, or physical contamination
 - Misbranding: mislabeling of a food product by omission or by mistake

Disease Control

- Illnesses – gastroenteritis, hepatitis, and others
 - Bacteria: pathogenic *E. coli*, *Salmonella*, *Shigella*, *Vibrio*, etc.
 - Parasites: *Entamoeba histolytica*, *Giardia intestinalis*, etc.
 - Viruses: Hepatitis A, norovirus
- Open lesions – boils, sores, infected wounds
 - *Staphylococcus aureus*, *Streptococcus pyogenes*, etc.

Sick individuals must be excluded to prevent cross contamination

Exclusion vs. Restriction

- **Exclusion** means a food employee is not permitted to work in or enter a food establishment as a food employee.
 - This requirement applies to areas where food is received, prepared, stored, packaged, served, vended, transported, or purchased.
- **Restriction** means a food employee's activities are limited to prevent the risk of transmitting a disease that is transmissible through food.
 - A restricted employee cannot work with exposed food, clean equipment, utensils, linens, or unwrapped single-service or single-use articles.

Disease Control (cont.)

- Personnel should report health conditions to their supervisor.
 - Jaundice (yellowing of eyes and skin)
 - Diarrhea
 - Vomiting
 - Fever
 - Sore throat with fever
 - Boils or cuts
 - Discharges from ears, nose or eyes
 - Excessive coughing or sneezing



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[https://www.foodprotection.org/
resources/food-safety-icons/](https://www.foodprotection.org/resources/food-safety-icons/)

Disease Control (cont.)

- Open lesions, boils and wounds must be adequately covered with impermeable materials.
- Bandages may end up as foreign material in food.
- Various types of covers:
 - Metal detectable bandages
 - Cohesive bandages – self-adhesive
 - Foam bandages – absorbent
 - Hydrocolloid dressings – pain relievers
 - Non-stick sterile bandages – frequent changes



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RISKY SCENARIO

Cleanliness

- Personnel working in direct contact with food, food-contact surfaces, and food-packaging materials must follow hygienic practices
- Protect against allergen cross-contact and against contamination of food.
- Add barriers against biological, chemical, and physical contamination.

Outer Garments

- Outer garments must be suitable to the operation.
- Assess risk of transmission of food safety hazards
 - RTE vs. non-RTE foods
- Are gloves always necessary?
 - If used, they must be intact, clean, and in sanitary condition.



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ASSESSING RISK OF CONTAMINATION

- Loading docks
- Storage
- Food manufacturing
- Packaging
- Warehousing

Personal Cleanliness

- Wash hands thoroughly
 - Before starting work
 - After each absence from the workstation
 - At any other time when the hands may have become soiled or contaminated.



<https://www.health.state.mn.us/people/handhygiene/wash/dontforget.html>

Hand Sanitizers

- At least 60% alcohol
- Help to reduce the microorganisms on the surface of the skin.
- Not as effective against norovirus and *Cryptosporidium*.
- Should not be used as a substitute for good hand washing.
- May not remove harmful chemicals, such as pesticides and heavy metals like lead

Unsecured Jewelry

- Remove all unsecured jewelry and other objects that might fall into food, equipment, or containers.
- Remove hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand.
- If hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition.
- Medical alert bracelets are allowed if they can be covered and kept in sanitary condition.

Minimize the chances that jewelry will end up as foreign material in product or damage equipment

Personnel Storage Areas and Activities

- Keep personal items out of food and wash areas.
 - Clothes, bags, etc.
- No eating, drinking, gum, or tobacco where food or utensils are exposed.
- Prevent sweat, hair, cosmetics, and any skin-applied products from contacting food or equipment.
- Allergens, foreign material – packaging, candy wrappers, cigarette filters, etc.

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RISKY SCENARIOS

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RISKY SCENARIOS

BACK

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MODULE 3:

PLANTS AND GROUNDS

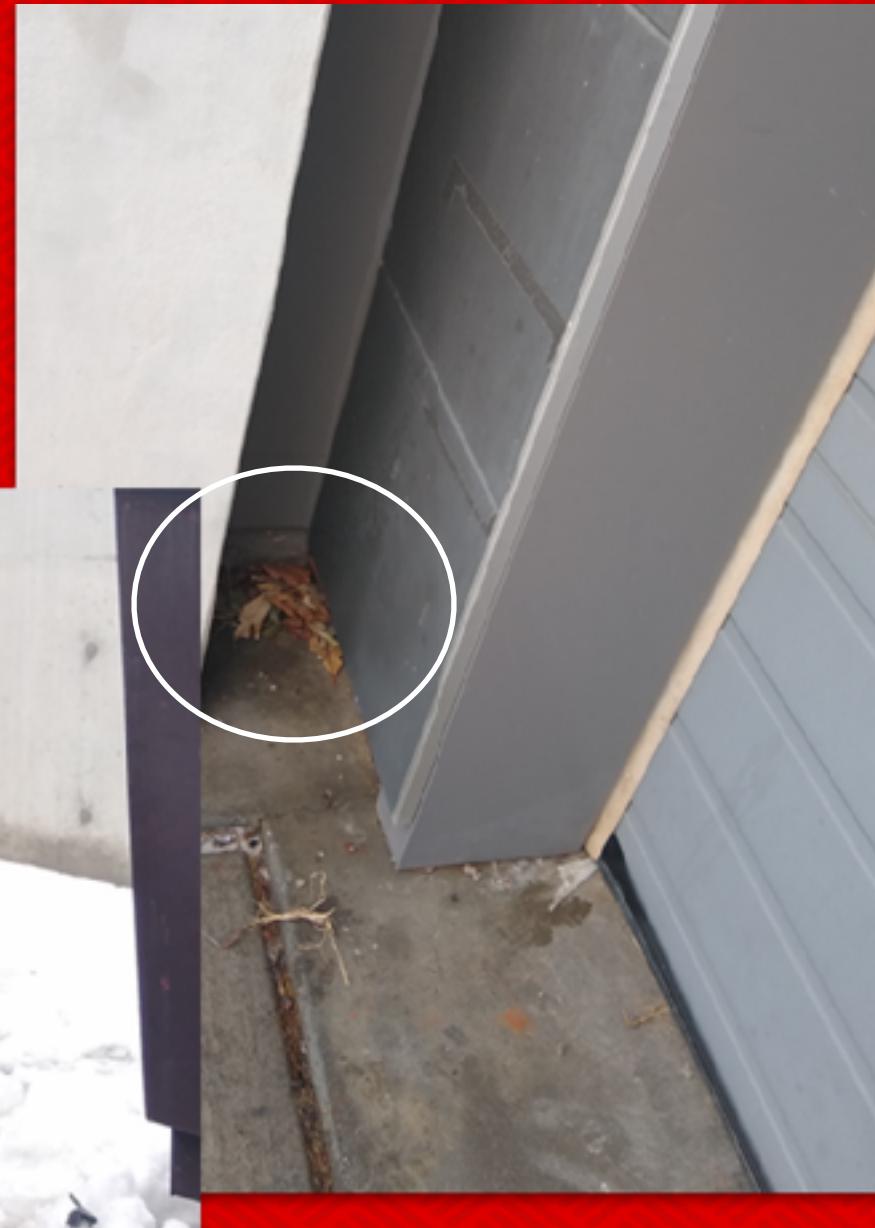
Grounds

- The area around a food plant must be kept clean and well-maintained to prevent food from becoming contaminated.
 - Store equipment properly and remove litter, waste, and overgrown weeds or grass that could attract or harbor pests.
 - Maintain roads, yards, and parking lots to prevent contamination in food handling areas.
 - Ensure proper drainage to avoid contamination from seepage, dirty footwear, or pest breeding areas.
 - Operate waste treatment and disposal systems correctly to avoid contaminating food areas.



- “Grounds” means the entire property, not just the building.
- Inspectors and auditors may examine these outside areas.
- If adjacent land isn’t under your control, use inspections, pest control, and other barriers to keep pests, dirt, and filth from entering the plant.

BACK



NEXT



Plant Construction and Design

- The plant must be properly sized, built, and designed to allow easy cleaning and safe food production.
 - Store items at least 6 inches off the floor to allow for cleaning and prevent contamination.
 - Keep items a few inches (commonly 18 in or more) away from walls to allow for air circulation, pest monitoring, and cleaning access.



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Plant Construction and Design (cont.)

- Separate certain operations by location, time, barriers, air flow, or enclosed systems) to reduce risks of allergen cross contact and cross contamination.
- Build floors, walls, and ceilings so they can be easily cleaned and kept in good condition.
- Prevent drips or condensation from pipes or fixtures from landing on food, food-contact surfaces, or packaging.
- Provide enough space between equipment and walls for workers to perform their duties safely without contaminating food.

Allergens and other chemical contaminants

Bacteria, molds, foreign material

Listeria monocytogenes, molds

Pest dropping and carcasses, organic matter, moisture

Plant Construction and Design (cont.)

- Ensure good lighting in all areas where food is handled or cleaned, including handwashing, locker, and toilet rooms.
- Use shatter-resistant lights or protective covers over exposed food to prevent glass contamination.
- Provide proper ventilation to reduce dust, odors, steam, and fumes that could contaminate food or cause allergen cross-contact.
 - Position fans and air systems to avoid blowing contaminants onto food or surfaces.
 - Always CLEAN to DIRTY
- Use screens or other barriers as needed to keep pests out.

Plant Construction and Design (cont.)

- Lighting levels are specified so that sufficient light is available to enable employees to perform certain functions such as:
 - Reading labels
 - Discerning the color of substances
 - Identifying toxic materials
 - Recognizing the condition of food, utensils, and supplies
 - Safely conducting general food establishment operations and clean-up
- Good lighting helps you see dirt and messes that need to be cleaned.

BACK

NEXT



WHICH LIGHTING IS BETTER?

