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## Appendix A

# Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products

## Introduction

Establishments producing ready-to-eat roast beef, cooked beef and corned beef products and certain ready-to-eat poultry products are required by FSIS to meet the lethality performance standards for the reduction of Salmonella contained in §§ 318.17(a)(1) and 381.150(a)(1) of the meat and poultry inspection regulations. Further, FSIS requires meat and poultry establishments, if they are not operating under a HACCP plan, to demonstrate how their processes meet these lethality performance standards within a written process schedule validated for efficacy by a process authority (§§ 318.17(2)(b) and (c) and 381.150 (2)(c) and (d)).

To assist establishments in meeting the lethality requirements, FSIS is issuing these compliance guidelines, which are based upon the time/temperature requirements contained in previous regulations. Establishments may choose to employ these guidelines as their process schedules. FSIS considers these guidelines, if followed precisely, to be validated process schedules, since they contain processing methods already accepted by the Agency as effective.

Also within these guidelines, FSIS has provided discussion regarding disposition of product following heating deviations and advice for the development of customized procedures for meeting the lethality performance standards.

## Guidelines for Cooked Beef, Roast Beef, and Cooked Corned Beef

1. Cooked beef and roast beef, including sectioned and formed roasts, chunked and formed roasts, and cooked corned beef can be prepared using one of the following time and temperature combinations to meet either a 6.5- $\log_{10}$  or 7- $\log_{10}$  reduction of Salmonella. 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:

Minimum Internal Temperature		Minimum processing time in minutes or seconds after minimum temperature is reached	
Degrees Fahrenheit	Degrees Centigrade	6.5- $\log_{10}$ Lethality	7- $\log_{10}$ Lethality
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.**

\* Past regulations have listed the minimum processing time for roast beef cooked to 145°F as "Instantly." However, due to their large size, most of these roasts dwell at 145°F, or even at higher temperatures, for at least 4 minutes after the minimum internal temperature is reached. FSIS has revised this time/temperature table to reflect this and emphasizes that, to better ensure compliance with the performance standard, establishments should ensure a dwell time of at least 4 minutes if 145°F is the minimum internal temperature employed.

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

2. Cooked beef, including sectioned and formed roasts and chunked and formed roasts, and cooked corned beef should be moist cooked throughout the process or, in the case of roast beef or corned beef to be roasted, cooked as in paragraph (3) of this compliance guide. The moist cooking may be accomplished by placing the meat in a sealed, moisture impermeable bag, removing the excess air, and cooking; by completely immersing the meat, unbagged in water throughout the entire cooking process; or by using a sealed oven or steam injection to raise the relative humidity above 90 percent throughout the cooking process.

3. Roast beef or corned beef to be roasted can be cooked by one of the following methods:

- Heating roasts of 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 (1) above;
- Heating roasts of any size to a minimum internal temperature of 145 °F (62.8 °C) in an oven maintained at any temperature if the relative humidity of the oven is maintained either by continuously introducing steam for 50 percent of the cooking time or by use of a sealed oven for over 50 percent of the cooking time, or if the relative humidity of the oven is maintained at 90 percent or above for at least 25 percent of the total cooking time, but in no case less than 1 hour; or

- Heating roasts of any size in an oven maintained at any temperature that will satisfy the internal temperature and time combinations of the above chart of this compliance guide if the relative humidity of the oven is maintained at 90 percent or above for at least 25 percent of the total cooking time, but in no case less than 1 hour. The relative humidity may be achieved by use of steam injection or sealed ovens capable of producing and maintaining the required relative humidity.

4. Establishments producing cooked beef, roast beef, or cooked corned beef should have sufficient monitoring equipment, including recording devices, to assure that the time (accuracy assured within 1 minute), the temperature (accuracy assured within 1 °F), and relative humidity (accuracy assured within 5 percent) limits of these processes are being met. Data from the recording devices should be made available to FSIS program employees upon request.

## **Guidelines for Cooked Poultry Rolls and Other Cooked Poultry Products**

1. Cooked poultry rolls and other cooked poultry products should reach an internal temperature of at least 160 °F prior to being removed from the cooking medium, except that cured and smoked poultry rolls and other cured and smoked poultry should reach an internal temperature of at least 155 °F prior to being removed from the cooking medium. Cooked ready-to-eat product to which heat will be applied incidental to a subsequent processing procedure may be removed from the media for such processing provided that it is immediately fully cooked to the 160 °F internal temperature.

