

LETHALITY, STABILIZATION, AND MULTIPLE HURDLES

Objectives

After completion of this module, the participant will be able to:

1. Define the following terms and explain their significance to the RTE food safety system:
 - a. Lethality
 - b. Stabilization
 - c. Performance standard
 - d. Target
 - e. Water activity (a_w)
 - f. Critical operational parameters
2. State the regulatory lethality and stabilization performance standards for cooked beef, and for cooked poultry, per 9 CFR 318.17 and 381.150.
3. State the compliance guidelines frequently used to support lethality, stabilization and multiple hurdle in the establishment's food safety systems.
4. Identify the critical operational parameters described in the lethality compliance guideline for cooking beef and poultry.
5. Describe the relationship between humidity and cooking temperatures as it pertains to the destruction of *Salmonella*.
6. Describe the food safety significance of untreated or untested ingredients added to RTE products after the lethality step.
7. Identify which microorganisms are controlled with the critical operational parameters provided in the stabilization compliance guideline.
8. Explain the food safety significance of drying in the jerky process, and state the target pathogen controlled by this step.
9. Explain how multiple hurdles are used in a food safety system.
10. Identify at least four common factors used in the multiple hurdles concept.
11. Describe the food safety significance of the fermentation step in a dry sausage process, and identify the pathogen of concern at this step.
12. Recognize the purpose of the options developed by the Blue Ribbon Task Force.

13. Identify the critical operational parameters measured when establishments use the degree-hour limit to support a dry sausage process.
14. Describe how inspectors verify that establishments have support for their lethality, stabilization and multiple-hurdle food safety systems.

References

1. FSIS Directive 7111.1, Rev. 2 - Verification Procedures For Lethality and Stabilization
2. FSIS Directive 5000.1, Rev. 6 - Verifying an Establishments' Food Safety System
3. FSIS Directive 5000.6, Rev. 4 - Performance of the Hazard Analysis Verification (HAV) Task
4. 9 CFR Part 318.17 - Requirements for the production of cooked Beef, roast beef, and cooked corned beef products
5. 9 CFR Part 318.23 - Heat-processing and stabilization requirements for uncured meat patties
6. 9 CFR Part 381.150 - Requirements for the production of fully cooked poultry products and partially cooked poultry breakfast strips
7. 9 CFR 417 - Hazard Analysis and Critical Control Point (HACCP) Systems

Introduction

Ready-to-Eat Foods products are meat or poultry products that are edible without additional preparation to achieve food safety. Two main processes which are critical for achieving safety in RTE products are known as lethality and stabilization. They are used to control the biological hazards in RTE products.

The **lethality** treatment is defined as the process step or steps used to destroy pathogenic microorganisms in a product to make the product safe for human consumption. FSIS expects that establishments will use a process that ensures that no *Salmonella* organisms remain in the finished product. The most common lethality treatment is heating the product.

After the product is cooked, spores of *Clostridium botulinum* and *Clostridium perfringens* that survive the cooking process can germinate, becoming vegetative cells that can multiply to hazardous levels if cooling is inadequate. The processes that establishments employ to limit the growth of spore-forming bacteria are called **stabilization**. The most common stabilization is cooling. However, other treatments, such as adjusting the product pH (fermentation or marinating), reducing the water activity (drying or salt-curing), or adding antimicrobials; may be used in combination with heating or each other to destroy pathogens.

When multiple treatments are used in to achieve lethality or stabilization, it is referred to as the **multiple hurdle** approach. The multiple hurdle approach is often used to produce shelf-stable products.

Shelf-stability is the condition achieved when meat and poultry products can be stored under ambient temperature and humidity conditions; if the package integrity is maintained during storage, shipping, and display at retail and in the home; and the product will not spoil or become unsafe throughout the manufacturer's specified shelf-life.

In this module, the different steps establishments use to achieve product safety will be discussed, along with the types of scientific supporting documentation establishments may have to support their decision-making.

Public Health Concerns for RTE

FSIS considers any RTE product to be adulterated if it contains pathogens of public health concern, or their toxins that can cause illness in humans. There are some pathogens where any level would make the product adulterated (such as *Salmonella*, *Listeria monocytogenes* (LM) and STEC) because it would be injurious to health. *Salmonella* is considered the pathogen of concern because it has been traditionally associated with certain types of RTE products. Thermal destruction of *Salmonella* is generally considered adequate to also destroy the other pathogens of concern.

There are other pathogens like *C. perfringens* which are only a public health concern when multiplication occurs at levels that could lead to toxin formation, which in such cases would indicate that the products were prepared, packed, or held under insanitary conditions. For *C. perfringens*, FSIS generally expects establishment processes to show less than 1 log growth, while for *C. botulinum*, conditions permitting any growth are a public health concern.

Critical Control Points in RTE

After an establishment conducts a hazard analysis and identifies one or more hazards as reasonably likely to occur in their process, the establishment needs to determine how it will control those hazards to prevent, eliminate, or reduce them to an acceptable level. The establishment has the flexibility to select and develop the CCPs as it determines appropriate, provided the CCP can be supported. The **CCP is a process step or a point in the process where control can be applied in many food processes.**

Many steps are commonly recognized as CCPs in various food processing and production systems. Steps necessary to achieve lethality and stabilization are commonly CCPs that many RTE processes such as RTE roast beef, ham, and cooked poultry depend on to eliminate or control hazards. Other processes such as those for fermented dry and semi-dry sausages depend on several control steps used in conjunction with each other, which is the multiple hurdle concept.

The establishment may use a number of types of scientific documentation to support the development and justification for designating a particular step or point in the process as a CCP. For instance, many peer-reviewed journal articles support the use of antimicrobial interventions, such as organic acid rinses and hot water rinses, at certain steps in the slaughter process. Likewise, there is much scientific literature identifying cooking as a means of destroying pathogenic microorganisms and chilling as a means of preventing their growth. An establishment may provide an explanation of why a specific process step was selected and established as a CCP in a **decision-making document**.

Lethality CCP Example 1: In a record separate from the hazard analysis, the establishment has documented the following decision at the cooking step. “The beef trimmings we receive for grinding will carry a certain amount of bacteria, both spoilage (e.g., *Pseudomonas spp.*) and pathogenic organisms (e.g., *Salmonella spp.*, *E. coli* O157:H7, and *L. monocytogenes*). The amount and types of bacteria present will vary depending on the conditions at the slaughter and processing establishment from which the meat is received. Cooking is the step in processing our uncured beef patties that separates the raw material environment from the ready-to-eat environment. The raw patties move from the raw side through a continuous oven/CO₂ tunnel into the cooked product side. The oven is properly maintained and the temperature distribution is checked bimonthly. We have adopted a hold time and internal temperature for cooking our patties from the table in section 318.23 of USDA’s regulations that reduces pathogens to non-detectable levels. The destruction of microbial pathogens is a food safety concern; thus, the cooking step will be addressed as a CCP in our HACCP plan.”

Stabilization CCP Example 2: In a record separate from the hazard analysis, the establishment has documented the following decision at the chilling step. The rate of chilling for our frankfurters, wieners, and hot dogs is important. Although our products have been cooked sufficiently to destroy vegetative pathogens (e.g., *Salmonella spp.* and *E. coli* O157:H7) a low level of spores (e.g., *Clostridium spp.* and *Bacillus spp.*) will remain viable. Because of their small diameter, these products chill quickly. After cooking, the sausages are initially chilled and then moved into the holding coolers. The temperature of the sausages is reduced at a rate well within FSIS’s cooling guideline for cured products found in Appendix B Option 3. If the product does not chill at the required rate, the germination and outgrowth of microbial spores and the growth

of other microbes could occur. Thus, the rate of chilling is a food safety concern that will be addressed as a CCP in our HACCP plan.

Combination CCP Example 3: The establishment has documented the selection of CCPs as part of a beef jerky hazard analysis as demonstrated below.

Process Step	Food Safety Hazard	Likely to occur?	Basis	Preventive measures	CCP
Cooking/ Lethality	B – Vegetative Pathogens (<i>Salmonella</i> , <i>E. coli</i> O157:H7) C – None P – None	Yes	Potential outgrowth of pathogens	Apply heat treatment in marination solution to eliminate vegetative cells	Yes
Drying	B – Growth of <i>Staphylococcus aureus</i> C – None P – None	Yes	Final product is shelf-stable and does not bear a “keep refrigerated” statement	Use of dehydrator to reduce the level of free water in finished product	Yes

Supporting Documentation for Critical Limits

The establishment must determine a food safety criterion or a critical limit that must be met for each control or preventive measure associated with a CCP. The critical limit determines whether the process is under control; it separates acceptable product from unacceptable product. As stated in 9 CFR 417.1, a **critical limit** is the **maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard**. A critical limit is usually a measurement, reading, or observation such as a temperature, time, a product property such as water activity (a_w) or acidity, a chemical property such as available residual chlorine or brine concentration, or the visual presence or absence of fecal material.

Critical limits have been established for many of the CCPs that are identified for the processes that produce RTE meat and poultry products, either through regulatory requirements or through technical and scientific literature. Like with the designation of a particular step or point in the process as a CCP, the establishment may use a number of types of scientific documentation to support the development and selection of a critical limit. Such scientific supporting documentation may include FSIS regulatory requirements, FSIS Compliance Guidelines, scientific articles, challenge studies, or expert advice. Every critical limit must have supporting documentation that demonstrates it is sufficient to

eliminate, prevent or reduce the occurrence of the specific food safety hazard to an acceptable level. Establishments may evaluate several sources when determining the appropriate food safety criteria or critical limits that must be met at each CCP.

