

Lethality, Stabilization, & Multiple Hurdles

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Lethality is the step used to destroy pathogens, often cooking.

Stabilization is the process used to prevent or limit the growth of spore-forming bacteria, often cooling.

Multiple hurdle concept is when multiple treatments are used to achieve lethality or stabilization.

Performance standards: Quantifiable pathogen reduction levels or growth limits **set by FSIS regulations**. Products without a performance standard must address hazards that are likely to occur with a CCP. Establishments must identify in the HACCP system:

- ✓ Lethality pathogen reduction target (e.g., 6.5-log reduction in *Salmonella*)
- ✓ Stabilization outgrowth controls

Examples of Regulatory Performance Standards:

- ✓ Lethality: 6.5-log reduction of *Salmonella* for cooked beef, roast beef, cooked corned beef
- ✓ Stabilization: No multiplication of *C. botulinum* and no more than 1-log increase of *C. perfringens*

RTE Shelf-Stable Meat Products:

When there are **NO specific regulatory performance standards**, then those processes must simply comply with the HACCP regulations.

Targets: Limits set by establishments to produce safe products in the absence of performance standards set by FSIS. The target limits **Must be validated!!**

Spore-forming bacteria: can survive cooking and grow during cooling. Rapid cooling of products will prevent growth of spore-forming bacteria.

- ***C. botulinum***- produces toxin in product
- ***C. perfringens***- is the target organism because the other spore-formers are slower growing. Optimal growth range during cooling is from 126°F down to 109.4°F

RTE and Cooked Product Validation Compliance- Establishments must decide how to design their process to control hazards. Establishments can use FSIS guidelines, published processes, or develop customized processes. All critical operational parameters must match the process and are implemented. All critical operational parameters **Must be validated!**

FSIS Compliance Guidelines: provide guidance and information to industry. They are not regulatory and are not mandatory. Establishments may use them to support the selection of CCP's and critical limits in their HACCP plan or critical operational parameters in a pre-requisite program. Current Compliance Guidelines include: Lethality Guideline- Appendix A, Stabilization Guideline- Appendix B, Lebanon Bologna Compliance Guideline, and Jerky Compliance Guideline.

Appendix A- Lethality: The following three conditions that must be addressed and met are:

1) Time, 2) Temperature & 3) Humidity.

Humidity must be met to avoid preventing premature drying of the product surface which slows the heat process and increases heat resistant bacteria.

Appendix A- Lethality:

Poultry Products must meet the above 3-conditions, plus establishments should also consider- Fat Content. A higher fat content can make it take longer for the product to heat.

Appendix B- Stabilization provides guidance for processors that cook meat and poultry products to meet FSIS's stabilization (cooling) performance standard. Cooling must be continuous and rapid cooling prevents growth Clostridia bacteria.

Appendix B provides several cooling options with different time & temperature combinations.

4 Cooling Options:

Option 1: All fully cooked, cured, and uncured, and partially cooked processes may use this option.

- **130°F to 80°F in 1.5 hours**
- **80°F to 40°F in 5 hours**

Option 2: Fully cooked, cured, and uncured processes may use this option.

- **Start chilling** product **within 90 minutes** of the end of cooking.
- Cool product temperature from:
 - **120°F to 80°F in 1 hour**
 - **80°F to 55°F in 5 hours**
- Continue chilling until 40°F

Option 3: (Fully Cooked Cured Products): **cured** product must have at least 100 ppm of ingoing sodium nitrite and 250 ppm erythorbate or ascorbate. Natural sources of nitrite and ascorbate may also be used.

- Cool the product temperature from:
 - **130°F to 80°F in 5 hours**
 - **80°F to 45°F in 10 hours**

Option 4: (Cured Products): This is the slowest cooling process provided by Appendix B. Products must be formulated with: 40 ppm sodium nitrite and brine concentration 6% **or** have a maximum water activity (Aw) of 0.92.

- Cool the product temperature from:
 - **120°F to 40°F in 20 hours**

Cooling Deviations: The following can be used to address cooling deviations under **ALL** Appendix B options:

- Corrective Actions must be addressed
- Computer modeling program can be used to assess the severity
- Product can be salvaged if model ensures product safety
- Re-cook if model indicates no growth of *C. botulinum* but more than 1-log₁₀ of *C. perfringens*

Shelf Stable-Jerky Products:

Jerky products are RTE, Dried and Shelf Stable

Jerky processing has 8 steps included in the steps are Heating (lethality treatment) and Drying (Stabilization). These 2 important steps control microbiological hazards.

Past problems with Jerky products included:

- Heat was absorbed by moisture evaporating from product.
- Surface dried prior to reaching lethal temperature.
- Heat resistance of bacteria increased with drying.
- Industry relied on MPR (Meat-Protein Ratio) to determine whether product was stabilized-rather than water activity (A_w).
- MPR of 0.75:1 is standard to label as "jerky"

FSIS Jerky Guideline describes requirements for lethality treatment (heat & humidity) **prior to drying** to produce safe product.

Establishments must decide how to design their process to control hazards. Establishments may use FSIS guidelines, published processes, or develop customized processes. All critical operational parameters match the process and are implemented. The process **Must be validated!!**

Humidity plays an important role in the jerky process. Altitude can impact the amount of moisture in the heating (lethality step) and can affect humidity.

2 ways to meet the humidity parameters:

1. Seal the oven
2. Add Humidity

Jerky establishments must demonstrate that the method used to maintain humidity is effective. Most establishments use wet and dry bulb thermometers and the difference in the measurements is used to determine the relative humidity.

After the lethality treatment, the product is dried to meet a water activity (A_w) level that will stabilize the finished product for food safety purposes.

- Drying/stabilization step results in water activity of .85 or other validated water activity level, to control growth of *S. aureus* in aerobic environment
- In anaerobic environment (vacuum package) water activity can be as high as .91
- Mold controlled with antimicrobial interventions

Multiple Hurdle Process: use of a combination of inhibitory factors used by processors to make certain products. These processes must control a system of factors and interactions in order to achieve a safe process.

Examples of multiple hurdle processes: time, temperature, pH, water activity (A_w), nitrite, salt, chemical inhibitors, relative humidity to name a few.

If multiple hurdles are used, they are usually more effective than if used alone.

An example: when pH is lower, the water activity (A_w) which limits growth will be higher.

FSIS recommends lethality of 5.0-log₁₀ reduction of *Salmonella* and 5.0-log₁₀ reduction of STEC for products containing beef.

When performing the Hazard Verification Task the IPP will verify that the establishment has:

- Supporting documentation and expected level of bacterial pathogen reduction identified.
- Critical operational parameters identified and incorporated into process as CCP or pre-requisite program.
- Gathered data demonstrates effective implementation.