

DRAFT COMPLIANCE GUIDELINES FOR READY-TO-EAT MEAT AND POULTRY PRODUCTS

On February 27, 2001, FSIS published a proposed rule "Performance Standards for the Production of Processed Meat and Poultry Products" (66 FR 12590). The proposed regulations include lethality and stabilization performance standards, *Listeria* testing requirements, and the rescission of requirements regarding trichina in pork products. To assist establishments in understanding these requirements, FSIS is issuing draft compliance guidelines. FSIS requests comment on these guidelines. These guidelines are based on previous Agency regulations, published scientific, challenge studies and other procedures validated to achieve the performance standards. Covered RTE products include cooked, fermented, salt-cured and dried meat and poultry products.

Except for thermally-processed, commercially-sterile products, the performance standards for lethality for all ready-to-eat (RTE) products require a 6.5 log₁₀ reduction of *Salmonella* throughout finished meat products and a 7.0 log₁₀ reduction of *Salmonella* throughout finished products that contain poultry. In addition, RTE fermented products that contain beef are required to have 5 log₁₀ reduction of *E. coli* O157:H7 throughout. Except for thermally-processed, commercially-sterile products, the performance standards for stabilization require no growth of *Clostridium botulinum* and no more than 1 log₁₀ growth *Clostridium perfringens* throughout all RTE meat and poultry products.

Compliance Guidelines For Meeting Lethality Performance Standards For Cooked Ready-to-eat Meat and Poultry Products

With the 1999 final rule, "Performance Standards for the Production of Certain Meat and Poultry Products" (64 FR 732), applicable to cooked beef, roast beef, chunked and formed roasts, corned beef and poultry products, the Agency included compliance guidelines for lethality (Appendix A of the final rule). These compliance guidelines include times and temperatures to achieve a 6.5 log₁₀ and 7.0 log₁₀ reduction of *Salmonella* in meat products. For poultry products, an endpoint temperature for cooking to achieve a 7.0 log₁₀ reduction of *Salmonella* is recommended. These same compliance tables could be used for all cooked RTE meat, including RTE cooked meat patties, because the proposed lethality performance standards are the same as those already in place for other RTE products.

Similarly, the compliance guidelines for stabilization performance standards found in Appendix B of the final rule, could also be used for compliance with the proposed RTE rule. These compliance guidelines will achieve the requirement of no growth of *Clostridium botulinum* and no more than 1 log₁₀ growth *Clostridium perfringens*. The compliance guidelines in Appendix A and Appendix B of that rule are reproduced here.

GUIDELINES FOR COOKED MEAT PRODUCTS

1. Cooked beef, pork, lamb and other meat products can be prepared using one of the following time and temperature combinations to meet either a 6.5-log₁₀ or 7-log₁₀ 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:

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| 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. Moist cooking may be accomplished by: a) placing the meat in a sealed, moisture impermeable bag, removing the excess air, and cooking; b) completely immersing the meat,

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unbagged in water throughout the entire cooking process; or c) 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 should have sufficient monitoring equipment, including recording devices, to ensure 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. However, 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 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.

New Time-Temperature Combinations for Cooking RTE Poultry

An FSIS employee recently co-authored an article entitled “Modeling non-linear survival curves to calculate thermal inactivation of *Salmonella* in poultry of different fat levels” soon to be published in a scientific journal. In the article, the authors developed a formula for predicting time/temperature combinations for achieving a 7- \log_{10} reduction of *Salmonella* in RTE poultry, as well as standard errors for these predictions. The times within the new time/temperature combinations, derived using this formula, are significantly higher than those assumed to be effective and published in our current compliance guide. FSIS requests comment on these new time/temperature combinations for RTE poultry.