Note: Like critical limits, critical parameters in prerequisite programs or other written procedures used to prevent a food safety hazard from being reasonably likely to occur in the establishment's process must be supported. The establishment may use some of the documentation listed above to demonstrate that the critical parameters are sufficient to prevent the hazard from occurring.

A more detailed description of some of the sources establishments use to support their lethality and stabilization critical limits is provided below.

Establishing Critical Limits –FSIS Performance Standards and Targets

Before establishing critical limits at each CCP in their processes, establishments should review FSIS regulations to determine if there are any regulatory requirements which apply to their product or process. Although an establishment has flexibility in designing its food safety system, ***if there is a specific regulatory requirement that applies to the product produced, the establishment's food system must be designed to meet that regulatory requirement.***

According to 9 CFR 417.2(c)(3), establishments must design their critical limits to meet all applicable performance standards or targets.

9 CFR 417.2(c)(3)—*Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met.*

As stipulated in 9 CFR 417.2(c)(3), establishments must ensure that the critical limits they incorporate into their HACCP plan at a CCP meet any applicable target or performance standard established by FSIS for the product they produce. Establishments that produce products subject to these regulations must have critical limits that are equivalent (equal to or more restrictive) to the times and temperatures specified in the regulation unless the establishment has requested and received a regulatory waiver. The directive that provides instructions for verifying lethality and stabilization process is **FSIS Directive 7111.1, Verification Procedures for Lethality and Stabilization.**

Performance standards are quantifiable pathogen reduction levels or growth limit requirements set by FSIS for lethality and stabilization of certain products.

Targets are quantifiable pathogen reduction levels or growth limits set by establishments to produce safe products in the absence of performance standards set by FSIS. Targets are used by establishments to demonstrate that the lethality and stabilization processes achieved by their food-safety systems prevent, eliminate, or reduce pathogens to acceptable levels. Establishments can choose to use Appendix A and B developed by FSIS or to identify and support their own targets.

Waivers Establishments may submit a waiver per 9 CFR 303.1(h) to use a process that varies from a regulatory requirement, including performance standard requirements. More information about waivers can be found in FSIS Directive 5020.1, Verification Activities for the Use of New Technology in Meat and Poultry Establishment and Egg Products Plants.

For certain ready-to-eat (RTE) products, FSIS has established regulatory performance standards because they have a higher public health risk. These products have historically been associated with food borne illnesses caused by specific pathogenic bacteria or their toxins (*Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, *C. perfringens* and *C. botulinum*). For instance, there have been:

- Salmonellosis food borne illness outbreaks associated with cooked beef, roast beef, corned beef and cooked poultry products,
- Listeriosis food borne illness outbreaks associated with post lethality exposed RTE products,
- *E. coli* O157:H7 food borne illness outbreaks associated with uncured undercooked meat patties, and
- *C. perfringens* food borne illnesses associated with temperature abused RTE products.

The **lethality** performance standards require establishments to treat certain RTE products to ensure a specific **log₁₀ reduction** of *Salmonella* microorganisms. Remember from the food microbiology module, that 1-log₁₀ reduction means that the population of bacteria has been reduced by 90%. For example, a 5-log₁₀ reduction would reduce a population of 100,000 organisms to 1 organism.

Heat treatment does not need to be the sole means by which the required lethality is achieved. For products that fall under a performance standard, heat treatment must be part of the lethality treatment. For example, establishments may use a **combination** of treatments such as the application of an antimicrobial agent to raw product to achieve a partial reduction in *Salmonella* organisms followed by the heat treatment to obtain the total reduction of *Salmonella* organisms required by the lethality performance standard

Alternative Lethality is a lethality treatment, other than ones prescribed in the regulations, that an establishment uses to meet performance standards. When using an alternative lethality, the establishment should ensure that its HACCP system is validated to ensure that no viable *Salmonella* organisms remain in the finished product. More detailed information about verification of alternative lethality can be found in Directive 7111.1.

The **stabilization** performance standard requires establishments **to prevent the growth of spore-forming bacteria** that can survive cooking and can grow during cooling. Stabilization refers to the process of cooling after the cooking step. After the product is cooked, spores of *Clostridium botulinum* and *Clostridium perfringens* can germinate, becoming vegetative cells that can multiply to hazardous levels if cooling is inadequate.

- *C. botulinum* produces a toxin when it grows in the product.
- *C. perfringens* produces a toxin when it goes from the vegetative form to the spore form in the person's intestine after consumption.

C. perfringens grows faster than other spore formers, like *C. botulinum*. Limiting the growth of *C. perfringens* also limits growth of other, slower growing spore-forming bacteria.

Outbreaks have been associated with meat and poultry products when they have been held for excessive lengths of time at warm temperatures. Heat treatments that kill pathogenic microorganisms can create an ideal environment for the multiplication of spore-forming bacteria that survive cooking. In fact, they **can thrive in warm product** after competitive spoilage microorganisms have been eliminated. Because *Clostridium perfringens* can grow between 125.6°F and 80°F it is particularly important that meat and poultry products are cooled within a reasonable amount of time so that the microorganisms are not given time to grow to hazardous levels. The best control to stabilize heat treated products is **rapid cooling** to reduce the amount of time the spores have to grow into cells.

The addition of **sodium nitrite (curing)** and sodium erythorbate or ascorbate (both cure accelerators) reduce the risk because the presence of these ingredients inhibits *Clostridium* growth.

There are many RTE products that are not specifically addressed with a regulatory performance standard. Establishments must consider the food safety hazards that are reasonably likely to occur in these processes and establish steps to prevent, eliminate or reduce those hazards to an acceptable level, per 9 CFR 417.2. FSIS expects establishments to include the lethality pathogen reduction targets, and stabilization log outgrowth controls for *C. perfringens* and *C. botulinum*, in its HACCP plan or supporting documentation.

Additional support. For products without specific stabilization regulatory performance standards, FSIS recommends establishments set a target to ≤ 1 -log growth of *C. perfringens* in the product. Establishments may be able to support a target of ≤ 2 -logs growth of if sufficient support is provided. To use a process that allows ≤ 2 -logs growth, establishments should provide additional support. More detailed information about verification of additional support can be found in Directive 7111.1.

FSIS Performance Standards and Targets

If an establishment produces....	Then its lethality treatment...	Then its stabilization treatment...
<p>Cooked beef Roast beef Cooked corned beef</p>	<p>Is to achieve a 6.5-log reduction of <i>Salmonella</i>.</p> <p>NOTE: The regulations 9 CFR 318.17(a)(1) allow establishments to set targets using an alternative lethality that ensures no viable <i>Salmonella</i> organisms remain in finished product. FSIS recommends ≥ 5-log reduction as an alternative lethality if establishments have additional support (e.g., testing of raw materials or a validated intervention).</p>	<p>Is not to allow multiplication of toxigenic microorganisms such as <i>C. botulinum</i> and no more than 1-log multiplication of <i>C. perfringens</i> per 9 CFR 318.17(a)(2).</p> <p>NOTE: Establishments may submit a waiver per 9 CFR 303.1(h) to use a process that allows ≤ 2-logs growth <i>C. perfringens</i> provided there are additional controls in place to ensure safety of the product.</p>
<p>RTE uncured beef patties</p>	<p>Is to follow one of the time/temperature combinations in 9 CFR 318.23(b)(1). These time/temperature combinations achieve a 5-log lethality of <i>Salmonella</i> in the product.</p>	<p>Is not to allow multiplication of toxigenic microorganisms such as <i>C. botulinum</i> and no more than 1-log multiplication of <i>C. perfringens</i> per 9 CFR 318.23(c).</p> <p>NOTE: Establishments may submit a waiver to use a process that allows ≤ 2-logs growth of <i>C. perfringens</i>.</p>

If an establishment produces...	Then its lethality treatment...	Then its stabilization treatment...
Other RTE cooked meat products	<p>Is to determine the food safety hazards that are reasonably likely to occur in its lethality process and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2(a)(1)).</p> <p>NOTE: FSIS recommends establishments set targets to achieve a 6.5 or 5-log reduction of <i>Salmonella</i> in their process. To use a 5-log reduction, establishments should provide additional support.</p>	<p>Is to consider the food safety hazards that are reasonably likely to occur in its stabilization processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2).</p> <p>NOTE: FSIS recommends establishments set a target to ≤ 1-log or ≤ 2-logs growth of <i>C. perfringens</i> in the product. To use a process that allows ≤ 2-logs growth, establishments should provide additional support</p>
RTE shelf stable meat products	<p>Is to consider the food safety hazards that are reasonably likely to occur in its lethality processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2).</p> <p>NOTE: FSIS recommends that establishments achieve 5-log reduction of <i>Salmonella</i>, a 5-log reduction of <i>E. coli</i> and sufficient reduction of <i>Lm</i> in their process, or an alternative lethality</p>	<p>Is to consider the food safety hazards that are reasonably likely to occur in its stabilization processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2).</p> <p>NOTE: FSIS recommends establishments allow ≤ 1-log or ≤ 2-logs growth of <i>C. perfringens</i> in the product. To use a process that allows ≤ 2-logs growth, establishments should provide additional support. For shelf-stable products, establishments should limit the growth of <i>S. aureus</i> to ≤ 2.0 logs during the process, especially during the drying step and ensure no growth of <i>S. aureus</i> can occur during storage.</p>

If an establishment produces...	Then its lethality treatment...	Then its stabilization treatment...
RTE cooked poultry	Is to achieve a 7-log ₁₀ reduction of <i>Salmonella</i> or an alternative lethality to comply with 9 CFR 381.150(a)(1).	Is not to allow multiplication of toxigenic microorganisms such as <i>C. botulinum</i> and no more than 1-log ₁₀ multiplication of <i>C. perfringens</i> per 9 CFR 381.150(a)(2). NOTE: Establishments may submit a waiver to use a process that allows no more than 2-logs growth of <i>C. perfringens</i> .
RTE shelf stable poultry products	Is to achieve a 7-log ₁₀ reduction of <i>Salmonella</i> or an alternative lethality to comply with 9 CFR 381.150(a)(1). NOTE: The regulations allow establishments to set targets using an alternative lethality that ensures no viable <i>Salmonella</i> organisms remain in the finished product. FSIS recommends achieving ≥ 5-log reduction as an alternative lethality for shelf-stable products. No additional support is needed to use this alternative lethality with shelf-stable products.	Is to consider the food safety hazards that are reasonably likely to occur in its stabilization processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2). NOTE: FSIS recommends establishments allow ≤1-log or ≤ 2-logs growth of <i>C. perfringens</i> in the product. To use a process that allows ≤ 2-logs of growth, establishments should provide additional support. For shelf-stable products, establishments should limit the growth of <i>S. aureus</i> to ≤ 2.0 logs during the process, especially during the drying step and ensure no growth of <i>S. aureus</i> can occur during storage.

