

Food Good Manufacturing Practices

Title 21 Code of Federal Regulations (CFR) Part 110



Slides Developed By:

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Center for Environmental Health
Food Drug and Radiation Safety Division
Food and Drug Branch

Presentation Goals

Key Terms

Four Major Components

Questions

Key Terms	<ul style="list-style-type: none">• should – used to state recommended or advisory procedures
<ul style="list-style-type: none">• adequate – what is needed to accomplish the intended purpose in keeping with good public health practice	<ul style="list-style-type: none">• shall – used to state mandatory requirements
<ul style="list-style-type: none">• suitable* – adapted to a use or purpose; proper; able; qualified	<small>* Merriam-Webster.com</small>

GOOD MANUFACTURING PRACTICES

Sanitary Controls
and Conditions

ADEQUATE

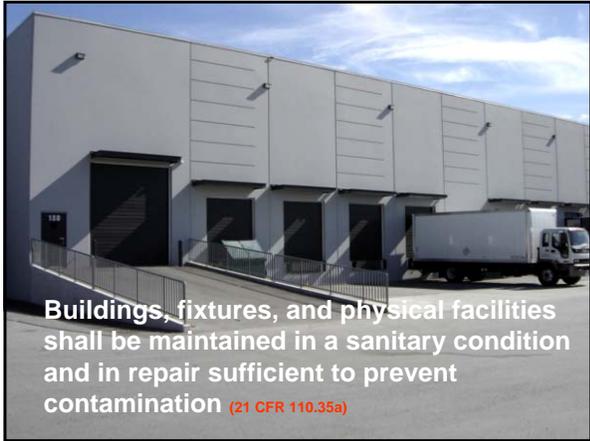
Processing Controls

SUITABLE

GMP Triple Threat







Buildings, fixtures, and physical facilities shall be maintained in a sanitary condition and in repair sufficient to prevent contamination (21 CFR 110.35a)



Grounds

The grounds **under control** of the operator must be maintained in a manner to protect against the contamination of food **(21 CFR 110.20 a1-4)**

- Storing equipment**
- Litter and waste**
- Weeds and grass**
- Roads and yards**
- Drainage**
- Waste systems**

Grounds

The grounds **not under control** of the operator and **not adequately maintained**: care shall be exercised to prevent food contamination through **(21 CFR 110.20a)**:

- Inspection
- Extermination
- Other means



Facilities

Plant buildings and structures shall be suitable in size, construction and design to facilitate maintenance and sanitary operations. **(21 CFR 110.20b5)**

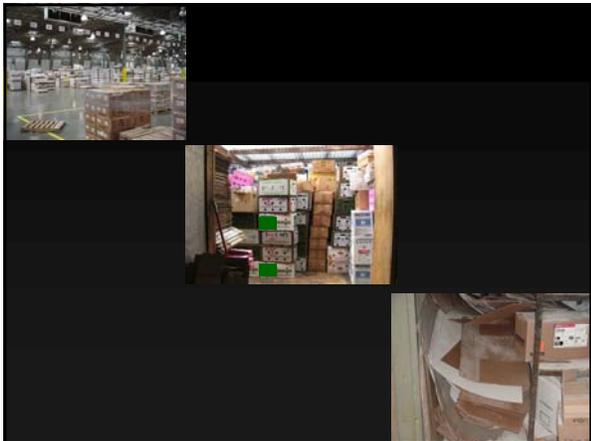
- Adequate lighting
- Safety fixtures



Facilities

Buildings and structures shall be of suitable size construction and design to facilitate maintenance and sanitary operations
(21 CFR 110.20b1 and b2):

- Space for equipment and storage
- Food safety controls
- Operating practices
- Effective design
- Other effective means



What do you see?



