UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

7111.1
Revision 1

6/22/17

VERIFICATION PROCEDURES FOR LETHALITY AND STABILIZATION

I. PURPOSE

This directive provides inspection program personnel (IPP) with instructions for verifying lethality and stabilization processes at establishments that make ready-to-eat (RTE) meat and poultry products. It also covers the stabilization processes in establishments that make not ready-to-eat (NRTE) heat treated, not fully cooked, meat and poultry products, including but not limited to partially cooked and char-marked meat patties and partially cooked poultry breakfast strips.

This directive replaces the older versions of the lethality and stabilization directives that were last issued in 1989 and 1999. FSIS combined the two older directives into one to streamline information. FSIS has updated and revised this directive in its entirety to clarify requirements for lethality and stabilization and make it consistent with Inspection Tasks that IPP perform, as described in FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System* and FSIS Directive 5000.6, *Performance of the Hazard Analysis Verification (HAV) Task*. This directive also includes new information for verifying lethality and stabilization processes during fermentation/acidification, salt-curing, and drying and for evaluating heating and cooling deviations. Lastly, this directive provides instructions for supervisory personnel in Section X assisting IPP to verify establishment's lethality and stabilization procedures as described in FSIS Directive 5000.1 and FSIS Directive 5000.6.

II. BACKGROUND

A. Lethality is the process or combination of processes that ensures that no *Salmonella* organisms remain in the finished product, as well as reduces other pathogens and their toxins or toxic metabolites. FSIS has requirements for the specific log reductions of *Salmonella* that must be achieved in RTE cooked beef, roast beef, and cooked corned beef products (9 CFR 318.17(a)(1)) and fully cooked poultry products (9 CFR 381.150(a)(1)) to ensure that no *Salmonella* organisms remain in the finished product as well as recommendations for alternative lethalities that achieve an equivalent probability that no *Salmonella* organisms remain in the finished product. Examples of lethality processes include cooking, fermentation, salt-curing, and drying. The most commonly used scientific support for cooking are the process tables previously found in FSIS Appendix A Compliance Guidelines for Meeting Lethality Performance Standards for certain Meat and Poultry Products. FSIS has now included the process tables from Appendix A in the revised *FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce RTE Products and Revised Appendix A*. In order for a meat or poultry product to meet the definition of a RTE product in 9 CFR 430.1 (that is a meat or poultry product in a form that is edible without any additional preparation to achieve food safety) it must undergo a lethality treatment and, if post-lethality exposed, meet one of the three Alternative requirements in 9 CFR 430.

B. Stabilization is the process of preventing the growth of *Clostridium botulinum* (*C. botulinum*) and limiting the growth of *Clostridium perfringens* (*C. perfringens*). *C. botulinum* and *C. perfringens* form spores that may survive cooking and multiply during cooling when the conditions favor their growth. *C. botulinum* causes illness by producing toxins in the product and *C. perfringens* causes illness by producing toxins in the human intestine when high levels are consumed. FSIS has requirements to prevent the growth of *C. botulinum* and limit the growth of *C. perfringens* for RTE cooked beef, roast beef, and cooked corned beef (9 CFR 318.17(a)(2)), partially cooked and char-marked meat patties (9 CFR 318.23(c)(1)), and fully cooked poultry and partially cooked poultry breakfast strips (9 CFR 381.150(a)(2)). Establishments may submit a waiver per 9 CFR 303.1(h) from the stabilization requirements to use a

process that allows greater *C. perfringens* growth. FSIS has recommendations for the amount of *C. perfringens* growth that should occur during stabilization of other products not covered by the requirements. The most common stabilization process is the rapid cooling of heat treated meat and poultry products after cooking through the temperature range through which *C. perfringens* and *C. botulinum* spores can multiply (e.g., 130°F to 50°F). Other stabilization processes include hot-holding at temperatures at or above 130°F to ensure that vegetative cells of pathogens are eliminated and don't multiply, as well as drying and fermentation that render the product shelf-stable or safe at room temperatures by reducing the pH or water activity. Low pH (≤ 4.6) and water activity (< 0.93) also prevent *C. perfringens* and *C. botulinum* growth. The most commonly used scientific support for stabilization is the options previously found in FSIS Appendix B *Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization)*. FSIS has now included these options along with additional options for stabilization in 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*.

III. CANCELLATION

FSIS Directive 7110.3, Time/Temperature Guidelines for Cooling Heated Products, Revision 1, 1/24/89

FSIS Directive 7111.1, Performance Standards for the Production of Certain Meat and Poultry Products, 3/3/99

IV. REQUIREMENTS FOR LETHALITY AND STABILIZATION OF RTE AND NRTE MEAT AND POULTRY PRODUCTS

A. FSIS considers all RTE products to be adulterated if they contain pathogens of public health concern (depending on the type and level) 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 (21 U.S.C. 601(m)(1)) and 453(g)(1)). 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 (21 U.S.C. 601(m)(4) and 453(g)(4)). For *C. perfringens*, conditions that allow for **3-log growth or higher** are a public health concern while for *C. botulinum*, conditions permitting **any growth of vegetative cells** are a public health concern.

B. NRTE products (e.g., char-marked patties, partially cooked poultry breakfast strips, or other heat treated products) contaminated with toxins such as botulinum toxin are also considered adulterated because cooking by consumers will not destroy the toxins rendering them injurious to health (21 U.S.C. 601(m)(1)) and 453(g)(1)). In addition, if levels of growth of *C. perfringens* (i.e., ≥ 3 logs) or *C. botulinum* (i.e., > 0.30 logs) occurs during stabilization that could be of public health concern, the product would be considered adulterated because it indicates products were prepared, packed, or held under insanitary conditions (21 U.S.C. 601(m)(4) and 453(g)(4)).

C. To ensure that products are not adulterated during lethality or stabilization FSIS has developed performance standards or targets for different pathogens in RTE and NRTE products that establishments should design their Hazard Analysis and Critical Control Points (HACCP) systems to meet. According to 9 CFR 417.2(c)(3), establishments must design their critical limits to meet all applicable performance standards or targets.

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

2. **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.

D. FSIS regulations provide establishments with the flexibility to set targets to achieve a lower log reduction of *Salmonella* or allow for a higher outgrowth of *C. perfringens*, if they provide support that the process results in a safe product. IPP are to be aware that FSIS recommends that establishments achieve a 6.5 or 5-log reduction of *Salmonella* in cooked meat. To use a 5-log reduction for cooked meat products, establishments should provide additional support. The 5-log lethality for cooked meat products is the lowest level acceptable when coupled with on-going evidence of source material contamination control or a combination of treatments that achieve lethality. IPP are also to be aware that the stabilization process may allow a higher log outgrowth (e.g. 2-logs growth of *C. perfringens* rather than a 1-log growth) if the establishment provides additional sufficient support for the safety of the product.