If an establishment produces...	Then its lethality treatment...	Then its stabilization treatment...
<p>NRTE partially cooked and char-marked meat patties, and partially cooked poultry breakfast strips</p>	<p>No lethality required, will be cooked by the consumer.</p> <p>NOTE: Establishments should ensure controls and preventative measures are in place to limit growth of <i>Salmonella</i> so that customary lethality processes (such as cooking) used by consumers will be adequate.</p>	<p>Must allow no multiplication of toxigenic microorganisms such as <i>C. botulinum</i> and no more than 1-log₁₀ multiplication of <i>C. perfringens</i> per 9 CFR 318.23(c)(1) and 9 CFR 381.150(b).</p> <p>NOTE: Establishments may submit a waiver to use a stabilization process that allows ≤ 2-logs growth of <i>C. perfringens</i> and no multiplication of <i>C. botulinum</i>.</p>
<p>Other NRTE, heat treated not fully cooked products other than partially cooked and char-marked patties and partially cooked poultry breakfast strips</p>	<p>No lethality required, will be cooked by the consumer.</p> <p>NOTE: Establishments should ensure controls and preventative measures are in place to limit growth of <i>Salmonella</i> so that customary lethality processes (such as cooking) used by consumers will be adequate to eliminate the food safety hazard.</p>	<p>Is to consider the food safety hazards that are reasonably likely to occur in its stabilization processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2).</p> <p>NOTE: FSIS recommends establishments allow ≤ 1-log or ≤ 2-logs growth of <i>C. perfringens</i> in the product. To use a process that allows ≤ 2-logs of growth, establishments should provide additional support. Establishments should also limit the growth of <i>S. aureus</i> to ≤ 2.0 logs during the process.</p>

FSIS Compliance Guidelines

FSIS has issued compliance guidelines for certain processes. They are published to provide guidance and information to the industry, especially small and very small establishments. The compliance guidelines are not regulatory requirements. Establishments may use the compliance guidelines to support the selection and development of the critical limits incorporated into their HACCP plans or critical parameters incorporated into a prerequisite program when they do not wish to use custom processes that require additional research or effort to generate the data necessary to support the critical limit or parameter. Establishments are not required to support their critical limits or parameters with the compliance guidelines. They may provide other types of data or documentation that supports the safety of their processes. Examples of FSIS compliance guidelines include:

- Appendix A - FSIS *Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A (Includes Appendix A, Time-Temperature Tables for Cooking RTE Poultry Products, and the 5-log Table),
- Compliance Guideline: Lebanon Bologna,
- Compliance Guidelines for Jerky, and
- Appendix B - FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B.

If the establishment uses an FSIS compliance guideline for selecting and establishing its CCPs and critical limits, it must have a copy of that guideline in its records to support its decision. The compliance guideline is sufficient scientific and technical supporting documentation to meet the requirement in 9 CFR 417.5(a)(2). The following are critical compliance guidelines.

Appendix A - Lethality Guideline - FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A

FSIS consolidated much of the advice for establishments regarding production of RTE products into this document by incorporating the time-temperature table for meat products (Appendix A), the 5-log Table, and the Poultry Time-Temperature Tables as scientific support for a lethality treatment. These guidelines also discuss:

- *Salmonella* contamination in RTE products may occur in the post-processing environment. In several recent cases, *Salmonella* has been associated with the addition of untreated ingredients added after the lethality step. Establishments that add ingredients after lethality should have support that each lot used is tested, treated, or otherwise processed for safety.
- During initial validation, establishments should identify all of the critical operational parameters (e.g., percent salt or fat, pH, water activity, humidity, pressure, etc.) identified in the scientific supporting documentation that may influence the effectiveness of the process. During the initial validation period, the establishment should verify that they are able to implement all of the critical operational parameters as used in the scientific support in order to ensure that the process can be successfully implemented in their own system.

If the lethality guideline/Appendix A is used as supporting documentation for the selection of CCP and critical limits, **all** the conditions of Appendix A must be addressed.

As shown below, the lethality guideline/Appendix A contains a table with two columns that have time and temperature combinations for preparing cooked beef, roast beef and cooked corned beef. These temperatures are product temperatures – minimum internal temperatures. One column of time and temperature combinations meets the performance standard by achieving a 6.5- \log_{10} reduction of *Salmonella*. The time and temperature combinations in the other column achieve a 7.0- \log_{10} reduction of *Salmonella*. These time and temperature combinations are included as a guide for establishments that want to process these beef products to exceed the required minimum 6.5- \log_{10} reduction and add an additional measure of safety. As shown in the table below, time and temperature combinations range from 130°F internal temperature for a minimum of 112 minutes to 158°F instantaneous internal temperature to achieve a 6.5- \log_{10} reduction in *Salmonella* for beef products.

Excerpt from FSIS lethality compliance guideline - Appendix A Compliance Guidelines for Meeting Lethality Performance Standards for certain Meat Products

Meat products can be prepared using one of the following time and temperature combinations. The stated temperature is the minimum that must be achieved and maintained in all parts of each piece of meat for a least the stated time. **Establishments should apply humidity when using this table or additional support should be provided for the process.**

<i>Degrees Fahrenheit</i>	<i>Degrees Centigrade</i>	<i>6.5-log₁₀ Lethality</i>	<i>7-log₁₀ Lethality</i>
130	54.4	112 min.	121 min.
131	55.0	89 min.	97 min.
132	55.6	71 min.	77 min.
133	56.1	56 min.	62 min.
134	56.7	45 min.	47 min.
135	57.2	36 min.	37 min.
136	57.8	28 min.	32 min.
137	58.4	23 min.	24 min.
138	58.9	18 min.	19 min.
139	59.5	15 min.	15 min.
140	60.0	12 min.	12 min.
141	60.6	9 min.	10 min.
142	61.1	8 min.	8 min.
143	61.7	6 min.	6 min.
144	62.2	5 min.	5 min.
145	62.8	4 min.	4 min.
146	63.3	169 sec.	182 sec.
147	63.9	134 sec.	144 sec.
148	64.4	107 sec.	115 sec.
149	65.0	85 sec.	91 sec.
150	65.6	67 sec.	72 sec.
151	66.1	54 sec.	58 sec.
152	66.7	43 sec.	46 sec.
153	67.2	34 sec.	37 sec.
154	67.8	27 sec.	29 sec.
155	68.3	22 sec.	23 sec.
156	68.9	17 sec.	19 sec.
157	69.4	14 sec.	15 sec.
158	70.0	0 sec.**	0 sec.**
159	70.6	0 sec.**	0 sec.**
160	71.1	0 sec.**	0 sec.**

** The required lethality is achieved instantly when the internal temperature of a cooked meat product reaches 158° F or above.

Other product process may use Appendix A - Although there are no specific lethality performance standards for other fully cooked meat products (such as, cooked pork with barbeque sauce) they may also be processed following the Guidance in Appendix A to achieve a 6.5 log₁₀ lethality. Therefore, establishments may use Appendix A to support their critical limits applied at the cooking or heat treatment CCPs in HACCP plans for other types of RTE meat, including pork.

Humidity in Appendix A – In addition to time and temperature, humidity is another critical factor in Appendix A, which establishments often overlook. High relative humidity during the cooking of meat or poultry is a critical parameter for ensuring the lethality of pathogens and producing RTE products. If adequate humidity is not maintained during heating, the product surface will not heat as quickly and the surface can dry out. In addition, surface drying may concentrate solutes such as sugar and salt. Bacteria can become more heat resistant as

their moisture level decreases, and increased concentrations of solutes, especially sugars, can also increase the heat resistance of bacteria. So, if the product surface dries out before the pathogens are destroyed their heat resistance increases and enhances their ability to survive heating.

Options for maintaining relative humidity in Appendix A include, for meat or poultry products of any size, when the cooking time is at least 1 hour and process temperature is above 145°F:

- Introducing steam for 50% of the cooking time but not less than 1 hour.
- Sealing the cooking unit or oven for 50% of the cooking time but not less than 1 hour.
- Introducing steam to achieve humidity at 90% for at least 25% of the cooking time or 1 hour.

The relative humidity levels suggested in Appendix A do not apply to all heat processes applied to meat and poultry products. The humidity levels only apply to heat processes that can evaporate moisture from the surface of the product, for example, large mass products like beef briskets and rounds where surface drying can occur before the destruction of the pathogen.

For some heat processes, humidity around the product is inherently maintained and does not have to be added or monitored. Such processes include, but are not limited to:

- Immersing the product in a liquid cooking medium,
- Cooking the product in a sealed, moisture impermeable bag (e.g., cook-in-bag meat or poultry),
- Applying direct heat, such as a grill, heating coil, flame, or rotisserie, which heats the surface rapidly enough to attain a lethal effect before evaporation or surface cooling occurs, and
- Using a product casing – almost all casings will prevent or inhibit moisture loss, so that the heat resistance of pathogens is not affected during the cooking process (e.g., sausages cooked in casings).