Your facility design must allow for product protection via either:



Partition
Space
Time



Facilities

Buildings and structures shall be of suitable size construction and design to facilitate maintenance and sanitary operations

(21 CFR 110.20b3,4):

Bulk Fermentation Vessels Construction

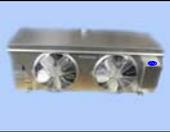
- adequately cleaned
- adequate space
- good repair (21 CFR 110.35a)

Facilities

Buildings and structures shall be of suitable size construction and design to facilitate maintenance and sanitary operations
(21 CFR 110.20b4):

Construction

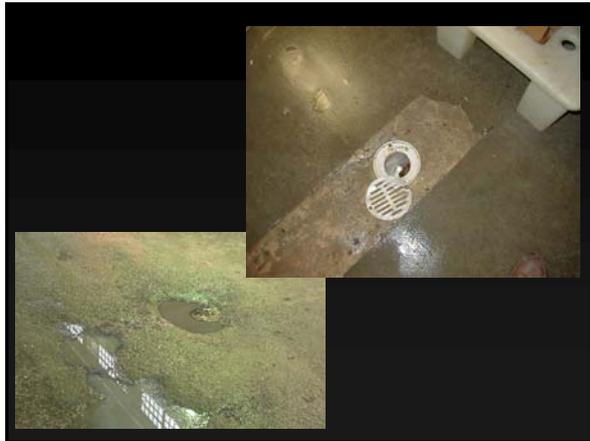
- drip and condensate



Sanitary Facilities (21 CFR 110.37b, c, f)

Each plant shall be equipped with **adequate sanitary facilities:**

- Plumbing
 - Properly sized
 - Avoid constituting a source of contamination
- Floor Drainage
 - No Back flow or Cross connections
- Sewage Disposal
- Rubbish and offal disposal







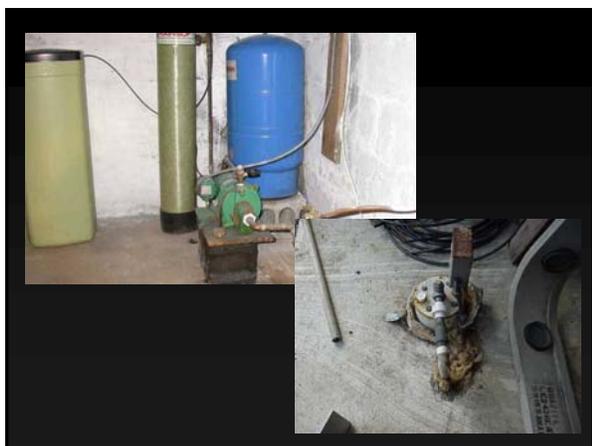
Water Supply

21 CFR 110.37a

- Adequate Source
- Safe and Sanitary Quality
- Suitable Temperature
- Appropriate Pressure

21 CFR 110.80a1

- Water used for washing, rinsing, or conveying food shall be of safe and sanitary quality.
- Water, if reused cannot increase the level of contamination in food.



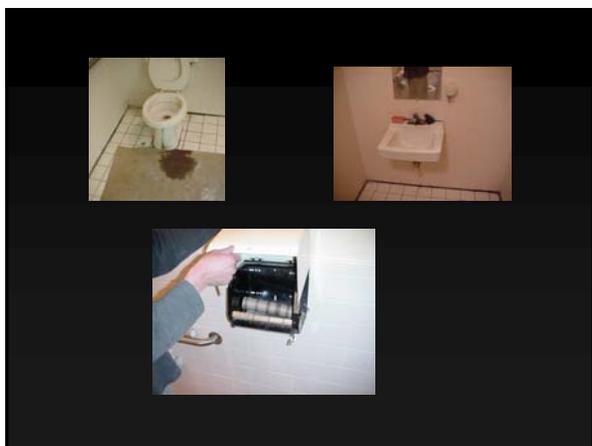


Sanitary Facilities (21 CFR 110.37d)

Toilet Facilities

- Readily Accessible
- Adequate

Sanitary Condition
Good repair
Self-closing doors
Properly located



Sanitary Facilities (21 CFR 110.37e)