NOTE: IPP are to be aware that risk assessments have demonstrated that achieving a 5-log reduction of *Salmonella* (instead of a 6.5-log reduction) in cooked products and allowing 2-logs outgrowth of *C. perfringens* (instead of a 1-log outgrowth) is less protective of public health. Therefore, to use these targets, establishments should provide additional support for their process as described in Section V.C. and Section V.D. below. Risk assessments have shown that for shelf-stable meat and poultry products, a 5-log reduction of *Salmonella* (instead of a 6.5-log or 7-log reduction) is sufficient therefore, no additional support is needed to use a 5-log reduction process in these products.

E. IPP are to be aware of the following related to performance standards and targets:

If an establishment produces….	**Then its lethality treatment…**	**Then its stabilization treatment…**
RTE cooked beef RTE roast beef RTE cooked corned beef	Is to achieve a 6.5-log reduction of *Salmonella* or an alternative lethality per 9 CFR 318.17(a)(1). **NOTE**: The regulations allow establishments to set targets using an alternative lethality that ensures no viable *Salmonella* 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). See Section V.C.	Is not to allow multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-log multiplication of *C. perfringens* per 9 CFR 318.17(a)(2). **NOTE**: Establishments may submit a waiver per 9 CFR 303.1(h) to use a process that allows ≤ 2-logs growth *C. perfringens*) provided there are additional controls in place to ensure safety of the product (see Section V.D) 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*.

If an establishment produces….	**Then its lethality treatment…**	**Then its stabilization treatment…**
RTE uncured beef patties	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 *Salmonella* in the product.	Is not to allow multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-log multiplication of *C. perfringens* per 9 CFR 318.23(c). **NOTE**: Establishments may submit a waiver to use a process that allows ≤ 2-logs growth of *C. perfringens*.
Other RTE cooked meat products	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)). **NOTE:** FSIS recommends establishments set targets to achieve a 6.5 or 5-log reduction of *Salmonella* in their process. To use a 5-log reduction, establishments should provide additional support (see Section V.C.).	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 set a target to ≤1-log or ≤ 2-logs growth of *C. perfringens* in the product. To use a process that allows ≤ 2-logs growth, establishments should provide additional support (see Section V.D.).
RTE shelf stable meat products	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). **NOTE:** FSIS recommends that establishments achieve 5-log reduction of *Salmonella,* a 5-log reduction of *E. coli* and sufficient reduction of *Lm* in their process or an alternative lethality as described in Section V.C.2.	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 *C. perfringens* in the product. To use a process that allows ≤ 2-logs growth, establishments should provide additional support (see Section V.D). For shelf-stable products, establishments should limit the growth of *S. aureus* to ≤ 2.0 logs during the process, especially during the drying step and ensure no growth of *S. aureus* can occur during storage.
RTE cooked poultry	Is to achieve a 7-$\log_{10}$ reduction of *Salmonella* or an alternative lethality to comply with 9 CFR 381.150(a)(1).	Is not to allow multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-$\log_{10}$ multiplication of *C. perfringens* 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 *C. perfringens*.

If an establishment produces….	Then its lethality treatment…	Then its stabilization treatment…
RTE shelf stable poultry products	Is to achieve a 7-$\log_{10}$ reduction of *Salmonella* 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 *Salmonella* 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 as described in Section V.C.2.	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 *C. perfringens* in the product. To use a process that allows ≤ 2-logs of growth, establishments should provide additional support (see Section V.D.). For shelf-stable products, establishments should limit the growth of *S. aureus* to ≤ 2.0 logs during the process, especially during the drying step and ensure no growth of *S. aureus* can occur during storage.
NRTE partially cooked and char-marked meat patties, and partially cooked poultry breakfast strips	No lethality required, will be cooked by the consumer. **NOTE:** Establishments should ensure controls and preventative measures are in place to limit growth of *Salmonella* so that customary lethality processes (such as cooking) used by consumers will be adequate.	Must allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-$\log_{10}$ multiplication of *C. perfringens* per 9 CFR 318.23(c)(1) and 9 CFR 381.150(b). **NOTE:** Establishments may submit a waiver to use a stabilization process that allows ≤ 2-logs growth of *C. perfringens* and no multiplication of *C. botulinum*.
NRTE, heat treated not fully cooked products other than partially cooked and char-marked patties and partially cooked poultry breakfast strips	No lethality required, will be cooked by the consumer. **NOTE:** Establishments should ensure controls and preventative measures are in place to limit growth of *Salmonella* so that customary lethality processes (such as cooking) used by consumers will be adequate to eliminate the food safety hazard.	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 *C. perfringens* in the product. To use a process that allows ≤ 2-logs of growth, establishments should provide additional support (see Section V.D.). Establishments should also limit the growth of *S. aureus* to ≤ 2.0 logs during the process.

V. PERFORMING A HACCP VERIFICATION TASK IN ESTABLISHMENTS THAT ACHIEVE LETHALITY BY COOKING AND STABILIZATION BY COOLING OR HOT HOLDING

A. IPP are to verify the implementation of the HACCP plan following the instructions in FSIS Directive 5000.1 *Verifying an Establishment's Food Safety System*. In addition, IPP are to use the HACCP Verification Task Table in FSIS Directive 10,240.4, *Verification Activities for the Listeria monocytogenes (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program,* when performing a HACCP Verification Task for a RTE product. The table in FSIS Directive 10,240.4 provides step by step instructions to supplement the instructions in FSIS Directive 5000.1. Additional instructions are also provided below for verifying cooking and cooling procedures that supplement the instructions in FSIS Directive 5000.1.

B. When verifying an establishment's cooking and cooling processes, IPP are to perform recordkeeping and review and observation components to verify that the establishment is effectively implementing, in particular, the lethality and stabilization procedures set out in its HACCP system. As part of the recordkeeping and review component, IPP are to:

1. For lethality, verify that establishment has included the performance standard or pathogen reduction targets it will meet as part of its HACCP plan or supporting documentation;

2. For stabilization, verify that the establishment has included the log outgrowth of *C. perfringens* (e.g., 1- or 2-logs growth) and *C. botulinum* (e.g., no multiplication defined as ≤ 0.3 log growth) that it will allow in the product as part of its HACCP plan or supporting documentation; and

3. For lethality and stabilization, issue a Noncompliance Record (NR) for not supporting decisions in the hazard analysis (HA) (9 CFR 417.5(a)(1)) if the establishment has not included the target or performance standard and cannot support that its process achieves an adequate log reduction or controls growth of pathogens.