Humidity also does not need to be addressed when establishments heat meat or poultry products that are 10 pounds or more in an oven maintained at 250 °F (121 °C) or higher throughout a process achieving one of the time/temperature combinations in Appendix A or the Poultry Time-Temperature Tables.

If an establishment uses Appendix A as support, and humidity is not added during the process or maintained by the process, it needs to provide additional scientific and technical supporting documentation to demonstrate that the heat treatment adopted in its HACCP plan is effective in controlling the identified hazard.

Heating come up time - If meat or poultry products are slow cooked, the cooking come-up time (time it takes to reach the final internal temperature),

should be no more than 6 hours between 50-130°F to ensure that *S. aureus* growth is limited when establishments are using FSIS Appendix A, the 5-log Table, or the Poultry Time-Temperature Tables as scientific support for a lethality treatment. Additional support may be provided that demonstrates come up times longer than 6 hours, for example, in hams, do not result in *S. aureus* growth > 2 logs

Heating Deviations

Establishments must perform corrective actions in response to a heating deviation per 9 CFR 417.3. Appendix A addresses heating deviations such as slow come-up times and long dwell times. Depending on the circumstances, establishments may want to use a validated microbial pathogen computer modeling (MPCM) program to estimate the relative growth of pathogenic bacteria. However, establishments may want to rely upon the expertise of a processing authority to determine the severity of heating deviations and subsequent appropriate disposition of the product in question. Dwell times of greater than 6 hours in the 50°F to 130°F range are especially hazardous not only because pathogenic microorganisms have optimal conditions to grow but also because certain toxigenic bacteria like *S. aureus* can produce heat stable toxins that are not inactivated by normal re-cooking procedures.

Instantaneous Temperatures in Lethality Guideline for Cooked Poultry

The performance standard for fully cooked poultry products requires a 7.0- log₁₀ reduction in *Salmonella*. The lethality compliance guideline, in the section on poultry, contains one temperature each for cooking uncured poultry (160°F) and for cooking cured poultry (155°F) to achieve the required 7.0-log₁₀ reduction in *Salmonella*. These are final internal product temperatures. Humidity should be maintained when cooking poultry products.

Time-Temperature Tables for Cooking RTE Poultry Products

Studies have shown that there is a difference in bacterial resistance due to the type of product species. A separate section of the lethality compliance guideline, Time-Temperature Tables for Cooking Ready-To-Eat Poultry Products, contains time and temperature combinations for fully cooking chicken and turkey.

The Poultry Time-Temperature Tables, included in the lethality compliance guideline, provide establishments with time and temperature combinations that can be used to cook chicken and turkey products with 1 to 12% fat levels. These processes achieve the required 7.0-log₁₀ reduction of *Salmonella*. The time and temperature combination table for chicken and turkey that **contains 7% fat** is given below. When using the Poultry Time-Temperatures tables, establishments should consider the use of humidity.

Excerpt from Time and Temperatures for Cooking RTE Poultry

Times for given temperature, fat level, and species needed to obtain 7- log₁₀ lethality of *Salmonella**

7% Fat		
Temperature (° F)	Time for Chicken	Time for Turkey
136	71.4 min	66.3 min
137	56.8 min	54.1 min
138	45.3 min	44.2 min
139	36.2 min	36.2 min
140	29 min	29.7 min
141	23.2 min	24.4 min
142	18.7 min	20.1 min
143	15.1 min	16.6 min
144	12.2 min	13.7 min
145	9.8 min	11.3 min
146	7.9 min	9.2 min
147	6.3 min	7.5 min
148	5 min	6.1 min
149	3.9 min	4.9 min
150	3 min	3.9 min
151	2.2 min	3 min
152	1.7 min	2.3 min
153	1.3 min	1.9 min
154	1 min	1.5 min
155	49.5 sec	1.2 min
156	39.2 sec	1 min
157	31 sec	49.2 sec
158	24.5 sec	40 sec
159	19.4 sec	32.4 sec
160	15.3 sec	26.3 sec
161	12.1 sec	21.4 sec
162	9.6 sec	17.3 sec
163	< 10.0 sec	14.1 sec
164	< 10.0 sec	11.4 sec
165	< 10.0 sec	< 10.0 sec

* The required lethality is achieved instantly at the internal temperature in which the holding time is < 10 seconds. The application of relative humidity as outlined in Appendix A, if applicable, must be considered.

The nature of the product in which a microorganism is heated can affect the way the product heats and the heat resistance of the microorganism. Product attributes such as fat content, water activity (a_w) and pH, and added ingredients such as nitrite and organic acids can increase or decrease the heat resistance of microorganisms. Fat acts as an insulator that decreases the rate of heating; thus the higher the fat content, the longer it takes to get the same level of destruction of the microorganism. This fact is reflected in the time and temperature combination guidelines. The guidelines provide separate tables for various percentages of fat.

Appendix B - FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B

FSIS requires establishments that produce RTE roast beef, cooked beef and corned beef products, fully cooked, partially cooked, and char-marked meat patties, and certain partially cooked and ready-to-eat poultry products to meet the stabilization performance standards for preventing or inhibiting the growth of spore-forming bacteria contained in 9 CFR 318.17, 318.23, and 381.150.

Appendix B can be used for support for all meat and poultry product chilling processes. And as with all of the published compliance guidelines, establishments are not required to use Appendix B, establishments are free to develop or identify other scientific or technical support for chilling critical operational parameters.

Continuous cooling through the given temperature range is very important. Excessive dwell time in the range of 130° to 80°F is especially hazardous because it allows rapid growth of Clostridia. Therefore, cooling between these temperature control points should be as rapid as possible.

Appendix B has four different time and temperature combinations for cooling.

Appendix B - Option 1

The internal temperature of the product is cooled:

- from 130°F to 80°F in 1.5 hours, and
- from 80°F to 40°F in 5 hours.

This cooling option can be applied universally to all fully cooked and small mass heated-treated but not fully cooked (NRTE) meat and poultry products that are uncured or cured and that receive an initial lethality treatment that eliminates all vegetative *C. perfringens*.

With regard to partially cooked products, FSIS has specific cooling requirements for certain small mass products in its regulations. These products are partially cooked meat patties, char-marked meat patties (9 CFR 318.23(c)(1)), and partially cooked poultry breakfast strips (9 CFR 381.150(b)). The time and temperature combinations in option 1 can be applied to cool these products. However, the “come-up” time to the final heating temperature should be 1 hour or less. Because partial cooking processes may not destroy all vegetative cells of *C. botulinum*, *C. perfringens*, and *B. Cereus*, partially cooked meat and poultry products may not be safe unless the establishment accounts for the cumulative

growth of these pathogens during the heating (partial cook) and cooling steps. Because the hazard may grow during a slow “come-up” time and/or slow cooling process, the degree of hazard depends on the establishment’s time and temperature control at the heating and cooling steps.

Appendix B – Option 1 Example: An establishment’s hazard analysis identified the growth of *C. botulinum* and *C. perfringens* spores as hazards likely to occur during chilling, and therefore identified the chill step as a CCP for its Oven Roasted Chicken Breast operation. It determined that an appropriate performance standard for the chilling step is to prevent the growth of *C. botulinum* and to limit the growth of *C. perfringens* to no more than a 1-log₁₀. The establishment selected this performance standard because it is the stabilization performance standard FSIS recommends for all fully cooked RTE meat and poultry products. The establishment decides to incorporate the appropriate cooling time and temperature combinations in Appendix B to establish the chilling CCP for its Oven Roasted Chicken Breast (product cooled from 130°F to 80°F in 1.5 hours or less and from 80°F to 40°F in 5 hours or less.) The establishment places a copy of Appendix B in the supporting documentation file.

Appendix B - Option 2

Chilling of the product:

- begins within 90 minutes after the end of the cooking step.

The internal temperature of the product is cooled from:

- 120°F to 80°F in 1 hour,
- 80°F to 55°F in 5 hours, and
- chilling continues until internal temperature of the product reaches 40°F.

This option applies to:

- Fully cooked products, meat or poultry
- Products may be cured or uncured

The establishment does not need to monitor the temperature drop from 120°F to 80°F for every stabilized lot of product, if data has been gathered during initial validation and as part of ongoing verification to support the critical operational parameters of this option can be met. Conditions affecting consistent cooling include cooler load (the amount of product in the cooler), the cooler temperature and air flow rate, and the product’s size, shape and weight.

Appendix B - Cured Products - Option 3

Establishments cooling **cured** RTE products have another option. To use the third stabilization option, establishments should ensure that at least 100 ppm

nitrite is added from either a purified or natural source along with at least 250 ppm of ascorbate or erythorbate as a cure accelerator.

Products may be cooled so that the internal temperature of the product is reduced:

- from 130°F to 80°F in 5 hours, and
- from 80°F to 45°F in 10 hours (15 hours total cooling time).

This cooling method provides a narrow margin of safety. If a cooling deviation occurs, an establishment should assume that their process has exceeded the performance standard for controlling the growth of *C. perfringens* and take corrective action. The presence of the nitrite and salt, however, should ensure compliance with the performance standard for *C. botulinum*.

Note: Natural sources of nitrite are not approved as curing agents, so product containing only natural sources of nitrite such as celery powder are considered uncured for labeling purposes. Establishments using natural sources of nitrite (and ascorbate) can, however, use these ingredients as antimicrobials for the purposes of following the third stabilization option. To use the third stabilization option, establishments should ensure that at least 100 ppm nitrite is added from the natural source along with at least 250 ppm of ascorbate or erythorbate as a cure accelerator and that the type and level of ingredients has been considered safe and suitable as antimicrobial agents per FSIS Directive 7120.1, Rev. 56. See AskFSIS questions “Use of celery powder and other natural sources of nitrite as curing agents” and “Appendix B: Stabilization Option 3 for products containing celery powder and other natural sources of nitrite.”