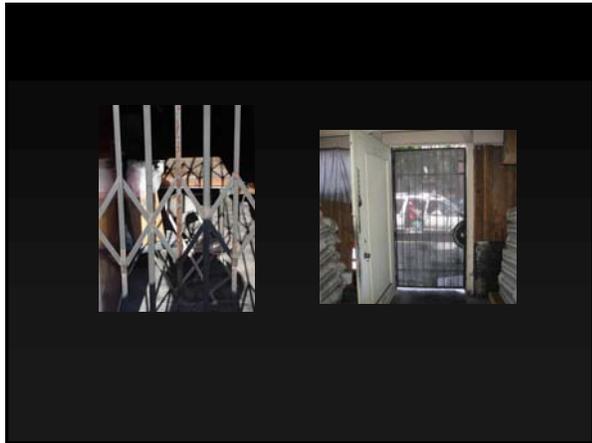
Handwashing Facilities

- Adequate (soap, towels)
- Hand sanitation facilities
- Convenient
- Running water
- Suitable temperature
- Fixtures designed not to re-contaminate
- Refuse receptacles
- Signage



Pest Control (21 CFR 110.20b7)

Provide adequate screening or other protection against pests.



Pest Control (21 CFR 110.35c)

- No pests allowed in plant
- Effective measures taken to exclude from processing areas
- Use of insecticides, rodenticides under precautions and restrictions





Personnel (21 CFR 110.10a)

Plant management shall take reasonable measures to ensure:

- **Disease control**
 - Medical Exam
 - Observation
 - Exclusion
 - Reporting

Personnel (21 CFR 110.10b)

Plant management shall take reasonable measures to ensure:

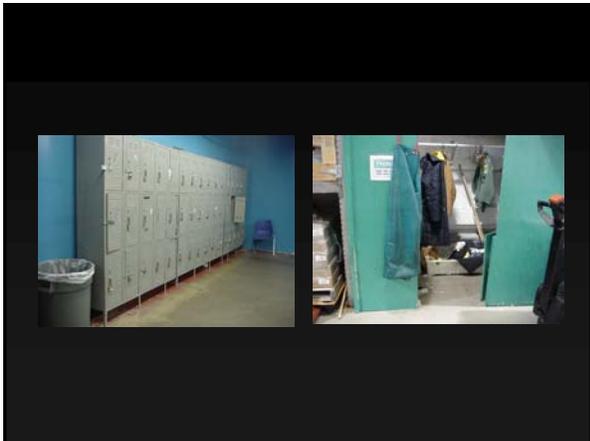
- **Cleanliness through Hygienic practices**
 - Outer Garments
 - Personal Cleanliness
 - Washing hands thoroughly



Personnel (21 CFR 110.10b)
Plant management shall take reasonable measures to ensure:

Cleanliness through Hygienic Practices

- Jewelry
- Gloves
- Hair restraints
- Storing clothing
- Areas of eating, drinking, smoking confined
- Foreign substances





Personnel

Plant management shall take reasonable measures to ensure:

Education and Training

(21 CFR 110.10c)

Proper Supervision

(21 CFR 110.10d and 110.80)





Equipment

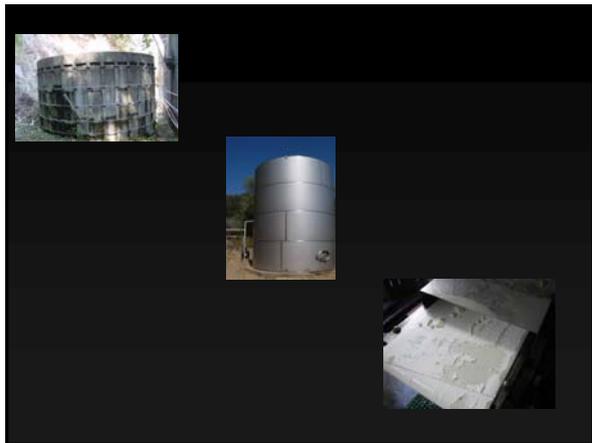
Shall be designed and of such material, and workmanship to be **adequately cleaned** and shall be **properly maintained**
 (21 CFR 110.40a,d and 21 CFR 110.80b1)