NOTE: If an establishment uses Appendix A or B as the support for its process, or cooks beef patties according to 9 CFR 318.23, it does not need to indicate the specific log reduction that its process achieves. It would be sufficient for the establishment to indicate that it uses one of these documents as the scientific support for its HACCP system.

C. During cooking, if the establishment chooses to achieve a 5-log reduction of *Salmonella* as described in the table in Section IV.D., IPP are to consider the following when verifying the establishment's support for its lethality treatment:

1. The establishment should provide support (e.g., Letters of Guarantee (LOG), Certificates of Analysis (COAs), or sampling information) for each lot demonstrating that levels of *Salmonella* were low enough to be controlled by a process achieving 5-log reduction with an appropriate safety margin (e.g. 2-logs). For example, an establishment may provide a LOG indicating that a certain log reduction (e.g. 1.5 or 2-logs) is achieved in the source materials through the use of a validated antimicrobial intervention; or

2. For shelf stable products, the establishment uses a combination of factors to achieve at least a 5-log reduction (e.g., treatment of source materials, marinating in low pH marinade, heat treatment, drying, and High Pressure Processing (HPP)). For example, if an establishment can support that treating the source materials achieves a 2-log reduction of *Salmonella*, marinating achieves a 2-log reduction, and drying achieves another 2-log reduction, it would be able to support the safety of the product; or

3. The establishment conducts a baseline study on the raw source material. The baseline study should be designed such that the establishment can demonstrate, with reasonable confidence, that less than 0.01% of the raw, formulated product contains concentrations > 10 Colony Forming Units (CFU)/gram of *Salmonella* before cooking. This is based on the premise that a 5-log lethality step would reduce a *Salmonella* level of < 10 CFU/gram to < 1 CFU/ 100 grams and provide a 2-log margin of safety. Consequently, the establishment should plan to collect about 10 samples per week (e.g., 500 samples per year). In addition, once the baseline is complete, the establishment should collect at least as many verification samples over a year as it did in its baseline study to ensure the ongoing effectiveness of the program.

   NOTE: IPP are to be aware that when designing the baseline study, establishments should consider seasonality of *Salmonella* contamination. Establishments should consult references to determine the optimal study design. For example, if the proportion of screen-test positive samples is less than 10%, then the establishment should increase the dataset size in order to obtain a sufficient number of screen-test positive samples that can be enumerated for *Salmonella*.

D. During cooling, if the establishment chooses to allow 2-logs outgrowth of C*. perfringens* as described in the table in Section IV.D., IPP are to consider the following when verifying the establishment's support for its stabilization treatment:

1. The establishment has support that it tests or treats the raw materials to reduce *C. perfringens* spores. This documentation should address the spore levels in the raw formulated product (not just the meat or poultry component) prior to cooking/heating; or

2. The establishment conducts a baseline study on the raw source material. This documentation should address the spore levels in the raw formulated product (not just the meat or poultry component) prior to cooking/heating. IPP are to be aware that FSIS recommends that the establishment design the baseline study such that the establishment can demonstrate, with reasonable confidence, that less than 0.01% of the raw, formulated product contains concentrations of *C. perfringens* spores > 100 CFU/gram before cooking. Such a study will likely entail collection of at least 500 observations based upon 10% of samples testing positive for *C. perfringens* spores. In addition, once the baseline is complete, the establishment would need to collect at least as many verification samples over a year as it did in its baseline study to ensure the ongoing effectiveness of the program. IPP are to verify that the establishment has support for the design of its study, and is collecting samples as described in its study.

E. For cooking or cooling, if IPP identify that the establishment is using the results of a computer-based pathogen modeling program and/or sampling to demonstrate product safety when verifying corrective action requirements for a deviation or an unforeseen hazard as instructed in FSIS Directive 5000.1, Chapter III, Part III.B.7, he or she are to follow the instructions in Section IX to evaluate the establishment's documentation.

NOTE: IPP are to be aware that FSIS recommends that establishments use pathogen-modeling programs that have been validated for the product and process in question, compare the results of several models if the models have not been validated, conduct modeling using at least 5 time/temperature data points, conduct modeling based on the worst-case scenario, and input accurate pH and salt concentrations into the model (if required by the model).

F. For cooking or cooling, IPP are to verify that the establishment implements corrective actions whenever inspection findings or establishment records (e.g. monitoring records) indicate that a deviation from a critical limit occurred, following the instructions in FSIS Directive III.B.7.e. As part of the verification, IPP are to determine whether the deviation represents a onetime occurrence or a trend. If IPP identify that the

deviation from the critical limit is part of a trend, he or she is to determine whether the corrective actions, to identify and eliminate the cause of the deviation (9 CFR 417.3(a)(1)), have been effective. Continual or repetitive deviations from the critical limit demonstrate that the establishment is unable to control its process and therefore, it should reassess as required by 9 CFR 417.4(b) and identify controls that can be implemented effectively. Continual or repetitive deviations may also result in the determination of an inadequate HACCP system (9 CFR 417.6).

G. For cooling, in the event of an unforeseen hazard related to a procedure that is addressed through a prerequisite program, IPP are to review the data to determine whether the unforeseen hazard represents a onetime occurrence or a trend. If the deviation represents a trend, IPP are to evaluate whether the establishment can continue to support the decision that hazards are not reasonably likely to occur on an ongoing basis. An establishment may not be able to continue to support its decisions in its HA that pathogens are not reasonably likely to occur if it has continual or repetitive deviations from its prerequisite program (9 CFR 417.5(a)(1)).

H. If a RTE product sample collected by IPP tests positive for *Salmonella* or *Lm,* product in the sampled lot is considered to be adulterated. IPP are to follow the instructions in FSIS Directive 10,240.4, Chapter V, when taking enforcement actions in response to positive sampling results.

VI. PERFORMING A HAZARD ANALYSIS VERIFICATION (HAV) TASK IN ESTABLISHMENTS THAT ACHIEVE LETHALITY BY COOKING AND STABILIZATION BY COOLING OR HOT HOLDING

A. IPP are to verify lethality and stabilization of pathogens when performing the HAV task as described in FSIS Directive 5000.6. Additional instructions are also provided below to specifically address cooking and cooling procedures that supplement the instructions in FSIS Directive 5000.6.