Appendix B - Cured Products - Option 4

This process may be used for the slow cooling of fully cooked meat and poultry products cured with nitrite or salt. During cooling, the products maximum internal temperature should not remain between:

- 120°F to 40°F for more than 20 hours.

The cooling process:

- Causes a continuous drop in product temperature; or
- Controls the products temperature so that it does not stay between 120°F and 80°F for more than 2 hours

This option applies to fully cooked products formulated:

- With greater than 40 ppm of sodium nitrite and a brine concentration (salt) of 6% or more, or
- With or without nitrite, but with a maximum water activity of 0.92

The FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B also contains recommended cooling time and temperature parameters for establishments that have a waiver from the performance standard stabilization requirements to use a process that allows up to 2-logs growth of *C. perfringens* in the product or that chooses to support a target that allows up to 2-logs growth of *C. perfringens* for products that don't fall under a waiver.

Cooling Deviations

Cooling deviations are also addressed in Appendix B. A cooling deviation is a situation when the established time intervals and temperatures are not met. The recommended time and temperature combinations in the guideline incorporate a small safety margin. Therefore, a small variation in meeting a time interval or temperature value by itself may not mean that the performance standard is not met.

A part of corrective actions, establishments are required to determine the cause of all cooling deviations, no matter how small, per 9 CFR 417.3(a) and ensure measures are established to prevent recurrence. If the cause of each small cooling deviation is not identified and corrected when first noticed, the problem will likely recur and may become more severe. Repetitive deviations from the critical limits demonstrate the establishment is unable to control the process and should reassess as required by 9 CFR 417.4(b) and identify controls that can be implemented effectively. If cooling is addressed through a prerequisite programs, as part of corrective actions, establishments are required to reassess to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

In the event that a cooling deviation occurs, a validated microbial pathogen computer modeling program can be useful in assessing the severity of a cooling deviation. Unless a predictive modeling program has been validated for the meat or poultry product of interest, it is not appropriate to rely solely upon the model's results to determine the safety of foods and processing systems. An example of a predictive model that has been validated for cured and uncured meat and poultry products is the ComBase *Perfringens* Predictor.

While a validated predictive modeling program cannot provide an exact determination of the amount of Clostridial growth, it can provide a useful estimate. The more data points, such as time and temperature measurements, that are available, the more accurate the model. In addition, it is important that establishment input accurate pH and salt levels, if applicable. Product may be salvaged if the results of computer modeling can ensure product safety.

The Agency policy/guidance concerning the disposition of product for cooling deviations is listed below:

- If no more than 1 log₁₀ growth of *C. perfringens* and no *C. botulinum* growth (mean net growth ≤ 0.30 log₁₀), then the process meets the stabilization performance standard or Agency policy and the product can be released.
- If there is more than a 1 log₁₀ growth of *C. perfringens* and no *C. botulinum* growth (mean net growth ≤ 0.30 log₁₀), then product may be either:
 - Recooked or
 - Microbiologically tested (N ≥ 10) or
 - Destroyed
- If there is greater than a 1 log₁₀ growth of *C. perfringens* and > 0.30 log₁₀ increase of *C. botulinum*, then the product should be destroyed

Lethality and Stabilization Compliance Guidelines for Jerky

Meat or poultry jerky is a RTE, dried product that is generally shelf-stable (it does not require refrigeration after proper processing). In general, jerky processing includes 8 steps:

- Strip preparation, slicing or forming the meat or poultry,
- Marination,
- Interventions,
- Surface preparation,
- Heating, the lethality treatment,
- Drying, the stabilization step,
- Post-drying heat step, and
- Handling and packaging.

Heating and drying are critical steps. The purpose of the heating step is to apply a lethality treatment to kill or reduce the numbers of microorganisms, including pathogens. Drying the jerky stabilizes the final product and prevents the growth of microorganisms, especially toxigenic pathogens.

In 2003, FSIS found that some meat and poultry jerky manufacturers might not be applying adequate heat processes to destroy pathogens and produce a safe product. Some of these establishments were located in dry parts of the country such as New Mexico, and product was produced under low humidity conditions which likely led to lower reductions in pathogenic microorganisms than expected. Some producers were applying dry heat to both heat treat and dry their jerky. As previously stated, the heating temperature and relative humidity during the cooking of meat and poultry are critical parameters for ensuring the lethality of pathogens. When high humidity is absent from the heating chamber most of heat is absorbed by the moisture evaporating from the product. The surface of the product will not reach a lethal temperature until most of the moisture is gone. In addition, if adequate humidity is not maintained or applied for the sufficient amount of time during the first part heating process, the product will lose moisture, which reduces the water activity (a_w) of the product and increases the concentration of solutes in the product. The reduced a_w and increased solute concentration increases the heat resistance of bacteria, including *Salmonella*. Thus, the amount of time needed at a particular temperature to destroy *Salmonella* increases. It is crucial that the processor prevent drying of the product until a lethal time and temperature combination is attained.

FSIS also found that some jerky manufacturers were relying on the maximum moisture-protein-ratio (MPR), rather than a_w , for determining whether their process adequately dried the jerky to produce a shelf-stable product. However, a_w as measured by laboratory analysis is the more appropriate indicator to verify that the jerky is properly dried. Water activity is a better measure of available water for microbial growth than MPR. Minimizing available water by achieving a water activity a_w that inhibits the growth of microorganisms is critical for stabilizing

jerky. An MPR of 0.75:1 or less is necessary to label the product “jerky,” but it is not sufficient to ensure a safe product.

As a result of these findings, FSIS developed the “Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Plants” to provide guidance and information to small operators that manufacture jerky. The compliance guideline lists eight processing steps in the production of meat and poultry jerky. Although an establishment’s process may not include all of the steps, a lethality treatment step and drying step must be used to produce a safe product. Drying should closely follow heating. Some processors combine the heating and drying procedures into one step. In this case, it is critical that the heating step include adequate humidity to prevent the product from drying prematurely and slowing or stopping the lethality process before the jerky is dried. The lethality treatment and drying is discussed in more detail below.

Jerky hazards—The establishment needs to control, reduce, or eliminate the biological hazards identified in its hazard analysis. For meat and poultry jerky, biological hazards will most likely include the microbiological hazards from *Salmonella* spp., *L. monocytogenes*, and *S. aureus*. For beef jerky, *E. coli* O157:H7 may also be a hazard reasonably likely to occur. In recent years, several jerky products have been found to be adulterated with *Salmonella* and *E. coli* O157:H7.

Lethality treatment— Establishments may choose a number of different types of scientific documents to support the lethality time/temperature/humidity combination used in the actual process. The lethality treatment of meat jerky should achieve at least a 5.0 log₁₀ reduction of *Salmonella* spp. and should also achieve sufficient reductions in the other bacterial pathogens of public health concern, for example, at least a 5.0 log₁₀ reduction for *E. coli* O157:H7 for products containing beef as recommended in the RTE *Salmonella* Compliance Guidelines.

The lethality treatment of poultry jerky should achieve at least a 5.0 log₁₀ reduction of *Salmonella* spp. Although poultry jerky is considered to fall under the performance standard in 9 CFR 381.150, the regulation allows for the use of an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product. Research has supported that a 5.0 log₁₀ reduction in *Salmonella* is sufficient for shelf-stable products.

Establishments may use Appendix A or other FSIS compliance guidelines as support for their critical limit for the lethality treatment to ensure a safe product, or they may support their process using another type of scientific supporting documentation. It is important to note that the temperatures listed in Appendix A and the “Time-Temperature Tables” are product temperatures, not oven temperatures. Establishments may utilize published journal articles or develop customized processes that achieve an appropriate reduction of pathogens. A

number of journal articles are available showing validated processes for jerky. Whichever support they chose, establishments must implement all critical operational parameters into their process. The process must be validated; it must be based on scientific literature and supported by data showing the process can be implemented as designed in the establishment

Relative Humidity - Time and temperature alone are not sufficient for an adequate lethality process. For meat and poultry jerky, relative humidity is also a critical operational parameter. Therefore, establishments should maintain the same level of relative humidity as is used in their scientific supporting documentation.

If an establishment uses Appendix A or the Time-Temperature Tables for Cooking Ready-To-Eat Poultry Products as their scientific support than they are expected to following one of the humidity options provided. Humidity may be maintained by injecting steam or sealing the oven for 50% of the cooking or heating process time but not less than one hour, or controlling the relative humidity at 90% for the times listed in the guidelines, unless the establishment can provide additional scientific and technical documentation that the process can achieve an adequate lethality with less humidity or less time at 90% relative humidity. Note that the Appendix A humidity options to seal the oven or inject steam only apply to time/temperature combinations of 145°F for 4 minutes or above.

Note: Establishments that are located at high elevations may need to increase the amount of moisture added to the smokehouse chamber to account for lower levels of humidity in the ambient air. Processing failures in the manufacture of jerky have occurred in establishments located at high altitudes.

Establishments may use the following measures to aid in meeting the humidity parameters in Appendix A.

➤ **Seal the oven**

Close the oven dampers to provide a closed system and prevent moisture loss. This would meet the requirements of Appendix A provided that the oven remains sealed for 50% of the cooking/thermal process time and no less than 1 hour.

➤ **Add humidity**

- Place one or more shallow, wide pans of hot water in the oven to provide humidity in the system.
- Injecting steam or a fine water mist in the oven can also add humidity.