<https://kenall.com/Home/Products/Food-Processing>

<https://www.industrialcommerciallighting.com/blog/food-preparation-lighting-requirements.html?srltid=AfmBOorkjknmn4nYBwTnU8AszOB-1Hje6pmG2CXLrJp-nGFyq3A7ywHC>

BACK

NEXT

Source: Sumin Li, UNL Food Processing Center



RISKY SCENARIO

Hygienic Design of Equipment

- Machinery and tools specifically engineered to prevent contamination and enable easy, effective cleaning in food production environments.
 - Smooth, non-porous surfaces (e.g., stainless steel)
 - No cracks, crevices, or dead spots where food, water, or microbes can accumulate
 - Sloped surfaces for proper drainage
 - Accessible for cleaning and inspection, often without disassembly
 - Corrosion-resistant materials that withstand cleaning chemicals
 - Sealed welds instead of bolts or overlapping joints

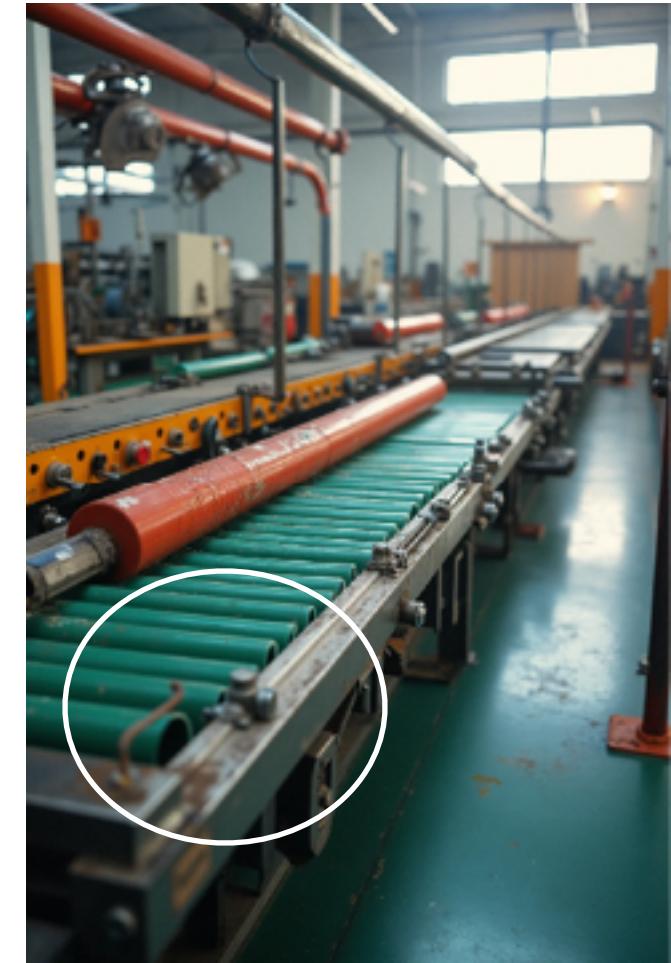
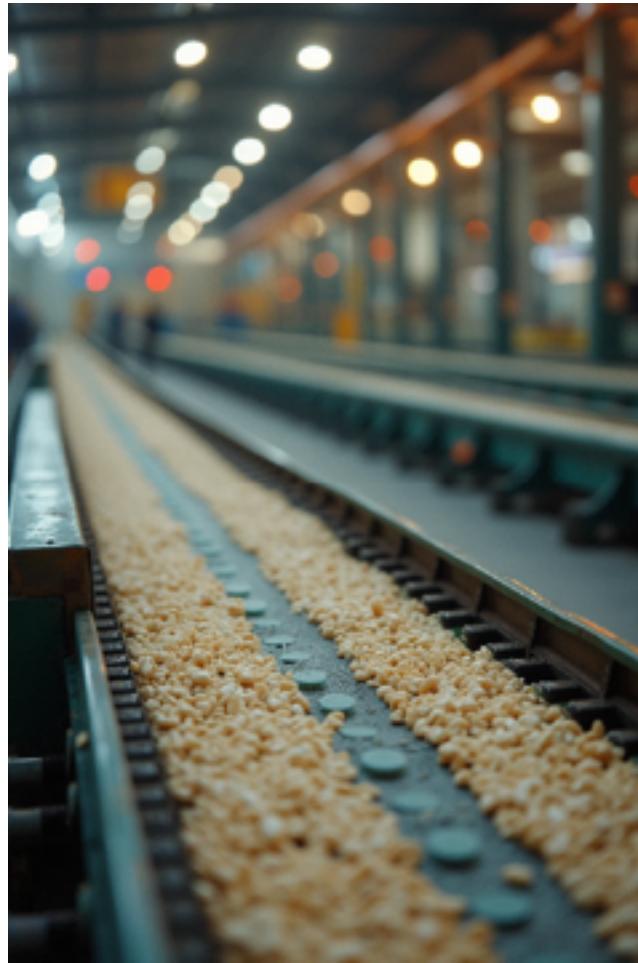
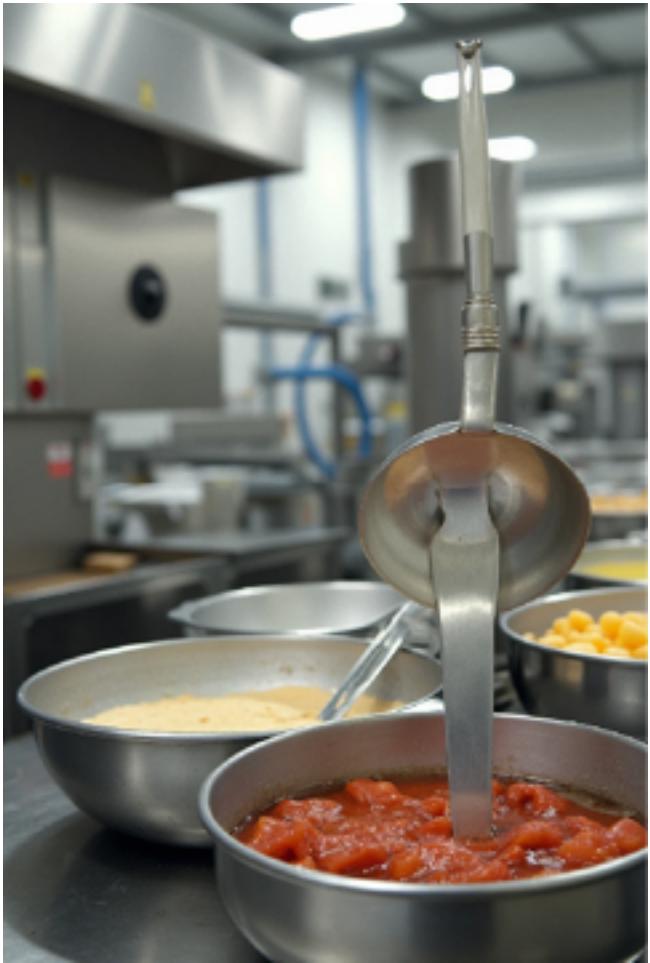
Cleanability