2. Establishments producing cooked poultry rolls and other cooked poultry products should have sufficient monitoring equipment, including recording devices, to assure that the temperature (accuracy assured within 1 °F) limits of these processes are being met. Data from the recording devices should be made available to FSIS program employees upon request.

## **Discussion**

### **Heating Deviations and Slow Come Up Time**

Determining the appropriate disposition of products following heating deviations can be even more difficult than determining the disposition of product after a cooling deviation. Heating deviations, which most often involve slow come-up time or an inordinate dwell time within the optimum temperature range for microorganism growth, can foster the multiplication of many pathogens. This multiplication sometimes can be so prodigious that even re-cooking may be ineffective in rendering the product safe. Also, certain toxigenic bacteria can release toxins into the product. Some of these toxins, such as those of Staphylococcus aureus, are extremely heat stable and are not inactivated by normal re-cooking temperatures.

Further, the sampling of product following a heating deviation may not yield sufficient information to determine the safety of the product in question. Heating deviations can favor the multiplication of many types of bacteria. It would be difficult and expensive to sample for all of them.

Depending on the circumstances, establishments may want to use computer modeling to estimate the relative multiplication of bacteria. For example, in a past incident involving an extreme heating deviation, product was put in an oven in which the temperature was inadvertently set to 95°F for about 12 hours. Computer modeling was easily applied in this case because much of the dwell time was at one temperature. The Agency determined that within a 6 hour time frame (with other growth conditions assumed to be favorable), the relative multiplication of many pathogens of concern could have exceeded five logs. Clearly the product could not be salvaged by reprocessing and was therefore destroyed. Under changing conditions of temperature, however, computer modeling becomes more difficult. One approach is to average lag/log times over small increments such as 5° and add these times to get an approximation of possible total relative growth over a larger increment of time. Establishments must keep in mind that the population of bacteria before processing is generally unknown and that assumptions in the high range often are used as input parameters in the modeling.

Establishments should ultimately 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 should be viewed as especially hazardous, as this temperature range can foster substantial growth of many pathogens of concern. And, a knowledge of the specific product and factors that would favor or inhibit the growth of various bacteria is essential.

## Computer Modeling Program Availability

The Microbial Food Safety Research Unit of the Eastern Regional Research Center, USDA Agriculture Research Service, has developed a bacterial pathogen modeling program. Entitled "Pathogen Modeling Program-Version 5.1 for Windows," it is available on the Internet from <http://www.arserrc.gov>. Other programs may be available commercially.

## Customized Processes

Although compliance with these guidelines will yield product that meets the lethality performance standards, some establishments may want to develop customized processing procedures that meet the codified lethality performance standards: 6.5<sub>10</sub> log of Salmonella in ready-to-eat beef products and 7 log<sub>10</sub> in ready-to-eat poultry products. Establishments also may want to develop and implement processes using alternative lethality. Keep in mind, however, that all processes also must achieve, throughout the product, an appropriate reduction of other pathogens of concern and their toxins or toxic metabolites. Establishments or their process authorities may develop customized procedures or alternative lethality that meet the performance standards by using information obtained from the literature and/or by comparing their methods with established processes. However, statistical calculations on results obtained from sampling alone are not sufficient to demonstrate that product satisfies reduced initial product conditions or that product meets the performance standards. Rather, the demonstration should be based on scientific rationale, supported by experimental data.

One of the most definitive tools at the disposal of an establishment or processing authority is the challenge study. Although challenge studies must be conducted in the laboratory rather than the establishment, they should be designed and conducted to accurately simulate the commercial process. Challenge studies should be undertaken by individuals who have a thorough knowledge of laboratory methods used in salmonellae research. A cocktail of various serotypes of Salmonella should be used in an inoculated pack study to demonstrate that the lethality performance standard is met. Relatively heat resistant pathogenic strains should be included in the cocktail to develop a worst case. The serotypes/strains selected should be among those that have been historically implicated in an appreciable



number of outbreaks.