B. When reviewing the establishment's validation, IPP are to verify that the establishment has scientific support for its lethality and stabilization steps. IPP are to be aware of the following during this step:

1. It is common for establishments to use the information in Appendix A and Appendix B to support their cooking (lethality) and cooling (stabilization) processes, respectively. When establishments use Appendix A and B or other scientific support, IPP are to verify that the establishment is following all of the critical operational parameters in its supporting documentation. If IPP find that the establishment has not followed all of the critical operational parameters in its scientific support, they are to issue a NR for not supporting the decisions in the HA (9 CFR 417.5(a)(1));

2. Humidity is a critical operational parameter for most cooking processes, including for pork and poultry. Therefore, if IPP find that establishments have not included humidity as part of their cooking process (as one of the critical limits of a CCP or a prerequisite program), and have not provided support for why humidity would not be needed in the process, then IPP are to issue a NR for not supporting the decisions in the HA (9 CFR 417.5(a)(1)); and

3. As previously stated, FSIS regulations require establishments design their critical limits to meet performance standards or targets. If an establishment chooses to achieve a lower log reduction (e.g., 5-logs of *Salmonella*) in its process during cooking or allow higher outgrowth during cooling (e.g., 2-logs growth of *C. perfringens)*, it would need to provide support for the safety of its process as described in V.C.& D. above.

C. IPP are to review the following table and follow the verification instructions when performing the HAV task in establishments that stabilize products by hot-holding or that incorporate a heating step that does not achieve full lethality after an initial lethality and stabilization (e.g., applying heat to the surface of a cooled ready-to-eat product).

If an establishment…	Then IPP are to verify the following during the HAV…	When determining compliance, IPP are to be aware that…	Based on the evaluation, IPP are to take the following actions…
Stabilizes its products by hot-holding Example: Establishments that hot-hold products such as meals or stuffed meat pies that are shipped hot to retail stores.	The establishment has considered all relevant hazards (e.g., *C. perfringens* and *C. botulinum*) associated with hot-holding. In addition, IPP are to verify that the establishment has considered any hazards associated with transportation and hot holding after the product leaves the establishment, including verifying that the establishment has properly labeled the product. The establishment has supported that the hot-holding temperatures (and if applicable, holding times) will not result in excessive growth of spore-forming bacteria.	During hot-holding, a common hazard is the potential outgrowth of spore-formers such as *C. perfringens* and *C. botulinum.* According to the FSIS Stabilization Guideline, uncured cooked products may be safely held for up to 4 hours if kept above 130°F, or for an extended period if kept above 140°F. Establishments may be able to support other time and temperature combinations.	If the establishment has not considered all relevant hazards, IPP are to gather information and discuss with the FLS to determine if a noncompliance exists, and whether adulterated products may have entered commerce. It may be necessary to discuss with an Enforcement, Investigations and Analysis Officer (EIAO) or submit an askFSIS question to make this determination. If the establishment does not have support for its hot-holding temperatures, issue a NR for not supporting decisions in the HA (9 CFR 417.5(a)(1)).
Incorporates a heating step that does not achieve full lethality after an initial lethality and stabilization process (e.g., applying heat to the surface of a cooled ready-to-eat product).	The establishment has considered whether pathogens (e.g., *C. perfringens* and *C. botulinum*) are a hazard at this step. The establishment has supported that the cumulative growth of pathogens (e.g., *C. perfringens* and *C. botulinum*) across the initial stabilization (cooling) and subsequent heat treatment and stabilization (cooling) is acceptable.	If the establishment applies a full lethality treatment (e.g. according to Appendix A) during the subsequent heating step then it would only need to provide support for the second stabilization (cooling) process and would not need to consider cumulative growth across all three steps.	If the establishment has not considered all relevant hazards, IPP are to gather information and discuss with the FLS to determine if a noncompliance exists with 9 CFR 417.2(a)(1), and whether adulterated products may have entered commerce. It may be necessary to discuss with an EIAO or submit an askFSIS question to make this determination.

If an establishment…	Then IPP are to verify the following during the HAV…	When determining compliance, IPP are to be aware that…	Based on the evaluation, IPP are to take the following actions…
Incorporates a heating step that does not achieve full lethality (continued). Examples: Establishments that produce honey glazed hams or corn dogs where heat is applied to set the batter but product does not achieve lethality, or that use hot water pasteurization that just heats up the surface as a post-lethality treatment.		Pathogen modeling using a validated modeling program is commonly used to support that the cumulative growth of pathogens (e.g., *C. perfringens* and *C. botulinum*) across the initial stabilization (cooling) and subsequent heat treatment and stabilization (cooling) is acceptable.	If the establishment does not have support for its hot-holding temperatures, issue a NR for not supporting decisions in the HA (9 CFR 417.5(a)(1)).

D. When performing a HAV task, if there are concerns about a technical aspect of the scientific or technical support, IPP are to gather as much information as possible, and discuss their concerns with their immediate supervisor. Their immediate supervisor may determine that it is necessary to discuss the concerns through the supervisory chain of command, request the assistance of an EIAO, or submit a question through askFSIS.

VII. PERFORMING A HACCP VERIFICATION TASK IN ESTABLISHMENTS THAT ACHIEVE LETHALITY AND STABILIZATION BY PROCESSES SUCH AS FERMENTATION/ACIDIFICATION, SALT-CURING, AND DRYING

A. As described in Section V.A., IPP are to follow the instructions in FSIS Directive 5000.1 along with the HACCP Verification Task Table in FSIS Directive 10,240.4, when performing a HACCP Verification Task for a RTE product. Additional instructions are also provided below for verifying fermentation/acidification, salt-curing, and drying procedures that supplement the instructions in FSIS Directive 5000.1.

B. IPP are to perform recordkeeping and review and observation components to verify that the establishment is effectively implementing, in particular, the lethality and stabilization procedures set out in its HACCP system. As part of the recordkeeping and review component, IPP are to:

1. For lethality (typically achieved over multiple steps such as fermentation/acidification, salt-curing, and drying), verify that the establishment has included the overall performance standard or pathogen reduction targets in the processing steps it will meet as part of its HACCP plan or supporting documentation;

NOTE: IPP are to be aware that FSIS recommends that the lethality treatment of shelf-stable meat and poultry products achieve at least a 5.0-$\log_{10}$ reduction of *Salmonella* and STEC (in beef products) in these products and address lethality of *Lm*. Establishments that are unable to demonstrate a 5-log reduction in *Salmonella* and STEC (in beef products) also have the option of applying alternative lethalities that provide an equivalent probability of no biological hazards of concern present in the finished product. FSIS has considered *Salmonella reductions* an indicator of lethality and has indicated that establishments do not need to also demonstrate that sufficient reductions of *Lm* and STEC (in beef products) are achieved. However, research has shown that STEC and *Lm* are more resistant than *Salmonella* to fermentation and drying in these products. Therefore, if an establishment's scientific support is only based on reductions in *Salmonella* and the product tests positive for STEC or *Lm*, or is associated with an outbreak of these pathogens, then FSIS recommends that the establishment validate the effectiveness of its lethality treatment at reducing the other pathogens as part of its corrective actions. FSIS also recommends that establishments conducting new challenge studies determine the log reductions in *Salmonella* as well as STEC (in products containing beef) and *Lm*.