- Ease with which a surface or material can be effectively cleaned to remove food residues, soil, and microorganisms.
 - **Stainless steel** (e.g., AISI 304, 316): Gold standard for food contact surfaces; highly cleanable, corrosion-resistant.
 - **Food-grade plastics** (e.g., HDPE, UHMW, PTFE): Used in conveyor belts, cutting boards, gaskets.
 - **Glass**: Smooth and non-reactive, used in containers and equipment covers.
 - **Ceramic tiles**: Common for walls/floors, though grout must also be cleanable.
 - **Rubber** (food-grade EPDM or silicone): Used in seals and hoses; must be smooth and non-absorbent.

BACK

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RISKY SCENARIO

BACK

NEXT

MODULE 4:

SANITARY OPERATIONS

Sanitary Operations

- Buildings, equipment, and facilities must be kept clean, in good repair, and sanitary to prevent food contamination.
- Utensils and equipment must be cleaned and sanitized in a way that avoids allergen cross-contact and protects food, food-contact surfaces, and packaging.
- Only certain toxic materials can be used or stored in food plants and must be clearly labeled:
 - For cleaning and sanitation – detergents, sanitizers
 - For lab testing
 - For maintenance and operation - lubricants
 - For other plant operations

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- **Unlabeled secondary container**
- **Container is not capped – spill, fumes**
- **Secondary container may not be resistant to the chemical**

RISKY SCENARIO

Pest Control

- Pests must not be allowed in any area of a food plant.
- Guard, guide, or pest-detecting dogs may be allowed only if they won't contaminate food or food-contact areas.
- Effective measures must be in place to keep pests out of processing, packing, and storage areas.
- Food must be protected from pest-related contamination.
- Pesticides may be used only with precautions that prevent contamination of food, food-contact surfaces, or packaging.

Pest Control (cont.)

- Pests can:
 - Contaminate food – hair, larvae
 - Spoil food by eating part of it
 - Carry disease
- Watch for droppings and tracks
 - Indicate type of pest present
 - May lead to entry points / nests
- Watch for product or container damage
 - Indicate type of pest present
- Note presence of dead pests
 - Baits are effective.

Insects

Flying

(adult moths / flies & larvae)



Crawling

(beetles / weevils / cockroaches)



Rodents

Mice (field/house)



Rats (roof)



Birds

Pigeons, crows, starlings, gulls



Other mammals

Skunks, raccoons, cats, and dogs

Risk Assessment for Pest Control

- What mix of pests are present?
- What attracts the pest?
- What are the habits of the pest?
- What are the most effective measures to control or eliminate the pest?
 - Exclusion of pests
 - Removing food sources by good practices
 - Controlling pests with appropriate methods
 - Specific procedures and records

Exclusion of Pests

- Keep doors closed or use tight fitting
 - Minimize gaps
 - Use door seals or self closers
- Keep windows screened or closed
- Screen air inlets and exhaust openings
- Use air curtains or strip curtains
- Eliminate perches for birds
- Eliminate cracks and holes in walls
 - Small cracks harbor insects
 - New construction often creates spaces



Source: Sumin Li, UNL Food Processing Center

Minimizing Pests Access to Food and Water

- **Garbage and spoiled products**
 - Remove promptly and clean affected areas
- **Garbage containers**
 - Keep clean, covered, and in good condition
- **Building perimeter**
 - Remove vegetation, keep clean, and ensure ground slopes away from the building
- **Process equipment**
 - Clean daily after use, including underneath and inside; disassemble when needed; vacuum electrical components

Capture or Destruction of Pests

- Traps work by:
 - Attracting the pest – smell, curiosity
 - Confine the pest - trip mechanisms, sticky pads
 - Killing the pest - baits (outside plant), mechanical levers or electric current
- Working with contractors:
 - Must be trained and licensed
 - Follow an SSOP to prevent cross contamination with pesticides
 - Hold contractor accountable for verification