- Preclude adulteration from:
 - lubricants
 - fuel
 - metal fragments
 - contaminated water
- Enables Maintenance



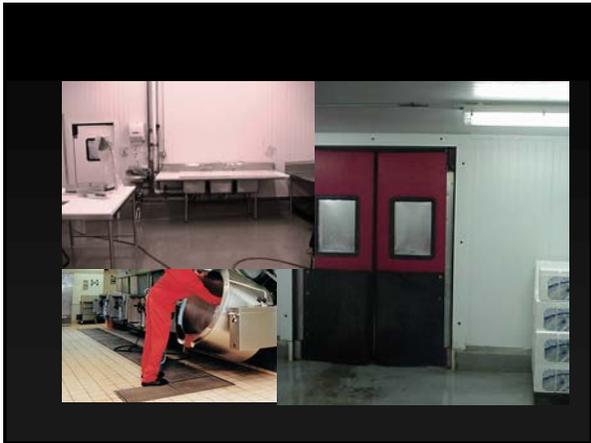
Equipment (21 CFR 110.40a,b)

- Designed to withstand food, cleaning and sanitizing
- Smoothly bonded seams
- Taken apart for thorough cleaning (21 CFR 110.80b1)

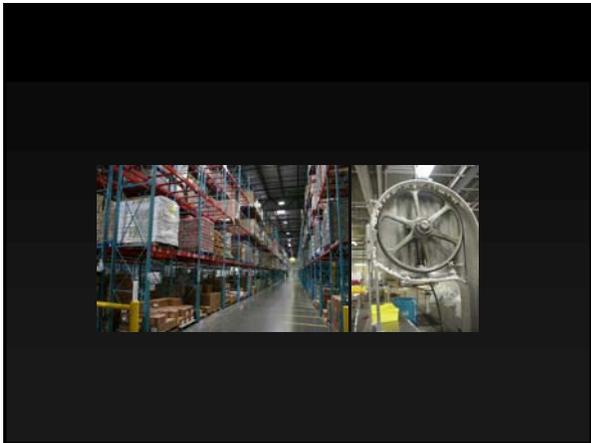


Equipment (21 CFR 110.40a)

- Installed and maintained to facilitate cleaning
- Corrosion resistant
- Non-toxic

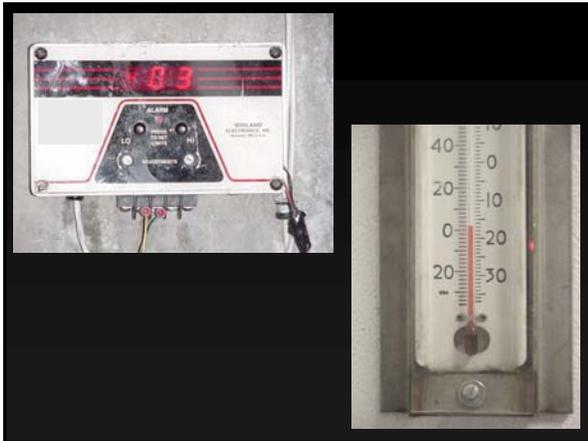


Equipment (21 CFR 110.40c)
Non-food contact surfaces
constructed to be kept clean
and
cleaned as necessary to protect
against contamination
(21 CFR 110.35d3)



