

Module 4: Canning Regulations— An Overview

9 CFR 431.1 Definitions

- **Canned Product:** Meat or poultry food product with water activity >0.85 which receives a thermal process either before or after being packaged in a hermetically sealed container.
- **Low Acid Product:** Canned product in which any component has $\text{pH} >4.6$.
- **Initial Temperature (I.T.):** Measured in coldest container at the start of the thermal process.
- **Process Temperature (PT):** Minimum maintained temperature of the heating medium.
- **Process Time (B_b):** Intended time containers are exposed to the heating medium in a retort while at or above PT.
- **Come-up time (CUT):** Elapsed at the start of B_b until the retort reaches required PT.
- **Hermetically sealed:** Airtight; does not allow the entrance of microorganisms during and after the thermal process.
- **Commercially sterile:** free of viable microorganisms (including spores) that are capable of reproducing in the food under normal nonrefrigerated storage and distribution conditions.

All thermal processing establishments must conduct a hazard analysis for thermally processed products, assess possible outcomes, and address food safety hazards through:

1. A HACCP plan if biological, chemical and/or physical hazards are considered reasonably likely to occur (RLTO);
2. A HACCP plan or canning regulations (§318.300 - 318.311 or 381.300 - 381.311) if biological hazards are considered RLTO; or
3. Canning regulations or similar prerequisite program if food safety hazards are considered not RLTO.

§431.2 Examination and Cleaning of Empty Containers

Visual and teardown examinations of container closure integrity must be conducted to ensure that empty containers and container materials are properly handled and free from structural damage and defects that may affect container integrity. Rigid containers (cans) are required to be cleaned prior to filling.

§431.3 Thermal Processing

All thermally processed products must be produced by the establishment in accordance with an on-file process schedule (PS) developed by a Process Authority (PA). The establishment must provide inspectors with a list of process schedules and procedures, monitor and control all critical factors, and make available all thermal process records. Any changes to formulation, procedures, etc. must be evaluated by the PA and the PS not changed without prior written submittal of the revisions to the inspector.

§431.4 Critical Factors

Establishments must ensure that critical factors identified in the PS are measured, controlled, and recorded to ensure they are within the limits of that PS. Critical factors include maximum

pH, nitrite ppm level or % salt, water activity, product consistency, viscosity, and/or particle size, head space, heating medium flow rate, and maximum fill-in weight or drained weight.

§431.5 Operations in the Thermal Processing Room

Process schedules must be posted or made available to the retort operator and inspector. A system for product traffic control must be established. Each basket or one visible container must be marked, heat-sensitive ink applied to each container, and exposed heat sensitive indicators removed before the vehicle is refilled. Container loading systems for crateless retorts must be designed to prevent unprocessed containers from bypassing the retort.

The establishment must measure and record the I.T. of the coldest container prior to processing. Time/temperature recording devices must agree within 15 minutes. pH meters or similar electronic instruments must be used to measure maximum pH when it is a critical factor.

§431.6 Equipment and Procedures for Heat Processing Systems

Equipment and procedures used for heat processing systems must be adequate to render the product commercially sterile. Thermal processing systems must be examined at least annually and system maintenance records must be maintained.

§431.7 Processing and Production Records

Establishments must obtain and record all data necessary to support that thermal products are prepared, processed, and handled in compliance with commercially sterile product regulations.

§431.8 Record Review and Maintenance

Establishments must prepare commercially sterile product production records when the specific event occurs. Entries must be made and the records reviewed, signed or initialed within one working day after the process, made available to the inspector, and retained for a specified time.

§431.9 Deviations in Processing

Process deviations (PD) occur when the actual process is less than the actual PS, a critical factor does not meet the specified limit, or a thermal processing system parameter is not met. FSIS Directive 7530.1, "Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product" provides the inspector instructions for submitting information regarding the deviation, evaluation, and product disposition.

§431.10 Finished Product Inspection

Establishment's must have finished product inspection procedures in place to ensure that only normal appearing commercially sterile product is distributed into commerce.

§431.11 Personnel and Training

§431.12 Recall Procedure