Food Contact Surfaces

- Potential direct contamination of food
 - Conveyor belts
 - Cutting boards
 - Mixing bowls
 - Utensils (knives, ladles, spatulas)
 - Interior surfaces of blenders or grinders
 - Food trays and pans
 - Surfaces of equipment (e.g., hoppers, fillers, chutes)
 - Packaging contact areas (e.g., sealing jaws, in-line fillers)



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Non-Food Contact Surfaces



- May serve as a reservoir for microbes and other contaminants, including allergens.
 - Equipment frames and supports
 - Exterior surfaces of mixers, tanks, and conveyors
 - Control panels and buttons
 - Forklift and pallet jack surfaces
 - Floors, walls, and ceilings
 - Drain grates and covers
 - HVAC vents and ducts
 - Storage racks and shelving (not directly touching food)
 - Light fixtures and protective covers
 - Trash bins (exterior surfaces)

BACK

NEXT

MODULE 5:

SANITARY FACILITIES AND CONTROLS

Water Supply

- Water used in the plant must be from a safe source and be clean enough for food processing.
- Enough running water at the right temperature and pressure must be available for food processing, cleaning, and employee hygiene.
 - Potable Water: Water that is safe and satisfactory for drinking and cooking.
 - Non-Potable Water: Water that may contain objectionable pollution, contamination, minerals, or infective agents and is considered unsafe and/or unpalatable for drinking.

Plumbing

- Plumbing must be properly designed, installed, and maintained to:
 - Deliver enough water where it's needed.
 - Remove sewage and liquid waste properly.
 - Prevent contamination of food, water, and equipment.
 - Provide floor drains where needed (e.g., for wet cleaning).
 - Prevent backflow or cross-connections between clean and dirty water systems.

Additional Considerations

- **Sewage Disposal**
 - Sewage must be safely removed through a proper sewer system or other approved method.
- **Toilet Facilities**
 - Plants must provide clean, accessible toilets that do not pose a risk of contaminating food or food-contact areas.
- **Hand-Washing Facilities**
 - Hand-washing stations must be easy to use, provide running water at the right temperature, and help prevent hand contamination of food and food-contact surfaces.
- **Rubbish and Offal Disposal**
 - Trash and waste must be handled to prevent odors, pests, and contamination of food, surfaces, water, and the ground.

BACK

NEXT

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IS THIS PERFECT?



RISKY SCENARIO



RISKIER SCENARIO

BACK

NEXT

MODULE 6:

EQUIPMENT AND UTENSILS

Equipment and Utensils

- Seams on food-contact surfaces must be smooth to prevent buildup of food, dirt, and allergens.
- Non-food-contact equipment in food areas must be easy to keep clean and sanitary.
- Freezers and cold storage must have accurate temperature monitoring devices.
- Instruments must be accurate, maintained, and sufficient in number.
- Compressed air or gases used in food or on food-contact surfaces must be treated to avoid contamination.

BACK

NEXT

MODULE 7:

PROCESSES AND CONTROLS

Processes and Controls

Sanitation must be supervised by trained personnel

Assign a Sanitation Manager with documented training in GMPs and sanitation procedures; conduct regular audits and training refreshers.

Prevent allergen cross-contact and contamination

Use color-coded tools and equipment for allergen and non-allergen lines; verify changeover cleaning with allergen swabs or rapid tests.

Perform necessary testing for sanitation or contamination

Implement routine ATP swabbing or microbiological testing (e.g., total plate count) after sanitation; conduct quarterly allergen verification tests.

Reject or treat contaminated food

If metal fragments are detected in finished product, stop distribution, quarantine affected lots, and evaluate use of a metal detector or rework process.

Raw Materials and Other Ingredients

Requirement	Operational Practice	Example
Inspect & clean	SOPs for receiving & cleaning	Wash leafy greens; inspect for damage
Safe storage	Allergen zoning; sealed containers	Store peanuts in labeled, sealed bins
Safe water use	Use potable water; control reuse	Reuse wash water only after filtering
Microbial control	Use approved suppliers; apply kill steps	Pasteurize raw eggs or test for <i>Salmonella</i>

Raw Materials and Other Ingredients (cont.)

Requirement	Operational Practice	Example
Toxin limits	COAs or in-house testing for aflatoxins	Reject corn without aflatoxin results
Rework handling	Label & store separately	Mark bins: "Rework Only – Date"
Frozen control	Monitor freezer; safe thawing	Thaw under 41°F, use within 24 hrs
Bulk ingredient safety	Separate lines/tanks for allergens	Use dedicated tank for soy lecithin
Allergen ID	Color-code & label allergens	Red bins for wheat flour – "ALLERGEN"

Environmental Control

Managing moisture and acidity levels to prevent microbial growth.

Safe Handling

Proper handling of leftovers and spoiled food to ensure safety.

Manufacturing Operations

Contamination Prevention

Protecting food from raw materials, allergens, and foreign objects.

Equipment Hygiene

Regular cleaning and sanitization of tools and machines to prevent contamination.

Temperature Control

Maintaining cold temperatures for perishable foods to inhibit spoilage.



Microbial Growth – pH

- Indicator of acidity in a matrix.
 - Scale from 0 to 14, where 7 is the pH of pure water at room temperature.
 - $\text{pH} < 7$ = acidic
 - $\text{pH} > 7$ = alkaline or basic
- Acid foods: natural $\text{pH} \leq 4.6$
- Acidified foods: foods to which acid(s) or acid food(s) are added $\text{pH} \leq 4.6$ and $a_w > 0.85$
- Low-acid foods: $\text{pH} > 4.6$ AND $a_w > 0.85$.