2. For stabilization (typically achieved over multiple steps such as fermentation/acidification, salt-curing, and drying), verify that the establishment has included the log outgrowth of *C. perfringens* (e.g., 1- or 2-logs growth) and *C. botulinum* (e.g., no multiplication defined as ≤ 0.3 log growth) that it will allow in the product as part of its HACCP plan or supporting documentation;

NOTE: IPP are to be aware that shelf-stable products typically have characteristics that preclude the growth of spore-formers (i.e., a pH ≤ 4.6 *before* cooling or water activity (a_w) <0.93 *before* cooling will prevent the growth of *C. perfringens* and *C. botulinum*).

3. For stabilization, also verify the establishment has identified the amount of growth of *S. aureus* it will allow during processing (e.g., during fermentation/acidification, salt-curing, or drying) and during storage under ambient conditions (e.g., up to 2-logs growth during processing and no growth during storage); and

4. For lethality and stabilization, issue a NR for not supporting decisions in the HA (9 CFR 417.5(a)(1)) if the establishment has not included the target or performance standard and cannot support that its process achieves an adequate log reduction or controls growth of pathogens.

C. IPP are to verify corrective action requirements as instructed in FSIS Directive 5000.1, Chapter III, Part III.B.7, for a deviation or if an unforeseen hazard related to fermentation/acidification occurs, such as a deviation from a degree-hour limit, salt-curing, or drying CCP or prerequisite program. During this verification, if IPP identify that the establishment is using the results of a computer based pathogen modeling program or sampling to demonstrate product safety he or she are to the follow the instructions in Section IX to evaluate the establishment's documentation.

VIII. PERFORMING A HAV IN ESTABLISHMENTS THAT ACHIEVE LETHALITY AND STABILIZATION BY PROCESSES SUCH AS FERMENTATION/ACIDIFICATION, SALT-CURING, AND DRYING

A. IPP are to verify lethality and stabilization of pathogens when performing the HAV task as described in FSIS Directive 5000.6. Additional instructions are also provided below to specifically address fermentation/acidification, salt-curing, and drying procedures that supplement the instructions in FSIS Directive 5000.6.

B. IPP are to review the following table and follow the verification instructions for the relevant products and production practices.

If an establishment…	Then IPP are to verify the following during the HAV…	When determining compliance, IPP are to be aware that…	Based on the evaluation, IPP are to take the following actions…
Achieves lethality by a multi-hurdle process (e.g., fermentation, salt-curing, drying). Examples: Lebanon bologna processes typically achieve lethality by a combination of fermentation, a low temperature-heat step, and drying.	The establishment has correctly classified the product as RTE or NRTE considering the standard of identity and common or usual name. The establishment has provided adequate scientific support that the lethality steps combined achieve the performance standard or target. The scientific support includes all of the critical operational parameters and the parameters match its process. The establishment has identified the performance standard or target that its process will achieve as part of its HACCP plan or prerequisite program.	IPP are to be aware that certain products such as jerky and biltong are required to be RTE because their common or usual name indicates to consumers a RTE product. IPP are to be aware that the scientific support may include FSIS compliance guidelines, journal articles, challenge studies, or results of pathogen modeling programs. Challenge studies do not have to be published or peer reviewed but they should contain equivalent detail to peer reviewed journal articles. It would not be appropriate for an establishment to rely on finished product testing alone to support that an adequate reduction in pathogens is achieved. Establishments may be able to support using critical operational parameters that are different from those in the scientific or technical support provided they have a justification supporting that the levels chosen are at least as effective as those in the scientific or technical support. Section IV.E. contains log reduction targets for each product type.	If the establishment has not correctly classified the product as RTE when it is required by common or usual name; or If the support is not similar to the process and the establishment does not have additional support or the documentation does not support adequate reduction in pathogens is achieved, IPP are to gather information and discuss with the FLS to determine if a noncompliance exists, and whether adulterated products may have entered commerce. It may be necessary to discuss with an EIAO or submit an askFSIS question to make this determination. If the establishment hasn't included the target or performance standard and cannot support that its process achieves an adequate log reduction or controls growth of pathogens, then IPP are to issue a NR for not supporting decisions in the HA (9 CFR 417.5(a)(1)).

If an establishment…	**Then IPP are to verify the following during the HAV…**	**When determining compliance, IPP are to be aware that…**	**Based on the evaluation, IPP are to take the following actions…**
Stabilizes its products by reducing the water activity, pH, or a combination of both instead of cooling. Examples: Fermented sausages, chitterlings, cooked ribs in barbeque, jerky, pork rinds	The establishment has considered whether pathogens (e.g., *C. perfringens* and *C. botulinum*) are a hazard at the fermentation, drying, salt-curing, or other step used to reduce the pH and/or water activity and can support the pH and/or water activity prohibits the growth of pathogens (e.g., *C. perfringens* and *C. botulinum*). The establishment cools their product in a timely manner although cooling does not need to be a CCP or prerequisite program.	According to the Stabilization Guideline, the growth of spore-formers is prevented in products with pH ≤ 4.6 *before* cooling and products with water activity (a_w) < 0.93 *before* cooling. Establishments may be able to support other pH and water activity values. IPP are to be aware that if an establishment uses a brine solution to lower the pH of its product that it can take time for the product to equilibrate to the pH of the brine. If a product takes too long to equilibrate, significant growth of *C. perfringens* and *C. botulinum* can occur.	If the establishment has not considered all relevant hazards or does not cool its products in a timely manner, IPP are to gather information and discuss with the FLS to determine if a noncompliance exists, and whether adulterated products may have entered commerce. It may be necessary to discuss with an EIAO or submit an askFSIS question to make this determination.
Produces a shelf-stable product by reducing water activity, pH, or a combination of both. Examples: Jerky, dehydrated meat soups, biltong	The establishment has considered whether pathogens (i.e., *S. aureus*) are a hazard in its product at the storage step and the establishment can support that no growth of *S. aureus* occurs during finished product storage.	In order to achieve a shelf-stable product, the FSIS Jerky Compliance Guideline recommends a water activity critical limit of ≤ 0.85 be targeted for products stored in oxygen containing environments such as ambient air, provided the establishment takes steps to prevent mold growth. If the product is vacuum packaged in an oxygen impervious packaging (creating an environment where no oxygen is present), then the water activity critical limit can be ≤ 0.91.	If the establishment has not considered all relevant hazards, IPP are to gather information and discuss with the FLS to determine if a noncompliance exists, and whether adulterated products may have entered commerce. It may be necessary to discuss with an EIAO or submit an askFSIS question to make this determination. If the establishment does not have support that no growth of *S. aureus* occurs during finished product storage issue a NR for not supporting decisions in the HA (9 CFR 417.5(a)(1)).

