Current Good Manufacturing Practices for Food
Title 21 Code of Federal Regulations (CFR)
Part 117, Subpart B

Presented By:
California Department of Public Health
Food and Drug Branch
Phone – (916) 650-6500
Email – FDBTraining@cdph.ca.gov

Part 117 – What applies to me?

Part 117 – What applies to me?

- Sales <$1,000,000
  - Subpart A – General Provisions
  - Subpart B – Current Good Manufacturing Practice
  - Subpart D – Modified Requirements
  - Subpart F – Records

- Sales ≥$1,000,000
  - All of the above (except D)
  - Subpart C – Hazard Analysis & Risk-Based Preventive Controls
  - Subpart G – Supply-Chain Program
Presentation Goals

Key Terms

Four Major Components

Questions

Key Terms

Must* – mandatory. Replaced “shall,” which was defined

Adequate – what is needed to accomplish the intended purpose in keeping with good public health practice

Should – and all advisory language removed

Suitable* – adapted to a use or purpose; proper; able; qualified

Definitions

Preventing Contamination

Food

Food Contact Surfaces

Food Packaging Materials
Buildings, fixtures, and physical facilities must be maintained in a sanitary condition and in repair adequate to prevent contamination. 21 CFR §117.35(a)
Grounds
The grounds under control of the operator must be maintained in a manner to protect against the contamination of food.

21 CFR §117.20(a)(1-4)
- 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:

§117.20(a)(5)
- Inspection
- Extermination
- Other means
Facilities

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

§117.20(b)(1), (2)

- Space for equipment and storage
- Food safety + allergen controls
- Operating practices
- Effective design
- Other effective means
What do you see?

Bad News
- pest droppings

Good News
- visual inspection
Your facility design must allow for product protection via either:

- **Partition**
- **Space**
- **Time**

Facilities

Plant buildings and structures *must* be suitable in size, construction and design to facilitate maintenance and sanitary operations. §117.20(b)(5)

- **Adequate lighting**
- **Safety fixtures**
Facilities
Buildings and structures must be of suitable size, construction, and design to facilitate maintenance and sanitary operations

§117.20(b)(3)

Outdoor Bulk Vessels
Construction
- adequately cleaned
- adequate space
- good repair

§117.35(a)

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

§117.20(b)(4)

Construction
- drip and condensate
Facilities

Buildings and structures must be suitable in size, construction and design to facilitate maintenance and sanitary operations.

§117.20(b)(6)

• Adequate ventilation

Sanitary Facilities §117.37(b), (c), (f)

Each plant must be equipped with adequate sanitary facilities
- Plumbing
  - Properly sized
  - Avoid being a source of contamination
- Floor drainage
  - No back flow or cross connections
- Sewage disposal
- Rubbish and offal disposal
Water Supply

§117.37(a)
• Adequate Source
• Safe and Sanitary Quality
• Suitable Temperature
• Appropriate Pressure

§117.80(b)(1)
• Water used for washing, rinsing, or conveying food must be of safe and sanitary quality
• Water, if reused cannot increase the level of contamination in food
Sanitary Facilities §117.37(d)

Toilet Facilities
- Adequate, readily accessible
- Must be kept clean
- Must not be a potential source of contamination
Sanitary Facilities §117.37(e)

**Handwashing Facilities**

- To ensure hands are not a source of contamination
- Adequate (soap, towels)
- Convenient
- Running water at suitable temperature
Facilities and Grounds

Sanitary Facilities (110.37 e)
- Handwashing Facilities
  - Cleaning and Sanitizing Agents
  - Sanitary Towel or hand drying devices
  - Signs
  - Refuse containers

Pest Control §117.20(b)(7)

Provide adequate screening or other protection against pests.
Pest Control §117.35(c)

• No pests allowed in plant
• Take effective measures to exclude from processing areas
• Pesticide use permitted only under precautions + restrictions
Why are good personnel practices necessary?

Personnel §117.10(a)
Management must take reasonable measures to ensure:

Disease control
- Medical Exam
- Observation
- Exclusion
- Reporting
Personnel  §117.10(b)
Management must take reasonable measures to ensure:

Cleanliness through hygienic practices
  • Outer garments
  • Personal cleanliness
  • Washing hands thoroughly

Personnel  §117.10(b)
Management must take reasonable measures to ensure:

Cleanliness through hygienic practices
  • Jewelry
  • Gloves
  • Hair restraints
  • Clothing storage areas
  • Confine eating, drinking, smoking
  • Allergen cross-contact
  • Foreign substances
Personnel

Management must take reasonable measures to ensure:

**Education and Training**
§117.4(b) and (d), and 117.9

**Proper Supervision**
§117.4(b) and (c)
Equipment

Must be designed and of such material, and workmanship to be adequately cleanable and maintained §117.40

• Avoid adulteration with:
  - lubricants
  - fuel
  - metal fragments
  - contaminated water

• Facilitate cleaning and maintenance
Equipment §117.40(a), (b)

- Designed to withstand food, cleaning and sanitizing
- Smoothly bonded seams
- Taken apart for thorough cleaning §117.80(c)(1)

Equipment §117.40(a)

**Must be:**
- Installed and maintained to facilitate cleaning
- Corrosion resistant
- Non-toxic
Equipment

Non-food contact surfaces

• Constructed to be kept clean §117.40(c)
• Cleaned as necessary to protect against allergen cross-contact and contamination §117.35(e)
Equipment

§117.40(e)

Accurate temperature measuring or recording devices required for freezers and cold storage units
Equipment §117.40(f) and (g)