In either case, the use of a wet bulb thermometer, in addition to the dry bulb thermometer, would enable the operator to determine whether adequate humidity is being applied.

The establishment is expected to maintain the relative humidity during the lethality treatment depending upon the humidity option it is following from the guidelines. In addition, establishments using any of the options in the Appendix A guidelines are also expected to either: 1) monitor the humidity level of their ovens (for example, by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement), or 2) provide documentation that demonstrating that humidity is maintained in the ovens when the oven dampers are closed or steam is injected. An establishment should have a procedure for checking that the dampers are properly working if they are using documentation to support that the humidity is maintained in the ovens when the dampers are closed.

Note: Some establishments may not monitor humidity at the same frequency as time and temperature. It is up to establishments to support the monitoring frequency and procedure per 9 CFR 417.5 (a)(1). IPP should be aware that establishments that choose a monitoring frequency less than each batch or lot should consider how they will support product safety in the event of a deviation if documentation is not available to support batches or lots of product produced since the last monitoring check demonstrated adequate humidity.

Wet and Dry Bulb Measurements—When the heating unit does not provide a direct measurement of humidity, wet and dry bulb measurements can be used to determine relative humidity. A wet bulb thermometer can be prepared by fitting a wet, moisture-wicking cloth around a dry bulb thermometer. To maintain a wet cloth during the process, submerge an end of the cloth in some water. The cloth must stay wet during the entire cooking step and should be changed daily, especially if smoke is applied. Using a wet bulb thermometer is especially important when the facility is located at a high altitude or areas of low humidity with high evaporation rates. Relative humidity can be calculated from wet bulb and dry bulb readings. As long as proper humidity is maintained, according to the scientific support chosen, the level of pathogen reduction attained by using the lethality compliance guidelines for cooking poultry or whole beef is sufficient to produce a safe jerky product.

Drying— 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. The a_w , not MPR, is the key to determining the proper level of drying. The a_w can vary greatly at any given MPR due to the presence and level of different solutes, such as sugar and salt. Therefore, a laboratory analysis for a_w should be used to verify proper drying. For labeling purposes, the finished product must also meet the MPR product standard.

A water activity of 0.85 or lower in the finished product should control the growth of *S. aureus* and any other pathogen of concern, as well as mold. Establishments that establish a maximum a_w of 0.85 in the finished product as the critical limit at the drying step may use the jerky guidelines to support their decision. Vacuum packaging product in an oxygen impervious film creates an anaerobic environment where no oxygen is present, which adds an additional degree of safety. In these cases the water activity critical limit could be 0.91 or lower. These limits are based on the growth and toxin production limits for *Staphylococcus aureus* under optimal conditions with and without oxygen present (ICMSF, 1996).

Mold growth, which is more of a quality than a food safety concern, may also be controlled by using antimicrobial interventions such as modified atmospheric packaging, adding oxygen scavengers to the package, or applying antimicrobial agents such as potassium sorbate or citric acid to the surface of the dried product.

Note: Vacuum packaged products with a water activity level > 0.85 and ≤ 0.91 should be kept refrigerated once the package is opened because the product would no longer be considered shelf-stable once it is exposed to oxygen. This is mainly a concern for products that would not be consumed within a single serving as these products are not likely to be vacuum packaged by the consumer between servings. Therefore, unless the establishment has support that the product is likely to be consumed in a single serving, vacuum packaged products with a water activity in the range of > 0.85 and ≤ 0.91 should be labeled with a statement such as "Refrigerate After Opening" (as described in 9 CFR 317.2(k)).

Jerky Guideline Example 1: A very small establishment that produces poultry jerky products is in the process of developing its HACCP plan. It establishes an internal temperature of 160°F as the critical limit at the cooking CCP in its HACCP plan, which is supported by the jerky guidelines and Appendix A. The establishment is aware that premature drying of the product surface could result in inadequate destruction of pathogenic microorganisms; however, it decides not to include 90% humidity as a critical limit because the cooking unit cannot maintain that level of humidity. Instead, the establishment decides to state in the HACCP that the dampers on the smokehouse are closed during the lethality step for over one hour to seal the oven and prevent moisture loss within the chamber, which is consistent with Appendix A. It will monitor the humidity using a wet bulb thermometer during the lethality step and verify the presence of humidity in the smokehouse is maintained during at least 50% of the processing time and in no case less than one hour and record results. The functioning of the dampers will be checked as part of a smokehouse maintenance program. The establishment includes a copy of Appendix A, Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products and the Jerky Guidelines in its supporting documentation file.

Jerky Guideline Example 2: A very small establishment that produces beef jerky products identified the growth of *S. aureus* as a hazard that is reasonably likely to occur over the shelf life of the product. A maximum a_w of 0.82 is established as the critical limit at the drying step in the establishment's HACCP plan. Since this a_w is less than 0.85, it will prevent the growth of *S. aureus* during storage under aerobic condition (meaning it does not have to be vacuum packaged). At water activity < 0.93 growth of spore-formers is prevented which is why validated cooling is not needed. The establishment also addresses mold growth by using short inventory dates and is thus consistent with the Jerky Guidelines. The establishment includes a copy of the jerky guidelines in its supporting documentation file.

Multiple Hurdles

Combinations of inhibitory factors that individually are insufficient to control microorganisms can often be effective. This has sometimes been referred to as the **multiple hurdles** concept – if enough hurdles or barriers are included, bacteria will not be able to overcome the hurdles and grow. For example, certain production processes are dependent on several parameters like salt, nitrite, and possibly other additives such as ascorbate/isoascorbate.

The multiple hurdle approach is used for many fermented or shelf stable meat products. For example, a summer sausage process may involve a combination of curing chemicals such as nitrite and salt, reduced a_w due to drying, reduced pH due to fermentation, and a mild heat process. This combination of hurdles results in a safe and shelf-stable product. The interaction of these factors affects specific microorganisms and chemical reactions. Controlling the various factors and interactions maximizes the total effect and achieves shelf-stability.

Microbiological minimum or maximum limits for growth are primarily due to temperature, water activity, pH and/or the presence of preservatives. The published limits apply only when all other factors are optimal for growth of the specific microorganism. In actual practice, other conditions are not optimal, and therefore organisms will usually not be able to grow at the published minimum or maximum level of the growth-inhibiting factor. In dried meats, if more than one hurdle effect is present the effects may be added together. This is known as a **synergistic effect**, and is be more effective than the individual factors alone. In a dried fermented meat product, the growth of microorganisms varies with storage temperature, water activity, pH, presence of additives (e.g., salt, nitrite) and lack of oxygen.

Some examples:

- When the water activity is lower, the pH range at which an organism can grow is more limited.
- When the pH is lower, the water activity that limits growth will be higher.
- The presence of preservatives can affect the pH at which an organism grows.
- Growth may take longer at lower temperatures when preservatives are present.

The following are some **common factors**.

- product time/temperature profile
- water activity (a_w) When other environmental conditions are optimal, most microorganisms do not exhibit growth below 0.91 water activity, with a few relevant exceptions, notably the staphylococci and fungi. Staphylococcus aureus, a common meat pathogen, can grow as low as 0.86 a_w depending upon the other growth conditions, particularly if oxygen is present.

- pH and/or titratable acidity (% acid)
- relative humidity
- ingoing sodium nitrite concentration
- % salt/brine concentration
- Chemicals (often called preservatives, antimicrobial compounds, or antimicrobials) may be added to foods to inhibit microbial growth or to kill microorganisms. Most chemicals cause inhibition rather than inactivation. Acids and their salts (e.g., lactic acid, sodium lactate), nitrites, some phosphates, and sodium chloride (salt) are common chemicals added to meat and poultry. **Sodium nitrite** is the active curing ingredient for typical meat curing. This chemical also helps provide microbial stability, and acts as a potent antioxidant. **Salt** (sodium chloride) is another ingredient, often used in the manufacture of dried meat products. Salt exhibits many functions including suppressing microbial growth and reducing water activity. Chemical acidulants are specific acids that are added to some dried meat product formulations to lower pH. Many establishments are now adding sodium lactate/diacetate or other organic salts as an antimicrobial agent to their RTE meat or poultry products in order to meet the *Listeria* requirements. Lactate and diacetate can inhibit the growth of *C. perfringens* during cooling.

Multiple Hurdle – Lethality

Most RTE products that rely on multiple hurdles for lethality are not specifically addressed with a regulatory performance standard. As explained earlier, establishments must consider the food safety hazards that are reasonably likely to occur in these processes and establish steps to prevent, eliminate or reduce those hazards to an acceptable level, per 9 CFR 417.2. FSIS expects establishments to include the lethality pathogen reduction targets, and stabilization log outgrowth controls for *C. perfringens* and *C. botulinum*, in its HACCP plan or supporting documentation. FSIS recommends that the lethality treatment of shelf-stable meat products achieve at least a 5.0-log₁₀ reduction of *Salmonella* spp. and at least a 5.0-log₁₀ reduction for shiga toxin-producing *Escherichia coli* (*E. coli*) (STEC) for products containing beef. The lethality treatment of shelf-stable poultry products should also achieve at least a 5.0-log₁₀ reduction of *Salmonella* spp. Although poultry jerky is considered to fall under the performance standard in 9 CFR 381.150 (i.e., a 7.0-log₁₀ reduction of *Salmonella* spp.), the regulation allows for the use of an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product. Research has supported that a 5.0-log₁₀ reduction in *Salmonella* is sufficient for such shelf-stable products. For most shelf-stable products, the pH (≤ 4.6) or water activity (0.93) preclude the growth of the primary hazards of concern (i.e., *Clostridium perfringens* and *Clostridium botulinum*).