21 CFR 114.3

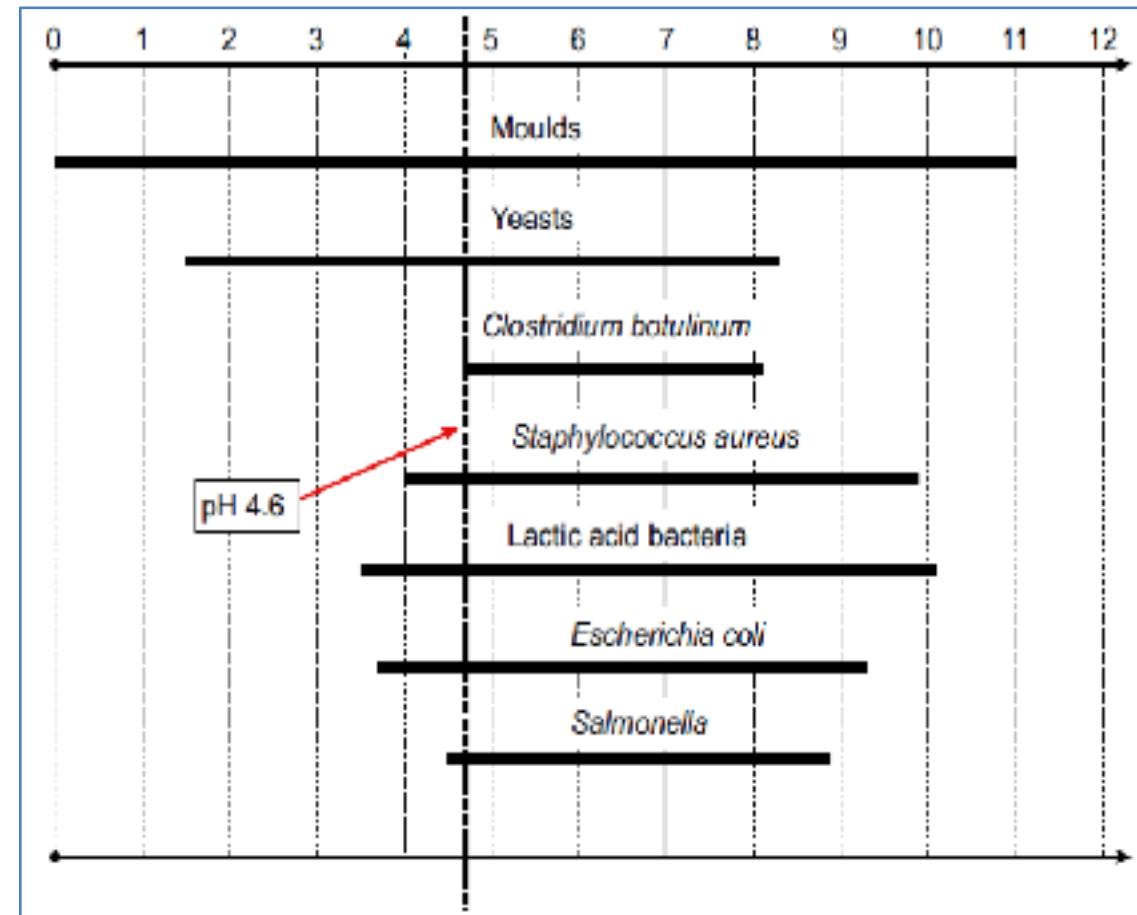
Food Commodity	Food Example	pH Range
Fruits	Lemon juice	2.0 – 2.4
	Apple	3.5 – 3.9
Vegetables	Tomato	4.2 – 4.4
	Carrot	5.9 – 6.1
Dairy	Milk	6.6 – 6.7
	Yogurt	4.2 – 4.4
Meat & Poultry	Raw chicken breast	5.9 – 6.1
	Ground beef	5.4 – 5.8
Seafood	Shrimp	6.8 – 7.0
	Cod fillet	6.2 – 6.4
Cereals & Grains	Cooked rice	6.1 – 6.3
	Bread (white)	5.3 – 5.7
Beverages	Cola	2.3 – 2.5
	Orange juice	3.6 – 3.9
Fermented Foods	Sauerkraut	3.5 – 3.6
	Kimchi	4.2 – 4.4
Eggs	Raw egg white	7.6 – 7.9
	Raw egg yolk	6.0 – 6.2

The lower the pH, the more acidic the food.

The higher the pH, the more basic/alkaline the food.

Microbial Growth – pH (cont.)