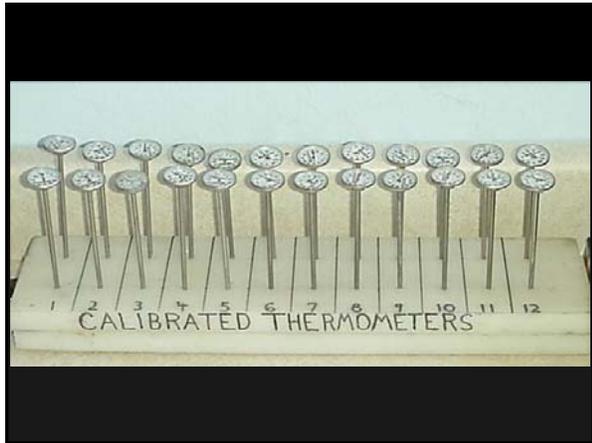
Equipment (21 CFR 110.40e)

- **Temperature monitoring devices** required for freezers and cold storage units – accurate, automatic controls or alarm



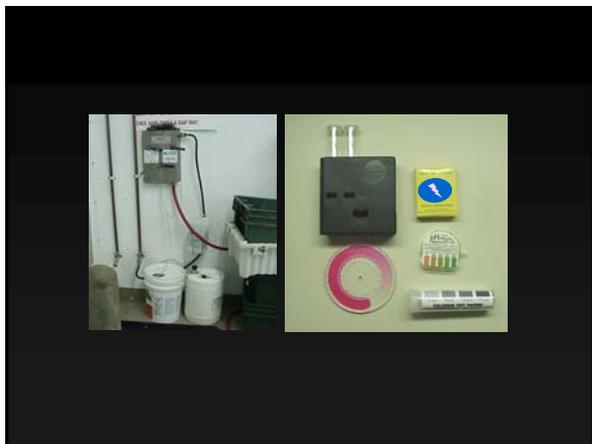
Equipment (21 CFR 110.40f and g)

- **Instruments** controlling or preventing the growth of microorganisms shall be:
 - accurate
 - maintained
 - appropriate in number
- **Compressed air** shall not be a source of contamination



Sanitary Controls (21 CFR 110.35a)

- Cleaning and sanitizing of **utensils** and **equipment** shall be conducted in a manner that protects against contamination



Sanitary Controls (21 CFR 110.35b)

- Cleaning and sanitizing **agents**
 - free from microorganisms
 - safe
 - adequate

Sanitary Controls (21 CFR 110.35b)

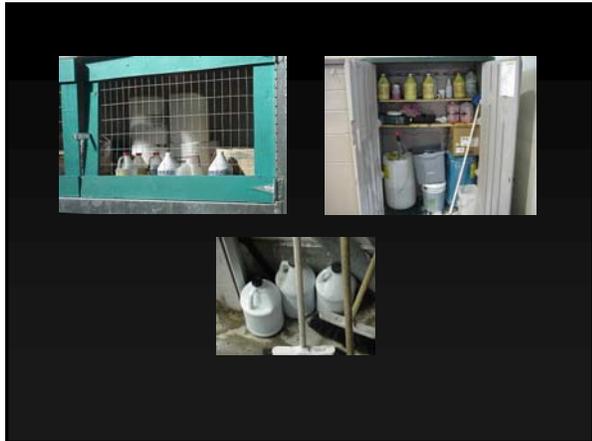
- Use:
 - as prescribed by law
 - protect against contamination
- Presence of Toxic agents
 - Cleaning and sanitizing
 - Laboratory
 - Maintenance and operations



Sanitary Controls (21 CFR 110.35b2)

- **Storage** of Toxic agents

- Properly Identified
- Held
- Properly stored



Sanitation of Food Contact Surfaces - FCS (21 CFR 110.35d)

Shall be cleaned as frequently as necessary to protect from contamination.