For lethality treatments, however, it is not sufficient for establishments to demonstrate certain factors such as low water activity or pH are met to prohibit

the growth of biological hazards like *Salmonella*. As previously explained, the establishment should identify and support the lethality pathogen reduction targets (e.g., 5-log reduction of *Salmonella*) its multiple hurdles will achieve.,

Multiple Hurdles Example: Lebanon bologna is a semi-dry sausage, and this process is a typical example of the multiple hurdles concept. The multiple hurdles for Lebanon bologna are fermentation and low temperature heating. There are several critical operational parameters that affect the efficacy of these hurdles. In order for a process that relies on fermentation and low temperature heating as lethality steps to demonstrate food safety – these parameters (at the levels found in the scientific support) should be followed:

Fermentation temperature/heating come up time, and hold time and temperature for a low temperature heat step – The temperature that the product is heated to, and the amount of time the product is held at this temperature, are critical to ensuring that adequate lethality is achieved.

1. **Differences in equipment** (e.g., smokehouses and ovens) used in the processing of Lebanon bologna can influence the effectiveness of the process and, in particular, the speed of fermentation or acidification and heating.
2. **Relative humidity** is an important parameter in all dried meat processes. A relatively high humidity is preferred to keep the product surface moist during the fermentation and intermediate heating steps, prior to drying. Controlling humidity prevents premature and uneven drying at the surface and also shortens the time it takes for the product core to reach the desired temperature.
3. **pH and time to reach target pH** – Semi-dry sausage products like Lebanon bologna are usually fermented to a pH of between 4.4 - 4.6. The establishment should be fermenting its product to the pH that is recommended in the support documents. In addition to the pH level itself, the time it takes the product to reach the desired pH is also important. If a product takes too long to reach the desired pH, the acid resistance and pathogenicity of *E. coli* O157:H7 and *Salmonella* may increase. In addition, these conditions may favor *Staphylococcus aureus* growth and enterotoxin production.
4. The **starter culture** used in the product should be similar in composition to that used in the support, to ensure that fermentation is achieved, and the rate of pH drop is as expected.
5. **Product Characteristics** –
 - a. **Casing diameter** - Product casing size and shape are critical operational parameters in fermented, semi-dry processes because they affect heat transfer. It is important that the diameter of the

product used in the establishment's process is the same or smaller than that of the product used in the supporting documentation. If the diameter of the establishment's product is larger, it is possible that the product core will take longer to reach the desired temperature and pH, and a lower level of pathogen reduction would be achieved.

- b. **Product formulation** – Product formulation plays a role in the fermentation process and in the heat transfer during the intermediate heating step. Product formulation also may affect microbial resistance to acid or heat. The establishment should have an understanding of the critical operational parameters associated with the product formulation (e.g., % salt, moisture level, nitrite or any other preservatives, and % fat) and should ensure that the material used in the supporting documentation is similar to their product with respect to those critical operational parameters.
- c. **Casing** – The casing influences moisture exchange. Products with impermeable, semi-permeable, or permeable casings exchange moisture with the environment differently and can, therefore, influence the rate of product acidification, the penetration of heat into the interior of the product, and the maximum internal temperature reached by the product.

Published Industry Processing Guidelines

In 1994, a food borne illnesses outbreak occurred due to the consumption of fermented dry-cured salami contaminated with *E. coli* O157:H7. Up until this point in time, the industry and FSIS believed that the addition of cure and salt to the raw meat ingredients, competitive exclusion, the reduction in pH from the fermentation process, and the subsequent drying of sausage products would be sufficient to prevent, eliminate, or reduce *E. coli* O157:H7 to an acceptable level. Shortly after the outbreak, FSIS held a series of meetings with a number of associations representing the fermented sausage industry. The objective of the meetings was to share information regarding the outbreak of *E. coli* O157:H7 illnesses attributed to the consumption of fermented sausage product and work cooperatively to develop preventive measures aimed at preventing future outbreaks. As a result of these meetings, industry representatives and FSIS agreed that manufacturers of dry and semi-dry fermented sausages would ensure that their processes destroyed *E. coli* O157:H7.

In 1996, a group called the **Blue Ribbon Task Force** of the National Cattlemen's Beef Association, consisting of scientists from FSIS, ARS, academia, and industry issued a report, "Dry Fermented Sausage and *E. coli* O157:H7," that identified several **options that would ensure a 5-log₁₀ reduction *E. coli***

O157:H7 in dry and semi-dry fermented sausages. These processes involve various combinations of fermentation temperature, pH at the end of fermentation, holding times and temperatures based on the diameter of the casing, cooking or heating and drying. Many establishments continue to follow these recommendations and you may see this report used as supporting documentation. These options include:

- **Utilize a heating step** as described in 9 CFR 318.17 or 318.23.

Currently, heating after fermentation in accordance with FSIS compliance guidelines or FSIS regulations is the only procedure accepted without additional support for destroying *E. coli* O157:H7.

- **Apply a validated heat treatment of equal lethality**, i.e., achieves a 5-log₁₀ reduction of *E. coli* O157:H7 only (does not apply to *Salmonella*).

Including a mild heat treatment (a kill step) into the process (above 125°F for a sufficient duration) after fermentation is an effective means of assuring the destruction of *E. coli* O157:H7.

- **Apply a validated minimum 5- log₁₀ reduction** or process that results in a level of *E. coli* O157:H7 in the final product below 1 cfu/100 gram.

The establishment's process may include a combination of antimicrobial interventions (such as competitive exclusion, pH, holding time and temperature, and drying) that collectively demonstrates a 5-log₁₀ reduction of *E. coli* O157:H7 or that the level of *E. coli* O157:H7 in the finished product is below 1 cfu/100 gram of product.

- **Sample raw ingredients** to demonstrate that there is less than one *E. coli* O157:H7 organism per 100g **and apply a 2-log₁₀ lethality treatment.**

Since fully cooking fermented sausages changes product characteristics such as flavor, distinction between lean and fat particles, and firmness, an establishment may prefer this option.

GMPs for Fermented Dry and Semi-Dry Sausage Products

Degree-hour Limit—Establishments that produce dry and semi-dry fermented sausages may use another industry processing guideline titled “Good Manufacturing Practices (GMP) for Fermented Dry and Semi-dry Sausage Products” developed by the American Meat Institute Foundation to support decisions in their HACCP plan. In addition to providing information on the 5 options for controlling *E. coli* O157:H7, it establishes a GMP for time and temperature (**degree-hour limit**) control for fermentation and direct acidulation.

To control the growth of *E. coli* O157:H7 and the growth and enterotoxin production by *Staphylococcus aureus*, it is important to reach a pH of 5.3 or lower as fast as possible during fermentation or direct acidification. Staphylococci can begin to grow at a temperature of 60°F or above. Therefore, while obtaining the pH of 5.3 or less, it is important to limit the time at which the sausage is above 60°F. This is the concept of degree-hours – the number of hours at a temperature above 60°F multiplied by the number of degrees above that temperature. A process is acceptable if the product reaches pH 5.3 within a certain number of degree-hours. Processes attaining a temperature less than 90°F before reaching pH 5.3 are limited to 1200 degree-hours. Processes reaching a temperature of 90°F-100°F prior to reaching pH 5.3 are limited to 1000 degree-hours. Processes exceeding 100°F before reaching pH 5.3 are limited to 900 degree hours.

NOTE: Meeting degree-limits does not ensure any specific log reduction in *E. coli* O157:H7. Therefore, establishments need additional support for the log reduction achieved by the fermentation if it is used as part of a multi-hurdle lethality treatment.

Calculating the Degree Hour Limit Example: An establishment ferments a batch of pepperoni at a constant chamber temperature of 80°F for a total of 55 hours which achieves a pH ≤ 5.3. The following table is derived from the GMP for Fermented Dry and Semi-dry Sausage Products guideline.

Maximum Temperature	Maximum Degree Hours
< 90°F	1200
90°F to 100°F	1000
> 100°F	900

Step 1: 80 (chamber temp.) – 60 (Staph growth limit) = 20

Step 2: 20 x 55 (total hours) = 1100 degree hours

Step 3: Meets the < 90°F / 1200 degree-hour limit (1100 hours is less than 1200 hours) to achieve a pH ≤ 5.3

GMPs for Fermented Dry and Semi-Dry Sausage Products Example: An establishment's hazard analysis has identified the growth of pathogens such as *Salmonella*, *E. coli* O157:H7 and *Staphylococcus aureus* as biological hazards being likely to occur during fermentation, and therefore has identified the fermentation step as a CCP for its RTE pepperoni product. It has established the following critical limit at the fermentation step in its HACCP plan "a pH ≤ 5.3 achieved by using a fermentation chamber temperature and time that meet the degree-hour limit documented in the GMP guidelines". The establishment maintains a copy of the *Good Manufacturing Practices (GMP) for Fermented Dry and Semi-dry Sausage Products* guidelines in its HACCP file.

Inspection Verification

FSIS Directive 7111.1 contains detailed instructions for verifying lethality and stabilization processes. Inspection program personnel should use the Hazard Analysis Verification task to verify that establishments have:

- Identified supporting documentation for their process (particularly the lethality and stabilization CCPs and critical limits),
- Identified support that demonstrates the expected level of bacterial pathogen reduction,
- Identified the critical operational parameters from the support that are relevant to the process,
- Implemented the critical operational parameters into the process, either as a CCP or as a prerequisite program, and
- Gathered data demonstrating the effectiveness of the implementation of the critical operational parameters (validation).

Inspection program personnel should use the HACCP Verification task to verify that establishments are effectively implementing the CCPs and prerequisite programs, and are meeting the critical limits.