Instruments and controls for measuring conditions that prevent the growth of microorganisms must be:
- accurate and precise
- maintained
- adequate in number

Compressed air must not be a source of contamination

Sanitary Operations §117.35(a)

Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and contamination
Sanitary Operations §117.35(b)(1)

Cleaning and sanitizing agents must be:
- Free from microorganisms
- Safe
- Adequate

*Must be Verified* by either:
- Letter of Guarantee,
- Certification, or,
- Examination
Sanitary Operations §117.35(b)

Use or store toxic agents only for:
- Cleaning and sanitizing
- Laboratory
- Maintenance and operations

Sanitary Controls §117.35(b)(2)

Toxic Agents must be:
• Identified: Labels!
• Held and stored to protect against contamination
Sanitation of Food Contact Surfaces
§117.35(d)

Must be cleaned as frequently as necessary to protect from allergen cross-contact and contamination.

- Wet Sanitation
- Dry Sanitation
Sanitation of Food Contact Surfaces
§117.35

- Single service articles §117.35(d)
- Sanitizing agents §117.35(e)
- Portable equipment §117.35(f)

Processes and Controls
§117.80

All operations must be conducted in accordance with adequate sanitation principles

Appropriate quality control operations must be employed

Adequate precautions must be taken to protect from allergen cross-contact and contamination
Processes and Controls
§117.80(b)(2)

Ingredients must not contain levels of microorganisms that may be injurious to health,
or
Ingredients must be pasteurized or otherwise treated.

Raw Materials
Manufacturing Operations
Raw Materials
§117.80(b)(1)

Must be:

Inspected, segregated or handled as necessary, to determine they are clean and suitable

Stored while protecting from allergen cross-contact and contamination, and minimizing deterioration

Washed and cleaned as necessary, to remove contaminants

Acceptable food storage practice?

Raw Materials
§117.80(b)(1)

Raw Materials and Ingredients must be inspected to ensure they are clean and suitable, and stored in a way to prevent allergen cross-contact, contamination, and deterioration.
Raw Materials
§117.80(b)(3)

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

Action Levels for Poisonous or Deleterious Substances

- Aflatoxin
- Aldrin & Dieldrin
- Benzene Hexachloride
- Cadmium
- Chlordane
- Chlordecone (Kepone)
- DDT, DDE, TDE
- Dimethylnitrosamine (Nitrosodimethylamine)
- Ethylene Dibromide (EDB)
- Heptachlor & Heptachlor Epoxide
- Lead
- Lindane
- Mercury
- Methyl Alcohol
- Mirex
- N-Nitrosamines
- Paralytic Shellfish Toxin
- Polychlorinated Biphenyls (PCBs)
Raw Materials
§117.80(b)(4), §117.110

Susceptible to pests or other undesirable microorganisms or extraneous materials shall comply with FDA defect action levels.
Raw Materials
§117.80(b)(5), (b)(7)

• Held in bulk containers must be held while protecting from allergen cross-contact, contamination, and adulteration

• Materials scheduled for re-work must be identified as such

Raw Materials
§117.80(b)(6)

Frozen ingredients must be kept frozen. If thawed, it must be done in a manner that prevents adulteration.

Manufacturing Operations
§117.80(c)

Comply by monitoring:

<table>
<thead>
<tr>
<th>Physical Factors</th>
<th>Manufacturing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>Freezing</td>
</tr>
<tr>
<td>Flow Rate</td>
<td>Dehydration</td>
</tr>
<tr>
<td>Aw</td>
<td>Heat Processing</td>
</tr>
<tr>
<td>pH</td>
<td>Acidification</td>
</tr>
<tr>
<td>Temperature</td>
<td>Refrigeration</td>
</tr>
<tr>
<td>Pressure</td>
<td>Irradiation</td>
</tr>
<tr>
<td>Humidity</td>
<td></td>
</tr>
</tbody>
</table>
Manufacturing Operations
§117.80(c)

All food manufacturing, including packaging and storage, must be conducted under conditions and controls necessary to minimize the potential for growth of microorganisms, allergen cross-contact, contamination, and deterioration.
Manufacturing Operations
§117.80(c)(3)

FOODS THAT CAN SUPPORT THE RAPID GROWTH OF UNDESIRABLE MICROORGANISMS MUST BE HELD AND PROCESSED IN A MANNER THAT PREVENTS THE FOOD FROM BECOMING ADULTERATED

Manufacturing Operations
H&SC §110980, 21 CFR §117.80(c)(3)

- Refrigerated foods at ≤ 45°F
- Frozen foods in frozen state
- Heat treating or acidifying foods held at ambient temperatures in hermetically sealed containers
Additional Considerations

- Hazard Analysis and Risk Based Preventive Controls
  - Food Allergen/Sanitation/Supply-Chain Controls
  - Recall Plan
  - Environmental Monitoring Program
- Reportable Food Registry
- FDA Bioterrorism Registration
- Validation of Processes
- Audit Programs (ISO/SQF/ETC)

Contacts

State Government

CDPH-Food and Drug Branch
P.O. Box 997435, MS 7602
Sacramento, CA 95899-7435
E-mail: FDD@cdph.ca.gov
(916) 650-6520

California Department of Food and Agriculture
1220 N Street
Sacramento, California, U.S.A. 95814
www.cdfa.ca.gov
(916) 654-0468

Federal Government

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov
1-888-INFO-FDA (1-888-463-6332)

U.S. Department of Food and Agriculture
620 Central Avenue, Building 2C
Alameda, CA 94501
www.fsis.usda.gov
(510) 337-5000 (Alameda District)