- FCS for Dry processing
- FCS for Wet processing

Sanitation of Food Contact Surfaces

(21 CFR 110.35d,e)

- Single service articles
- Sanitizing agents
- Portable equipment
(21 CFR 110.35e)

Equipment

Plant buildings and structures shall be suitable in size, construction and design to facilitate maintenance and sanitary operations. (21 CFR 110.20b6)

- Adequate ventilation



Processes and Controls (21 CFR 110.80)

All operations shall be conducted in accordance with adequate sanitation principles

Appropriate quality control operations shall be employed

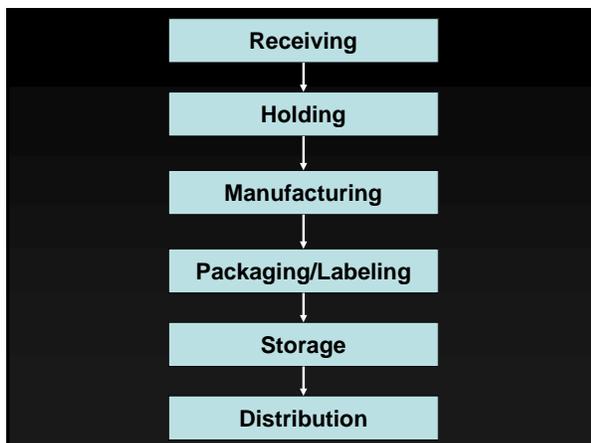
All reasonable precautions shall be taken to protect from contamination

Processes and Controls (21 CFR 110.80a2)

Ingredients shall not contain levels of microorganisms that may cause disease

or

Ingredients shall be pasteurized or otherwise treated

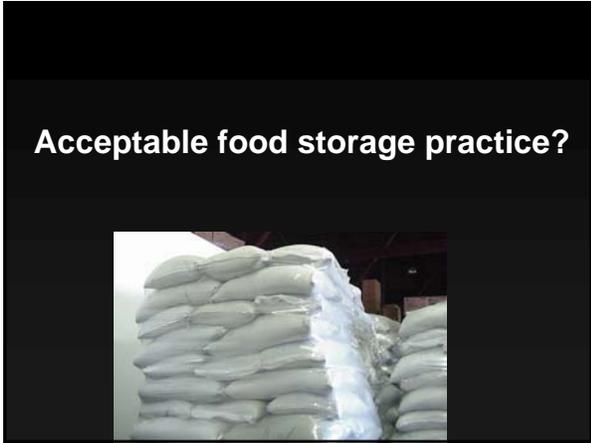


Raw Materials
Manufacturing Operations

Raw Materials
(21 CFR 110.80a1)

Shall be:

- Inspected, segregated or handled** as necessary, to determine they are clean and suitable
- Stored** to protect from contamination and minimize deterioration
- Washed and cleaned**, as necessary, to remove contaminants

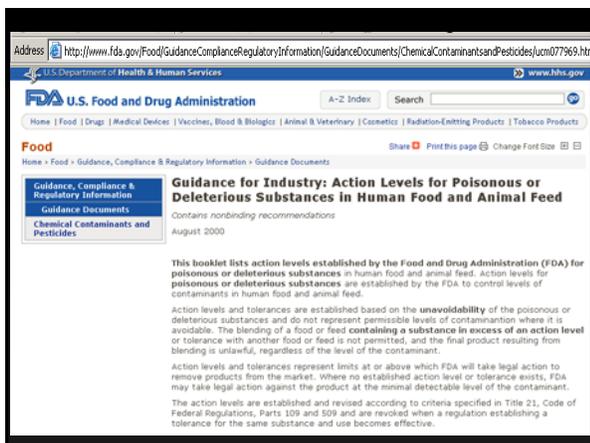


Raw Materials (21 CFR 110.80a1)

Containers should be inspected to ensure they do not contribute to contamination or deterioration

Raw Materials (21 CFR 110.80a3)

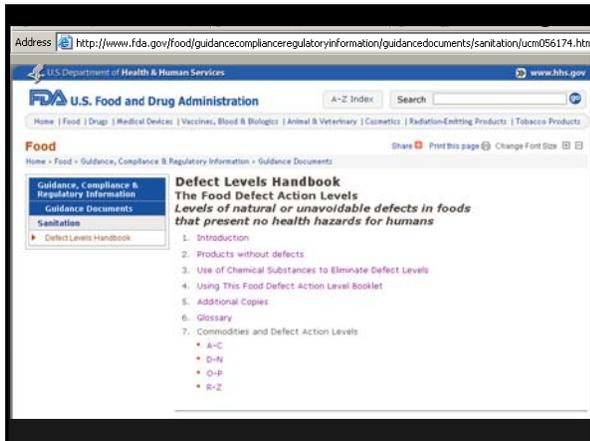
Susceptible to aflatoxin or other natural toxins shall comply with FDA regulations, guidelines, and action levels.