Summary

In this module we discussed the importance of cooking (lethality) and cooling (stabilization) CCPs and critical limits. We discussed the use of multiple hurdles in food safety systems, such as Lebanon bologna, that depend on a combination of parameters to ensure safety. We reviewed FSIS regulatory requirements that apply to lethality and stabilization, and reviewed the key compliance guidelines that you should be familiar with. We reviewed your inspection verification responsibility to ensure that establishments provide support for the design of their CCPs and critical limits, and that they implement all critical operational parameters.

5. In each scenario below, determine whether the establishment can use the FSIS lethality compliance guideline (Appendix A) to support its critical limits for meeting the lethality performance standard.
 - a. The establishment cooks cured beef briskets in a sealed, moisture impermeable bag to an internal temperature of 145°F for 4 minutes.
 - b. The establishment cooks oven roasted turkey breast to an internal temperature of 150°F for 72 seconds in an oven that has steam continuously injected for 50% of the cooking time but not less than 1 hour.
 - c. The establishment roasts beef rounds to an internal temperature of 158°F in a smokehouse that is sealed for 50% of the cooking time but not less than 1 hour.
 - d. The establishment smokes RTE boneless hams of about 8 lbs. in a smokehouse to an internal temperature of 171°F.
6. An establishment produces cooked corned beef products, a cured product formulated with at least 100 ppm sodium nitrite. It has the following critical limits listed in the HACCP plan at the chilling CCP: cool the product's internal temperature from 130°F to 80°F in 4 hours and from 80°F to 45°F in 14 hours. Can the establishment use FSIS stabilization compliance guideline (Appendix B) option 3 to support its critical limits? Why or why not?

Resources

American Meat Institute Foundation. 1997. Good Manufacturing Practices for Fermented Dry and Semi-Dry Sausage Products. (The Degree-Hour Concept)
http://www.aamp.com/documents/AMIF_degreehours.pdf

Dry Fermented Sausage and E. coli O157:H7, Blue Ribbon Task Force, National Cattlemen's Association (The Five Options)
http://www.beefissuesquarterly.com/CMDocs/BeefResearch/Safety_Meeting_Exec_Summaries/1996_dry_fermented_sausage.pdf

ICMSF (International Commission on Microbiological Specifications for Foods). 1996. *Microorganisms in Foods 5. Characteristics of Microbial Pathogens*. Blackie Academic & Professional, London.

Appendix A - Lethality Compliance Guideline - FSIS *Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A
<https://www.fsis.usda.gov/wps/wcm/connect/bf3f01a1-a0b7-4902-a2df-a87c73d1b633/Salmonella-Compliance-Guideline-SVSP-RTE-Appendix-A.pdf?MOD=AJPERES>

Appendix B - Stabilization Compliance Guideline - FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B
<https://www.fsis.usda.gov/wps/wcm/connect/9ac49aba-46bc-443c-856b-59a3f51b924f/Compliance-Guideline-Stabilization-Appendix-B.pdf?MOD=AJPERES>

Jerky Compliance Guidelines and Information
<https://www.fsis.usda.gov/wps/wcm/connect/5fd4a01d-a381-4134-8b91-99617e56a90a/Compliance-Guideline-Jerky-2014.pdf?MOD=AJPERES>

Lebanon Bologna Compliance Guideline
http://www.fsis.usda.gov/wps/wcm/connect/d5be2be1-3c57-45f6-af53-e71393eaaeb6/Compliance_Guideline_Lebanon_Bologna.pdf?MOD=AJPERES

Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products
http://www.fsis.usda.gov/wps/wcm/connect/8dd0f238-08d7-4ca0-a31a-77fa3ca8acf6/C-17_New_Technology_FY2004_Final_Report.pdf?MOD=AJPERES

Performance Standards for the Production of Certain Meat and Poultry Products
Docket No. 95-033F

<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F.pdf>

Pathogen Modeling Programs

USDA ARS Pathogen Modeling Program Online:

<https://pmp.errc.ars.usda.gov/PMPOne.aspx>

USDA ARS Pathogen Modeling Program Version 7.0 and 6.1 versions:

<https://www.ars.usda.gov/northeast-area/wyndmoor-pa/eastern-regional-research-center/residue-chemistry-and-predictive-microbiology-research/docs/pathogen-modeling-program/pathogen-modeling-program-models/>

UK IFR ComBase Perfringens Predictor Model:

<http://www.ifr.ac.uk/safety/growthpredictor/>

Regulations

Sec. 417.2(c)(3) Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met.

Sec. 417.5(a)(1) and (2) Supporting Documentation - (a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

- (1) The written hazard analysis prescribed in Sec. 417.2(a) of this part, including all supporting documentation;
- (2) The written HACCP plan, including decision-making documents associated with the selection and development of CCPs and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

Sec. 318.17 Requirements for the production of cooked beef, roast beef, and cooked corned beef products.

(a) Cooked beef, roast beef, and cooked corned beef products must be produced using processes ensuring that the products meet the following performance standards:

(1) Lethality. A 6.5- \log_{10} reduction of *Salmonella* or an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product, as well as the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration, must be demonstrated to be achieved throughout the product. The lethality process must include a cooking step. Controlled intermediate step(s) applied to raw product may form part of the basis for the equivalency.

(2) Stabilization. There can be no multiplication of toxigenic microorganisms such as *Clostridium botulinum*, and no more than 1- \log_{10} multiplication of *Clostridium perfringens* within the product.

Sec. 318.23 Heat-processing and stabilization requirements for uncured meat patties.

(a) Definitions. For purposes of this section, the following definitions shall apply:

- (1) Patty. A shaped and formed, comminuted, flattened cake of meat food product.
- (2) Comminuted. A processing term describing the reduction in size of pieces of meat, including chopping, flaking, grinding, or mincing, but not including chunking or sectioning.
- (3) Partially-cooked patties. Meat patties that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.
- (4) Char-marked patties. Meat patties that have been marked by a heat source and that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.

(b) Heat-processing procedures for fully-cooked patties. (1) Official establishments which manufacture fully-cooked patties shall use one of the following heat-processing procedures:

Permitted Heat-Processing Temperature/Time Combinations for Fully-Cooked Patties

Minimum internal temperature at the center of each patty (Degrees)		Minimum holding time after required internal temperature is reached (Time)	
Fahrenheit	Or centigrade	Minutes	Or seconds
151.....	66.1.....	.68	41
152.....	66.7.....	.54	32
153.....	67.2.....	.43	26
154.....	67.8.....	.34	20
155.....	68.3.....	.27	16
156.....	68.9.....	.22	13
157 (and up).....	69.4 (and up)	.17	10

(2) The official establishment shall measure the holding time and temperature of at least one fully-cooked patty from each production line each hour of production to assure control of the heat process. The temperature measuring device shall be accurate within 1 degree F.

(3) Requirements for handling heating deviations. (i) If for any reason a heating deviation has occurred, the official establishment shall investigate and identify the cause; take steps to assure that the deviation will not recur; and place on file in the official establishment, available to any duly authorized FSIS program employee, a report of the investigation, the cause of the deviation, and the steps taken to prevent recurrence.

(ii) In addition, in the case of a heating deviation, the official establishment may reprocess the affected product, using one of the methods in paragraph (b)(1) in this section; use the affected product as an ingredient in another product processed to one of the temperature and time combinations in paragraph (b)(1) in this section, provided this does not violate the final product's standard of composition, upset the order of predominance of ingredients, or perceptibly affect the normal product characteristics; or relabel the affected product as a partially-cooked patty product, if it meets the stabilization requirements in paragraph (c) of this section.

(c) Stabilization. (1) Fully cooked, partially cooked, and char-marked meat patties must be produced using processes ensuring no multiplication of toxigenic microorganisms such as *Clostridium botulinum*, and no more than a 1 log₁₀ multiplication of *Clostridium perfringens*, within the product.

(2) For each meat patty product produced using a stabilization process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file, available to FSIS, a process schedule, as defined in Sec. 301.2 of this chapter. Each process schedule must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to an establishment in order to evaluate and approve the safety and efficacy of each process schedule.

(3) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

(4) Partially cooked patties must bear the labeling statement "Partially cooked: For Safety Cook Until Well Done (Internal Meat Temperature 160 degrees F.)." The labeling statement must be adjacent to the product name, and prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to

be read and understood by the ordinary individual under customary conditions of purchase and use.

(5) Char-marked patties must bear the labeling statement "Uncooked, Char-marked: For Safety, Cook Until Well Done (Internal Meat Temperature 160 degrees F)." The labeling statement shall be adjacent to the product name, at least one-half the size of the largest letter in the product name, and prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Sec. 381.150 Requirements for the production of fully cooked poultry products and partially cooked poultry breakfast strips.

(a) Fully cooked poultry products must be produced using processes ensuring that the products meet the following performance standards:

(1) Lethality. A 7- \log_{10} reduction of *Salmonella* or an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product, as well as the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration, must be demonstrated to be achieved throughout the product. The lethality process must include a cooking step. Controlled intermediate step(s) applied to raw product may form part of the basis for the equivalency.

(2) Stabilization. There can be no multiplication of toxigenic microorganisms such as *Clostridium botulinum*, and no more than a 1 \log_{10} multiplication of *Clostridium perfringens* within the product.

(b) Partially cooked poultry breakfast strips must be produced using processes ensuring that the products meet the performance standard listed in paragraph (a)(2) of this section. Labeling for these products must comply with Sec. 381.125. In addition, the statement "Partially Cooked: For Safety, Cook Until Well Done" must appear on the principal display panel in letters no smaller than 1/2 the size of the largest letter in the product name. Detailed cooking instructions shall be provided on the immediate container of the products.

(c) For each product produced using a process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file, available to FSIS, a process schedule, as defined in Sec. 381.1

(b). Each process schedule must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to an establishment in order to evaluate and approve the safety and efficacy of each process schedule.

(d) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.