If an establishment…	Then IPP are to verify the following during the HAV…	When determining compliance, IPP are to be aware that…	Based on the evaluation, IPP are to take the following actions…
Produces a shelf-stable product by reducing water activity, pH, or a combination of both (continued)	The establishment has taken steps to address mold growth.	FSIS recommends that establishments label vacuum packaged products with a water activity in the range of > 0.85 and ≤ 0.91 with a statement such as "Refrigerate After Opening" (as described in 9 CFR 317.2(k)) unless the establishment has support that the product is single serve. IPP are to be aware that establishments may have support for other water activity limits alone or in combination with pH. IPP are to be aware that measures to prevent mold growth may include using short inventory pull dates, low pH, antimycotics, coatings, packaging, or any combination of these measures. Some yeasts and molds are beneficial (e.g., some are added to extend shelf life). However, others are not added by the establishment and cause spoilage.	If the establishment has not taken steps to address mold, IPP are to gather information and discuss with the FLS to determine if a noncompliance exists, and whether adulterated products may have entered commerce. It may be necessary to discuss with an EIAO or submit an askFSIS question to make this determination.
Adds ingredients post-lethality Examples: Pepper coated on the outside of a sausage, Hydrolyzed Vegetable Protein (HVP), cilantro, tomatoes, or other salad ingredients added to a RTE meat or poultry component	The establishment has considered all possible hazards from ingredients (e.g., pepper) added after the lethality treatment and has support for the safety of the ingredients.	Past outbreaks have occurred because contaminated ingredients have been added to the product post-lethality (for example, contaminated pepper added to a sausage product post-lethality resulted in a salmonellosis outbreak).	If the establishment has not considered all relevant hazards, IPP are to gather information and discuss with the FLS to determine if a noncompliance exists, and whether adulterated products may have entered commerce. It may be necessary to discuss with an EIAO or submit an askFSIS question to make this determination.

If an establishment…	**Then IPP are to verify the following during the HAV…**	**When determining compliance, IPP are to be aware that…**	**Based on the evaluation, IPP are to take the following actions…**
Adds ingredients post lethality (continued)	If the establishment has made a change in its process (e.g., using a new ingredient or supplier), the establishment has addressed possible hazards associated with use of the ingredient and has support for the safety of the ingredients.	In most cases, Letters of Guarantee (LOG) alone would not be sufficient to support the safety of the ingredients added to the product unless they indicate how each lot of ingredients is processed, tested or otherwise treated to ensure its safety. LOG can be used to support the safety of pre-packaged ingredients (e.g., ketchup or mustard) that have not been associated with previous recalls or outbreaks.	If the establishment does not have adequate support for the safety of the ingredients it adds post-lethality, issue a NR for not supporting decisions in the HA (9 CFR 417.5(a)(1).
Produces an acidified product that is cold filled. Acidified foods are low acid foods to which acid or acid ingredients are added to produce a final equilibrium pH of 4.6 or below. Examples: Pickled pig's feet and pickled sausages.	The establishment has considered hazards associated with the production process and there is a lethality step. If the product is shelf-stable, IPP are to also verify that the establishment considered the intended shelf life once the container is opened and labeling (i.e., "Refrigerate After Opening). Also, if the product is not hermetically sealed, IPP are to verify that in addition to pathogens (*Lm*, STEC, and *Salmonella*), the establishment has considered the growth of yeasts and molds.	IPP are to be aware that if establishments are using pH as a control for spore-formers, it is very important that the product achieves a low pH quickly and *before* cooling. IPP are also to be aware that if an establishment uses a brine solution to lower the pH of their product that it can take time for the product to equilibrate to the pH of the brine. If a product takes too long to equilibrate, significant growth of *C. perfringens* and *C. botulinum* can occur. IPP are to be aware that if mold and yeast growth is not *prevented it may over time change pH* allowing other spoilage organisms such as *Lactobacillus* to grow which over time may compromise the stability of the product.	If the establishment has not considered all relevant hazards, IPP are to gather information and discuss with the FLS to determine if a noncompliance exists, and whether adulterated products may have entered commerce. It may be necessary to discuss with an EIAO or submit an askFSIS question to make this determination. If the establishment has not considered the intended shelf life once the container is opened and labeling (i.e., "Refrigerate After Opening) issue a NR citing 317.2(k). If the establishment has not taken measures to prevent mold and yeast growth issue a NR for not supporting decisions in the HA (9 CFR 417.5(a)(1).

C. When performing a HAV task, if there are concerns about a technical aspect of the scientific or technical support, IPP are to gather as much information as possible, and discuss their concerns with their immediate supervisor. Their immediate supervisor may determine noncompliance exists or that it is necessary to discuss the concerns through the supervisory chain of command, request the assistance of an EIAO, or submit a question through askFSIS.

IX. DEVIATIONS FROM CRITICAL LIMITS AND UNFORESEEN HAZARDS

A. Heating Deviations: If a heating deviation occurs, IPP are to verify that the establishment met the requirements of 9 CFR 417.3. Heating deviations may occur for the following reasons:

1. The establishment fails to meet a time/temperature parameter in its lethality CCP for meat or poultry products;

2. The establishment fails to maintain sufficient humidity during the cooking step; or

3. Slow heating come-up time occurs due to a power outage or equipment malfunction which allows product to remain at temperatures that allow pathogen growth (50°F to 130°F") for greater than 6 hours.

B. IPP are to be aware that if the dwell time is longer than 6 hours (e.g., due to slow cooking come-up time), recooking alone may not be sufficient to ensure the safety of the product. That is because pathogen growth can occur, leading to the formation of toxins, such as *S. aureus* and *Bacillus cereus* (*B. cereus*) enterotoxins. These enterotoxins are extremely heat stable and are not inactivated by normal cooking temperatures; therefore it is not always possible to recook the product to ensure its safety.