The screenshot shows the FDA website page for "Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed". The page includes the FDA logo, navigation links, and the main title of the document. The document is dated August 2000 and contains nonbinding recommendations. The text on the page states that the booklet lists action levels established by the FDA for poisonous or deleterious substances in human food and animal feed. It also explains that action levels and tolerances are established based on the unavailability of the substance and do not represent permissible levels of contamination. The page further notes that action levels and tolerances represent limits at or above which the FDA will take legal action to remove products from the market.

Raw Materials (21 CFR 110.80a4)

Susceptible to **pests** or other **undesirable microorganisms** or **extraneous materials** shall comply with FDA defect action levels.



Raw Materials (21 CFR 110.80a5,7)

- Held in **bulk containers** shall be held to protect from contamination.
- Materials scheduled for **re-work** shall be identified as such.

Raw Materials
(21 CFR 110.80a6)

- **Frozen ingredients** shall be held frozen. If thawed, it shall be done in a manner that prevents adulteration.

Manufacturing Operations
(21 CFR 110.80b2)

Compliance through **monitoring** of:

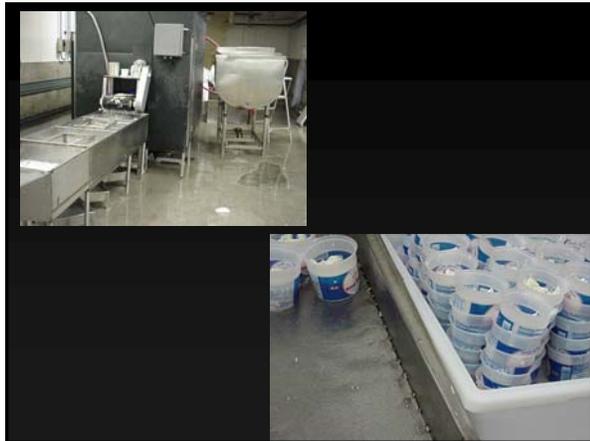
- Physical Factors
- Time
- Flow Rate
- Aw
- pH
- Temperature
- Pressure
- Humidity

Manufacturing Operations
(21 CFR 110.80b2)

All food manufacturing, including packaging and storage shall be conducted under conditions and controls to minimize the potential for the **growth of microorganisms and contamination**.

**Manufacturing Operations
(21 CFR 110.80b3)**

FOODS THAT CAN SUPPORT THE RAPID GROWTH OF MICRO-ORGANISMS OF PUBLIC HEALTH SIGNIFICANCE SHALL BE HELD AND PROCESSED IN A MANNER THAT PREVENTS THE FOOD FROM BECOMING ADULTERATED



**Manufacturing Operations
(21 CFR 110.80b3)**

- Refrigerated foods at $\leq 45^{\circ}\text{F}$
- Frozen foods in frozen state
- Hot foods at $\geq 140^{\circ}\text{F}$
- Heat treating or acidifying foods held at ambient temperatures in hermetically sealed containers

Manufacturing Operations Food Safety Systems

- Hazard Analysis Critical Control Points (HACCP)
(21 CFR 110.80b,12,i)
- ISO



Additional Process Controls

- Recall Program
- Complaint Program
- Monitoring
- Environmental Testing
- Product Analysis
- Validation of Processes
- Reportable Food Registry (RFR)
- Validation of Processes
- Audit Program
- Bioterrorism