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### For Further Information:

FSIS Technical Service Center  
106 South 15th Street  
Suite 904  
Omaha, NE 68102  
PHONE: (402) 221-7400  
FAX: (402) 221-7438

E-mail: [tech.center@usda.gov](mailto:tech.center@usda.gov)

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## Appendix B

# Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization)

## Introduction

Establishments producing ready-to-eat 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 are required by FSIS to meet the stabilization performance standards for preventing the growth of spore-forming bacteria (9 CFR §§ 318.17(a)(2), 318.23(d)(1), and 381.150(a)(2), respectively). Further, FSIS requires meat and poultry establishments, if they are not operating under a HACCP plan, to demonstrate how their processes meet these stabilization performance standards within a written process schedule validated for efficacy by a process authority (§§ 318.17(b) and (c); 318.23(d)(2) and (3); and 381.150(c) and (d)).

To assist establishments in meeting the stabilization requirements, FSIS is issuing these compliance guidelines, which are based upon FSIS Directives and the product cooling requirements contained in previous regulations. Establishments may choose to employ these guidelines as their process schedules. FSIS considers these guidelines, if followed precisely, to be validated process schedules, since they contain processing methods already accepted by the Agency as effective.

Also within these guidelines, FSIS has provided discussion regarding disposition of product following cooling deviations and advice for the development of customized procedures for meeting the stabilization performance standards.

## Stabilization Guidelines

It is very important that cooling be continuous through the given time/temperature control points. Excessive dwell time in the range of 130° to 80°F is especially hazardous, as this is the range of most rapid growth for the clostridia. Therefore cooling between these temperature control points should be as rapid as possible.

1. During cooling, the product's maximum internal temperature should not remain between 130°F and 80°F for more than 1.5 hours nor between 80°F and 40°F for more than 5 hours. This cooling rate can be applied universally to cooked products (e.g., partially cooked or fully cooked, intact or non-intact, meat or poultry) and is preferable to (2) below.

2. Over the past several years, FSIS has allowed product to be cooled according to the following procedures, which are based upon older, less precise data: chilling should begin within 90 minutes after the cooking cycle is completed. All product should be chilled from 120°F (48°C) to 55°F (12.7°C) in no more than 6 hours. Chilling should then continue until the product reaches 40°F (4.4°C); the product should not be shipped until it reaches 40°F (4.4°C).

This second cooling guideline is taken from the former ("Requirements for the production of cooked beef, roast beef, and cooked corned beef", 9 CFR 318.17(h)(10)). It yields a significantly smaller margin of safety than the first cooling guideline above, especially if the product cooled is non-intact product. If an establishment uses this older cooling guideline, it should ensure that cooling is as rapid as possible,

especially between 120 °F and 80°F, and monitor the cooling closely to prevent deviation. If product remains between 120 °F and 80 °F more than one hour, compliance with the performance standard is less certain.

3. The following process may be used for the slow cooling of ready-to-eat meat and poultry cured with nitrite. Products cured with a minimum of 100 ppm ingoing sodium nitrite may be cooled so that the maximum internal temperature is reduced from 130 to 80 °F in 5 hours and from 80 to 45 °F in 10 hours (15 hours total cooling time).

**This cooling process 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 *Clostridium perfringens* and take corrective action. The presence of the nitrite, however, should ensure compliance with the performance standard for *Clostridium botulinum*.**

Establishments that incorporate a "pasteurization" treatment after lethality and stabilization treatments (e.g., applying heat to the surface of a cooled ready-to-eat product after slicing) and then re-stabilize (cool) the product should assess the cumulative growth of *C. perfringens* in their HACCP plans. That is, the entire process should allow no more than 1-log<sub>10</sub> total growth of *C. perfringens* in the finished product. When employing a post-processing "pasteurization," establishments may want to keep in mind that at temperatures of 130 °F or greater, *C. perfringens* will not grow.

Support documentation for this process was filed by the National Food Processors Association on April 14, 1999. It is available for review in the FSIS Docket Room, Room 102, Cotton Annex, 300 12th St., SW, Washington, DC 20250-3700.

## Discussion

### Cooling Deviations

In spite of the best efforts of an establishment to maintain process control, cooling deviations will occasionally occur. Power failures or breakdowns of refrigeration equipment cause situations that cannot always be anticipated. However, it is important that the establishment plan how to cope with such eventualities before they occur.