- Control of microbial growth via pH/ acidity:
 - Acidifiers/alkalizers – processing water, brines
 - Antimicrobials – surface decontamination
 - Acidulants/Pickling – product ingredient/formulation
 - Fermentation – controlled acidification rate



Microbiology of Canned Foods (2015). In A Complete Course in Canning and Related Processes. 14th ed. Woodhead Publishing p 13.
<http://dx.doi.org/10.1016/B978-0-85709-678-4.00001-4>

Controlling Acidity

What to Do

Measure pH regularly

Use acidifiers properly

Record and verify pH readings

Example

Test pH of salsa after mixing; ensure it's below 4.6 before packaging

Add vinegar or citric acid to pickled vegetables to reach safe pH level

Maintain a pH log and calibrate pH meters daily during production

Microbial Growth – Water Activity (a_w)

- Available water for chemical, enzymatic, and biochemical reactions.
- Scale from 0 to 1, where 1 is the water activity of pure water at room temperature.
 - Bacteria require a high a_w (0.91-0.99) to **grow**, while fungi can tolerate 0.8 to 0.75.
 - Bacteria and fungi can **survive** in much lower a_w for prolonged time
 - **GROWTH ≠ SURVIVAL**

Food Commodity	Food Example	Water Activity (aw)
Fresh Fruits	Apple	0.98 – 0.99
	Banana	0.95 – 0.97
Vegetables	Carrot	0.97 – 0.99
	Lettuce	0.99
Dairy	Milk	0.97 – 0.99
	Cheese (hard)	0.85 – 0.90
Meat & Poultry	Raw chicken	0.98 – 0.99
	Ground beef	0.97 – 0.99
	Dry-cured ham	0.87 – 0.92
Seafood	Fresh fish (e.g. cod)	0.98 – 0.99
	Salted fish	0.75 – 0.85
Cereals & Grains	Bread (fresh)	0.94 – 0.96
	Cooked rice	0.98 – 0.99
	Wheat flour	0.65 – 0.70
Baked Goods	Cookies	0.30 – 0.50
	Cake (moist)	0.85 – 0.90
Confectionery	Chocolate (solid)	0.40 – 0.55
	Jelly	0.80 – 0.88
Fermented Foods	Sauerkraut	0.95 – 0.98
	Salami (semi-dry)	0.88 – 0.92
Eggs	Whole egg (raw)	0.97 – 0.99

The lower the a_w , the harder it is for microbes to grow.

Microbial Growth – a_w (cont.)

- Low water activity foods:
 - $a_w < 0.85$
 - Also known as low moisture foods
- Low water activity is a barrier for microbial growth.
 - Dry foods are not inherently safe.
 - *Cronobacter sakazakii*, *Salmonella*, STEC, etc.
 - **GROWTH ≠ SURVIVAL**

Table 3-2—Approximate a_w values for growth of selected pathogens in food

Organism	Minimum	Optimum	Maximum
<i>Campylobacter</i> spp.	0.98	0.99	
<i>Clostridium botulinum</i> type E*	0.97		
<i>Shigella</i> spp.	0.97		
<i>Yersinia enterocolitica</i>	0.97		
<i>Vibrio vulnificus</i>	0.96	0.98	0.99
<i>Enterohemorrhagic Escherichia coli</i>	0.95	0.99	
<i>Salmonella</i> spp.	0.94	0.99	>0.99
<i>Vibrio parahaemolyticus</i>	0.94	0.98	0.99
<i>Bacillus cereus</i>	0.93		
<i>Clostridium botulinum</i> types A & B**	0.93		
<i>Clostridium perfringens</i>	0.943	0.95 to 0.96	0.97
<i>Listeria monocytogenes</i>	0.92		
<i>Staphylococcus aureus</i> growth	0.83	0.98	0.99
<i>Staphylococcus aureus</i> toxin	0.88	0.98	0.99

ICMSF 1996.

**proteolytic

*nonproteolytic

<https://www.fda.gov/downloads/food/foodborneillnesscontaminants/ucm545171.pdf>

Controlling Moisture

What to Do

Keep dry ingredients in low-humidity rooms

Use moisture meters

Seal packaging tightly

Example

Store dry mixes or spices in dehumidified storage rooms under 60% RH

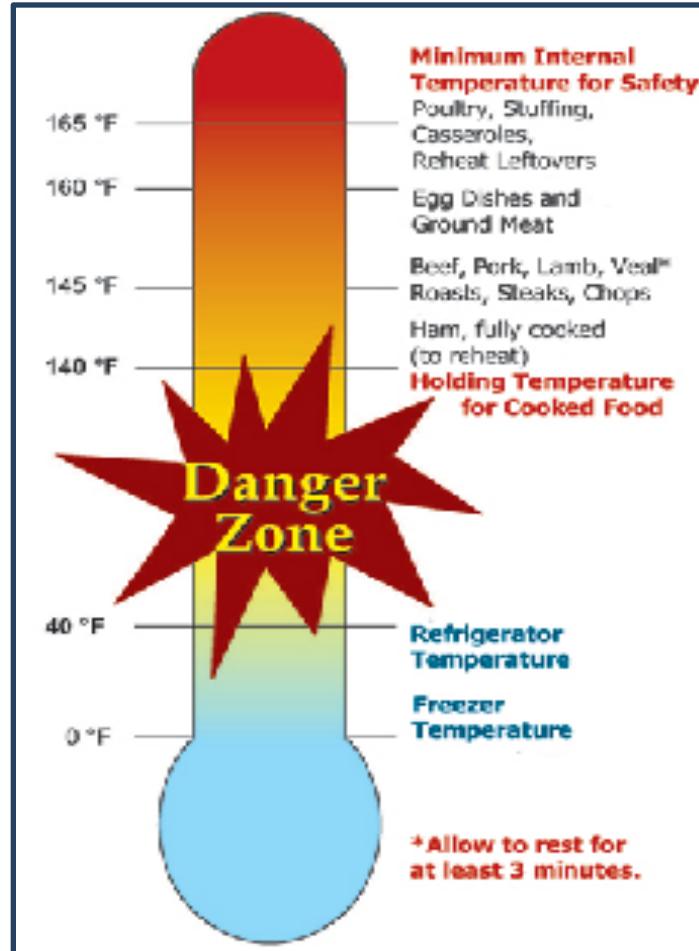
Check water activity (a_w) in granola bars to ensure it stays below 0.85

