

Low-Acid Foods Regulations and Requirements in the United States

Low-acid foods (pH > 4.6 and water activity > 0.85) packaged in hermetically sealed containers are regulated strictly in the United States to ensure safety from pathogens, especially *Clostridium botulinum*.

1. Regulatory Authorities:

- FDA (Food and Drug Administration) – Title 21 CFR Part 113
- USDA (for meat/poultry-containing products)
- FSMA (Food Safety Modernization Act) also applies for preventive controls

All processors must register their facility and file scheduled thermal processes with the FDA via Form FDA 2541.

2. FDA Regulations (21 CFR Part 113):

- Applies to thermally processed low-acid foods in hermetically sealed containers.
- Scheduled Process: Must be established by a qualified process authority.
- Filing: Submit FDA form 2541 (Food Canning Establishment Registration).
- Process Filing: File scheduled processes (Form 2541e) for each product and container type.
- Validation: Must demonstrate commercial sterility.
- Monitoring: Record critical processing factors (e.g., temperature, time, pressure).
- Record Keeping: Maintain records for at least 3 years.
- Equipment: Must be approved, maintained, and calibrated.
- Training: Operators must complete certified training (e.g., Better Process Control School).

3. USDA Regulations:

- USDA regulates low-acid foods that contain significant meat, poultry, or egg content.
- Key USDA Regulations:
- 9 CFR Parts 318 and 381 (Thermal Processing of Meat and Poultry Products)
- Establishments must have USDA Grant of Inspection.

- HACCP plans are mandatory and reviewed by USDA FSIS (Food Safety and Inspection Service).
- * Validation of lethality steps and critical limits is essential.
- Regular inspection and compliance verification by FSIS inspectors.
- Labeling approval is required under FSIS rules.
- USDA plants producing shelf-stable low-acid products must follow both FSIS and FDA technical guidance for thermal processing.

4. Thermal Process Requirements:

- Process must be established by a Process Authority.
- Must achieve an appropriate F_0 value (lethality).
- Heat penetration and distribution studies required.
- Use of recording instruments to monitor temperature, pressure, and time.

5. Microbiological Safety

Although finished-product testing is limited, manufacturers must control:

- Spores of *Clostridium botulinum*
- Environmental pathogens (as part of FSMA Preventive Controls)
- Shelf-life validation for spoilage and safety

6. Recordkeeping Requirements:

- Processing logs (time, temperature, flow rate, pressure).
- Deviations and corrective actions.
- Equipment calibration.
- Container integrity checks.
- Employee training documentation.

7. Facility Compliance:

- FDA and USDA conduct routine and unannounced inspections.

- Required corrective actions for any deviation from critical limits or process failures.
- Good Manufacturing Practices (21 CFR Part 117) must be implemented in all facilities.

8. Imports:

- Imported low-acid foods must comply with FDA or USDA standards.
- Products are subject to inspection and detention if found non-compliant.

Meeting FDA and USDA requirements ensures food safety, protects public health, and secures regulatory approval for domestic and international distribution.

For more information, visit:

- FDA: <https://www.fda.gov>
- USDA FSIS: <https://www.fsis.usda.gov>

For expert assistance with process design, validation, or regulatory review:

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