The recommended time/temperature combinations in these guidelines incorporate a small safety margin. Therefore, an occasional small lapse in and of itself may not cause a problem in every instance. If the cause of a small cooling deviation is not traced and corrected when first noticed, however, the problem will likely recur and possibly become more frequent and more severe. The processor should consider an occasional small deviation an opportunity to find and correct a control problem. Of course, a large deviation or continual small ones will always constitute unacceptable risk.

After it is determined that a cooling deviation has occurred, the processor should:

1. Notify the inspector, the QC unit, and other concerned units, such as refrigeration maintenance and production.
2. Hold the involved product and determine the potential adulteration by bacteria, particularly clostridial pathogens. If adulteration is confirmed or appears to be likely, inform the inspector.
3. Postpone further product manufacturing using that chill facility until the processor has:
  - a. determined the cause of the deviation;
  - b. completed adjustments to assure that the deviation will not recur; and
  - c. informed the inspector and the production units of the determinations and adjustments and make any needed amendments in the written processing procedures.

### Computer modeling and sampling

In the event that a cooling deviation does occur, the product may often be salvaged if the results of computer modeling and/or sampling can ensure product safety. Because of a lack of information concerning the distribution of *C. perfringens* in product, sampling may not be the best recourse for determining the disposition of product following cooling deviations. However, computer modeling can be a

useful tool in assessing the severity of a cooling deviation. While computer modeling cannot provide an exact determination of the possible amount clostridial growth, it can provide a useful estimate. A technical document (available from the FSIS Docket Room) provides description of the calculations that are used to estimate relative growth.

With careful continuous monitoring of the heating and cooling time/temperature profile of each lot, there will always be many available data points, enhancing the accuracy of computer modeling. Conversely, when there are few documented time/temperature data points, the accuracy of the modeling decreases markedly. If time/temperature monitoring has not been conducted through the end point internal product temperatures of 40° F or less, sampling is not an option and the product should be destroyed.

### **Options after computer determination of cooling deviation severity.**

If computer modeling suggests that the cooling deviation would likely result in more than one log increase in *C. perfringens*, without any multiplication (remains in lag phase ) of *C. botulinum*, then the establishment can choose to recook or sample the product.

Recook only when:

- All product was either immediately refrigerated after the deviation or can be immediately recooked after the deviation; and
- 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 must be cooled in strict conformance to existing guidelines. When the product is to be reworked with another raw product, the recooking procedure for the combined product must achieve a minimum internal temperature of 149°F, to address the cooling deviation, and further to an increased time/temperature if necessary to be in accord with any other requirement relative to microbiological safety for the intended final product. Subsequent to recooking, the product must be cooled in strict conformance to existing guidelines.

### **Custom Stabilization Processes**

While compliance with the guidelines above will yield product that meets the cooling performance standards, some establishments may want to develop customized stabilization procedures. Because customized process schedules must be validated by process authorities for efficacy, most establishments will probably rely upon processing authorities to develop such procedures, demonstrate their efficacy, and attest to their safety. Process authorities may obtain information from the literature, or likely compare peer reviewed methods in determining safe procedures that meet the performance standards.

Probably one of the most definitive tools at the disposal of the processing authority is the inoculated pack study. Such studies should, of course, be conducted only in the laboratory, not in the plant. Further, such studies should be undertaken by individuals who have a thorough knowledge of laboratory methods used in clostridial research. *C. perfringens* can be used alone in an inoculated pack study to demonstrate that the cooling performance standard is met for both microorganisms, *C. perfringens*, and *C. botulinum*. This is because conditions of time/temperature that would limit the growth of *C. perfringens* to one log or less would also prevent multiplication of *C. botulinum*, which is much slower. A cocktail of various strains of *C. perfringens* spores is often used for this purpose. Relatively "fast" toxigenic strains should be used to develop a worst case. However, the strains selected should be among those that have been historically implicated in an appreciable number of outbreaks, especially in products similar to those being prepared in the establishment.

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#### **For Further Information:**

FSIS Technical Service Center  
106 South 15th Street  
Suite 904  
Omaha, NE 68102  
PHONE: (402) 221-7400  
FAX: (402) 221-7438  
E-mail: [tech.center@usda.gov](mailto:tech.center@usda.gov)

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