C. In cases where the establishment fails to meet a time/temperature parameter in its lethality CCP for meat or poultry products, and the establishment chooses to recook the product, IPP are to verify that the product did not remain between 50°F to 130°F for greater than 6 hours. IPP are also to verify that the establishment supports that the cooking time and temperatures and humidity (if needed) during the recook are sufficient to achieve full lethality (e.g., the establishment follows Appendix A).

D. In cases where the deviation results in a dwell time more than 6 hours between 50°F to 130°F, IPP are to verify that the establishment recooked the product and provided additional support for the safety of the product. IPP are to verify:

1. If the establishment uses computer modeling to support the safety of its product, IPP are to verify that the establishment has used a validated model;

2. If the establishment tested the product following pathogen modeling, IPP are to verify it tested a statistically significant number of samples of the product for *Staphylococcus aureus* enterotoxin (e.g. using testing criteria from the International Commission on Microbiological Specifications for Foods (ICMSF).

E. If it has been determined the establishment shipped products that were prepared, packed, or held under insanitary conditions (21 U.S.C. 601(m)(4) and 453(g)(4)), regulatory control actions as per 9 CFR 500 may be taken. These actions will be determined by the District Office team with information provided by IPP. Additional actions taken may include: a recall of the affected product, Suspension, Notice of Intended Enforcement (NOIE), a for-cause Public Health Risk Evaluation (PHRE), and FSIS may conduct follow up sampling of products produced.

F. Cooling Deviations: If a cooling deviation occurs, IPP are to verify that the establishment met the requirements of 9 CFR 417.3. If the establishment chooses to perform computer modeling to assess the severity of a cooling deviation, IPP are to verify the pathogen modeling program has been validated for the product and process in question or the establishment has provided supporting documentation for the model chosen. IPP are to be aware that there are no validated models for *C. botulinum* or *B. cereus*, therefore, FSIS does not object to establishments relying on available models (i.e., ARS cooling model for *C. botulinum* in beef broth) as they are the best tools currently available to assess growth.

G. IPP are to be aware that establishments can release product if the results of pathogen modeling supports ≤ 1.0-$\log_{10}$ growth of *C. perfringens* and no *C. botulinum* growth (mean net growth ≤ 0.30 log). IPP are to be aware that establishments can also support release of product if the results of pathogen modeling support ≤ 2.0-$\log_{10}$ growth of *C. perfringens* and no *C. botulinum* growth (mean net growth ≤ 0.30 log) if the establishment provides additional supporting documentation to support releasing the product (for example, sampling that supports spore levels are low (≤100 cfu/g) in raw formulated products). If IPP have questions regarding the supporting documentation, he or she is to discuss the question with their supervisor and submit a question to askFSIS for assistance as needed.

H. IPP are to verify the establishment takes one of the following actions if the results of pathogen modeling shows there is more than a 1.0-$\log_{10}$ growth of *C. perfringens* and no *C. botulinum* growth (mean net growth ≤ 0.30 log) and less than 3.0-$\log_{10}$ growth of *B. cereus* and the establishment does not have support that spore levels in the product are low:

1. Recooks the product;

2. Holds the affected lot of product and microbiologically tests using a statistically based sampling plan; (In order to meet this option FSIS recommends that establishments use the l ICMSF Tables and at least a case 11 sampling plan where at least 10 samples are collected); or

3. Provide additional documentation to support product safety; or

4. Destroys the product.

NOTE: IPP are to be aware that FSIS recommends that establishments assess *B. cereus* growth only when modeling estimates *C. perfringens* growth is ≥ 3.0-log10 (and no *C. botulinum* growth) because *C. perfringens* grows faster than *B. cereus*.

I. IPP are to verify that the establishment destroys the product if there is greater than a 1.0-$\log_{10}$ growth of *C. perfringens* or other supportable stabilization target (e.g., 2-logs growth) and greater than a 0.30 log increase of *C. botulinum*.

J. If, after conducting pathogen modeling and/or sampling, the establishment decides to recook the product and it is using Appendix B as its scientific support for stabilization, IPP are to verify the following recommendations from Appendix B are met or the establishment has other scientific support for the recooking procedures:

1. All product was either immediately refrigerated after the deviation or can be immediately recooked after the deviation;

2. The recooking procedure can achieve a final internal product temperature of at least 149°F (65°C) for two minutes. Subsequent to recooking, the product is to again be cooled according to the establishment's support; and

3. When the product is to be reworked with another raw product, the recooking procedure for the combined product is to achieve a minimum internal temperature of 149°F (two minutes holding time) to address the cooling deviation. The time\temperature for the combined product should be increased further if necessary to be in accord with any other requirement relative to microbiological safety for the intended final product. The reworked product is to again be cooled to meet these same stabilization performance standards or targets.

NOTE: IPP are to be aware that the cooking recommendation to achieve a final internal product temperature of at least 149°F (65°C) for two minutes is greater than the time/temperature combination in Appendix A (i.e., 149°F for 85 seconds to achieve a 6.5-$\log_{10}$ reduction in *Salmonella* in meat products). FSIS recommends establishments recook product to a final internal product temperature of at least 149°F (65°C) for two minutes because *C. perfringens* is more heat resistant once a product has been cooked and Appendix A time/temperature parameters would not be sufficient to address the hazard without additional scientific support.

K. If it has been determined the establishment shipped products that were prepared, packed, or held under insanitary conditions (21 U.S.C. 601(m)(4) and 453(g)(4)), regulatory control actions as per 9 CFR 500 may be taken. These actions will be determined by the District Office team with information provided by the in plant team. Actions taken may include; a recall of the affected product, Suspension, Notice of Intended Enforcement (NOIE), a for-cause PHRE, and FSIS may conduct follow up sampling of products produced.

L. Other Processing Deviations: If a deviation from processing steps other than cooking and cooling occurs, IPP are to verify that the establishment met the requirements of 9 CFR 417.3. IPP are to be aware that if an establishment uses degree-hours to ensure *Staphylococcus aureus* growth is controlled during fermentation and the pH does not reach 5.3 within the time as recommended by the AMI's Good Manufacturing Practices for Fermented Sausage Products, sampling can be used to support product disposition. If IPP have questions regarding the supporting documentation, IPP are to discuss the question with their supervisor and submit a question to askFSIS for assistance as needed.