Use moisture barrier film to keep dried fruit from absorbing moisture

Microbial Growth – Temperature

- Most harmful bacteria grow best at room or moderate temperatures.
- Some can still grow in the fridge (at or below 5°C / 41°F).
- Freezing stops bacteria from growing, but many can grow again after thawing.
- Freezing can kill parasites in food.
 - Example: *Anisakis* in fish (FDA)
 - Example: *Trichinella* in pork (USDA)

Temperature Danger Zone



- What is temperature abuse?
 - Temperature/time combination that allows growth of pathogenic microorganism in the food matrix.
 - 41-135 °F (4-57.2 °C)
 - Effect on microbial growth:
 - Higher growth rate
 - Shorter generation times

https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/safe-minimum-internal-temperature-chart/ct_index

BACK

NEXT

MODULE 8:

WAREHOUSING AND DISTRIBUTION

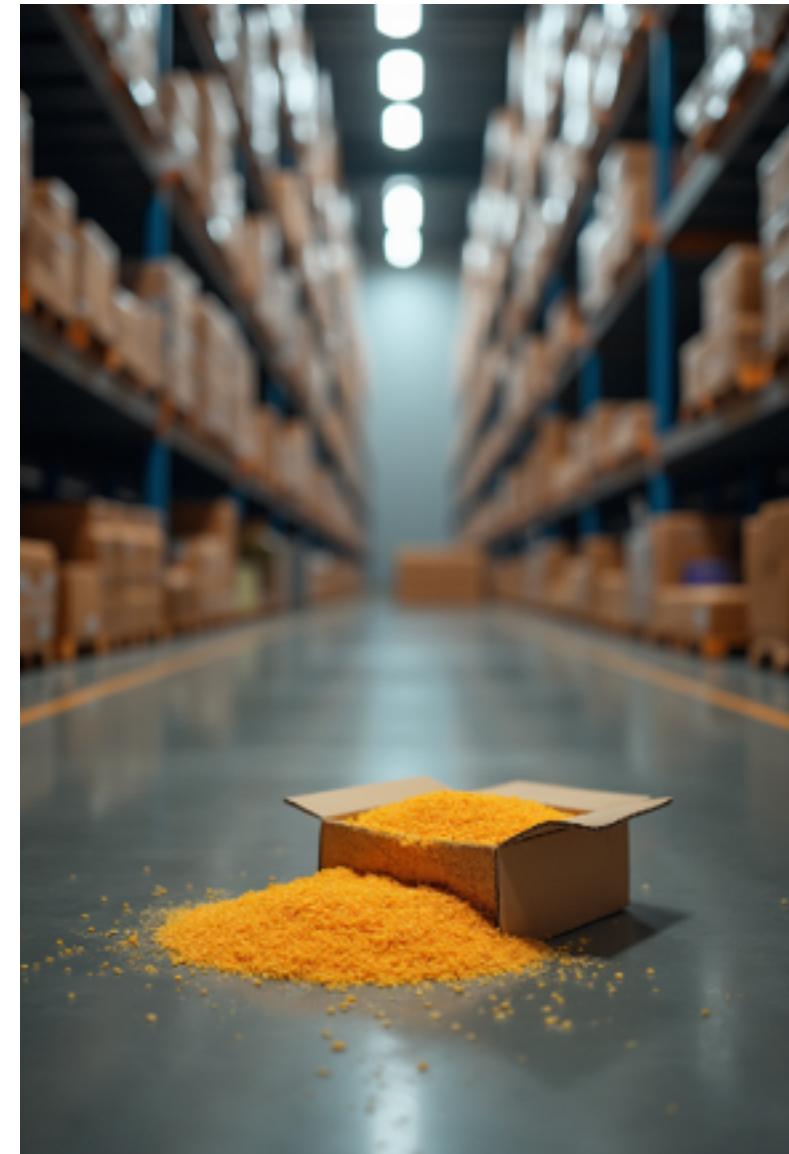
Warehousing and Distribution

1. Temperature Control
2. Pest Control
3. Cleaning and Sanitation
4. Cross-Contamination Prevention
5. Traceability and Labeling
6. FIFO and Stock Rotation
7. Good Handling Practices
8. Vehicle Sanitation and Control

BACK

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BACK

NEXT

MODULE 9:

DEFECT ACTION LEVELS

Defect Action Levels

- Defect action level means a level of a non-hazardous, naturally occurring, unavoidable defect at which FDA may regard a food product “adulterated” and subject to enforcement action.
- Food companies must always use quality control to keep natural or unavoidable defects as low as possible.
- They cannot mix bad food with other food to try to make it seem okay — the final product is still considered unsafe.

<https://www.fda.gov/food/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements/food-defect-levels-handbook>

BACK

GOOD MANUFACTURING PRACTICES FOR THE FOOD INDUSTRY



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