X. SUPERVISORY PERSONNEL RESPONSIBILITIES

A. Supervisors are to assist IPP in evaluating the supporting documentation that establishments provide to support product safety in the event of a deviation from a lethality or stabilization CCP or prerequisite program.

B. Supervisors are also to assist IPP in obtaining answers to their concerns and questions regarding the scientific support for the establishment's lethality or stabilization process.

C. If an establishment lacks scientific support for the lethality or stabilization of a product, supervisors are to recommend that IPP issue a NR citing noncompliance with 417.5(a)(1).

D. Supervisors are to consider all aspects of the establishment's process, including sampling history to assess the information and possible health hazard risks, contact an EIAO, or submit an askFSIS question, if necessary, to make a determination as to whether the lack of scientific support could result in product adulteration. Supervisors are to be aware that establishments may be using long standing production practices and do not have scientific support in their HA demonstrating that their process addresses *Salmonella*, STEC (in products containing beef), *Lm*, *C. perfringens*, *C. botulinum*, or *S. aureus* (in shelf-stable products). However, the combination of parameters used by the establishment may result in a safe product.

E. If a supervisor determines that the combination of parameters used by the establishment may result in an unsafe product (e.g., because FSIS sample results have been positive for *Salmonella* or *Lm*), then he or she are to recommend IPP take regulatory control action and contact the District Office (DO).

F. Supervisors are to assist IPP in verifying the establishment's response to an NR written for lack of scientific support for the lethality or stabilization procedures of a RTE product to ensure the establishment identifies adequate scientific support. When evaluating the scientific support, supervisors are to consider the following:

1. If the establishments CCPs, prerequisite programs, or other programs incorporate the limits described in the supporting documentation or if the establishment provides data or scientific principles to support the use of different critical operational parameters, then the establishment can use this scientific support and no in-plant microbiological data is needed to comply with 9 CFR 4174.(a)(1) and 9 CFR 417.5(a)(1).

2. If the establishment does not provide data or scientific principles to support the use of different critical operational parameters, and the differences in parameters are small, establishments may consider collecting in-plant microbiological data during the 90 day initial validation period to support the combination of steps achieve adequate reduction in bacterial pathogens of concern.

   For example, if an establishment producing a dried meat product identifies a journal article that matches its process, however, it intends to use a slightly lower drying temperature (e.g. 2 or 3°F lower than that used in the support) then FSIS would not object to it choosing to collect in-plant microbiological data to provide additional support for its process. In this example, the establishment could take a statistically based number of samples each day it produces the product during a 90 day calendar period and analyze the finished product for *Salmonella, E. coli* O157:H7 (for products containing beef), and *Lm*. Products could be shipped into commerce after test results on each individual lot are received because the products would be considered to meet the definition of RTE in 9 CFR 430.1 (that it is in a form that is edible without additional preparation to achieve food safety).

3. If data or scientific principles are not available to support the use of different critical operational parameters, and the differences in parameters are large, establishments should gather additional scientific support either through peer-reviewed journal articles or challenge studies and should not rely on in-plant microbiological data alone. Establishments can use the 90 day initial validation period to identify alternative scientific support (i.e., journal articles or challenge studies) provided they are gathering in plant validation data on the critical operational parameters of their process to meet the requirements of 9 CFR 417.4(a)(1). Products could be shipped into commerce during the 90 day initial validation period if each individual lot of product is tested as described in 2. above because the products would be considered to meet the definition of RTE in 9 CFR 430.1 (that it is in a form that is edible without additional preparation to achieve food safety).

G. If, at the end of 90 day validation period, the establishment has not gathered adequate scientific support, then additional enforcement or administrative actions may be warranted.

H. IPP are to be aware that as part of the response to an NR written for lack of scientific support for the lethality or stabilization, some establishments may decide to reclassify the products as NRTE. If the establishment decides to reclassify the product as NRTE, supervisors are to verify the following information:

1. There is no concern of growth of *C. botulinum* or excessive growth of *S. aureus* growth as these pathogens produce heat-stable enterotoxins that would not be destroyed by typical cooking procedures;

2. The product is not defined by a standard identity (e.g., hot dogs or barbeque) as a fully-cooked product according to 9 CFR 319 or 381 or by a common or usual name (e.g., biltong, jerky, and pate) as fully cooked. If IPP have questions about whether the product can be reclassified as NRTE they are to submit them to askFSIS;

3. The product label represents the product as one that is NRTE, requires cooking for safety, and is therefore accurate and not misleading in compliance with 9 CFR 317.8 and 381.129. For example, use of the terms "Baked" or "Broiled" on the label of a NRTE product (e.g., "baked chicken") would be false and misleading because they indicate that the product is cooked and, therefore, suggest the product is RTE;

4. The label contains validated cooking instructions. Supervisors are to be aware that the times and temperatures in FSIS guidance have not been validated for dried products (e.g., biltong);

5. The product is not categorized in a Fully-Cooked Not Shelf Stable HACCP processing category as this would not be consistent with a NRTE product; and

   NOTE: Products can receive a full lethality treatment and not be placed in the Fully Cooked-Not Shelf-Stable Category if they are considered NRTE by the establishment.

6. The establishment clearly states the intended use of the product in the flow chart or HA as required by 9 CFR 417.2(a)(2). The intended use statement should describe the customary preparation practices for the safe consumption of the product and the basis for the establishment's determination that these practices constitute customary preparation.

I. Supervisors are to contact an EIAO or submit an askFSIS question, if necessary, to make a determination as to whether the establishment's corrective actions are sufficient.

XI. DATA ANALYSIS

The Office of Policy and Program Development (OPPD) will work with the Office of Data Integration and Food Protection (ODIFP), and the Office of Public Health Science (OPHS), to track *Salmonella* positive sample results from RTE products and recalls of RTE and NRTE products associated with lethality and stabilization deviations to determine if policy updates are needed. In addition, OPPD will review askFSIS questions related to the Directive one year after its issuance to determine if policy clarification is needed.

XII. QUESTIONS

Refer questions regarding this directive to the Risk, Innovations, and Management Staff (RIMS) through askFSIS. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided.

Subject Field: Enter **Directive 7111.1**
Question Field: **Enter your question with as much detail as possible.**
Product Field: Select **General Inspection Policy** from the drop-down menu.
Category Field: Select from the drop-down menu.
Policy Arena: Select **Domestic (U.S.) Only** or **International (Import/Export)** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**

NOTE: Refer to FSIS Directive 5620.1, *Using askFSIS*, for additional information on submitting questions.

Assistant Administrator
Office of Policy and Program Development