Times for given temperature, fat level, and species needed to obtain
7- \log_{10} lethality

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----- fat%=1 -----

| Temperature F | time for Chicken unit | . . . | time for Turkey unit |
|------------------|--------------------------|-------|-------------------------|
| 136 | 63.3 min | | 64 min |
| 137 | 50.1 min | | 51.9 min |
| 138 | 39.7 min | | 42.2 min |
| 139 | 31.6 min | | 34.4 min |
| 140 | 25.2 min | | 28.1 min |
| 141 | 20.1 min | | 23 min |
| 142 | 16.1 min | | 18.9 min |
| 143 | 13 min | | 15.5 min |
| 144 | 10.4 min | | 12.8 min |
| 145 | 8.4 min | | 10.5 min |
| 146 | 6.8 min | | 8.7 min |
| 147 | 5.5 min | | 7.1 min |
| 148 | 4.4 min | | 5.8 min |
| 149 | 3.5 min | | 4.7 min |
| 150 | 2.7 min | | 3.8 min |
| 151 | 2.1 min | | 3 min |
| 152 | 1.5 min | | 2.3 min |
| 153 | 1.2 min | | 1.8 min |
| 154 | 55.9 sec | | 1.5 min |
| 155 | 44.2 sec | | 1.2 min |
| 156 | 35 sec | | 59 sec |
| 157 | 27.7 sec | | 47.9 sec |
| 158 | 21.9 sec | | 38.8 sec |
| 159 | 17.3 sec | | 31.5 sec |
| 160 | 13.7 sec | | 25.6 sec |
| 161 | 10.8 sec | | 20.8 sec |
| 162 | <10.0 sec | | 16.9 sec |
| 163 | <10.0 sec | | 13.7 sec |
| 164 | <10.0 sec | | 11.1 sec |
| 165 | <10.0 sec | | <10.0 sec |

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

----- fat%=2 -----

| Temperature F | time for Chicken unit | time for Turkey unit |
|------------------|--------------------------|-------------------------|
| 136 | 64.5 min | 64.3 min |
| 137 | 51 min | 52.2 min |
| 138 | 40.5 min | 42.5 min |
| 139 | 32.2 min | 34.6 min |
| 140 | 25.7 min | 28.3 min |
| 141 | 20.5 min | 23.2 min |
| 142 | 16.4 min | 19 min |
| 143 | 13.2 min | 15.6 min |
| 144 | 10.6 min | 12.8 min |
| 145 | 8.6 min | 10.6 min |
| 146 | 6.9 min | 8.7 min |
| 147 | 5.5 min | 7.1 min |
| 148 | 4.4 min | 5.8 min |
| 149 | 3.5 min | 4.7 min |
| 150 | 2.7 min | 3.7 min |
| 151 | 2 min | 2.9 min |
| 152 | 1.5 min | 2.3 min |
| 153 | 1.2 min | 1.8 min |
| 154 | 56.9 sec | 1.5 min |
| 155 | 45 sec | 1.2 min |
| 156 | 35.6 sec | 59.3 sec |
| 157 | 28.2 sec | 48.1 sec |
| 158 | 22.3 sec | 39 sec |
| 159 | 17.6 sec | 31.7 sec |
| 160 | 14 sec | 25.7 sec |
| 161 | 11 sec | 20.9 sec |
| 162 | <10.0 sec | 16.9 sec |
| 163 | <10.0 sec | 13.7 sec |
| 164 | <10.0 sec | 11.2 sec |
| 165 | <10.0 sec | <10.0 sec |

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

----- fat%=3 -----

| Temperature F | time for Chicken unit | time for Turkey unit |
|------------------|--------------------------|-------------------------|
| 136 | 65.7 min | 64.6 min |
| 137 | 52.1 min | 52.4 min |
| 138 | 41.3 min | 42.7 min |
| 139 | 32.9 min | 34.9 min |
| 140 | 26.2 min | 28.5 min |
| 141 | 21 min | 23.3 min |
| 142 | 16.8 min | 19.1 min |
| 143 | 13.5 min | 15.7 min |
| 144 | 10.8 min | 12.9 min |
| 145 | 8.7 min | 10.6 min |
| 146 | 7 min | 8.7 min |
| 147 | 5.6 min | 7.1 min |
| 148 | 4.5 min | 5.8 min |
| 149 | 3.5 min | 4.7 min |
| 150 | 2.7 min | 3.7 min |
| 151 | 2 min | 2.9 min |
| 152 | 1.5 min | 2.3 min |
| 153 | 1.2 min | 1.9 min |
| 154 | 58 sec | 1.5 min |
| 155 | 45.9 sec | 1.2 min |
| 156 | 36.3 sec | 59.5 sec |
| 157 | 28.7 sec | 48.3 sec |
| 158 | 22.7 sec | 39.2 sec |
| 159 | 18 sec | 31.8 sec |
| 160 | 14.2 sec | 25.8 sec |
| 161 | 11.2 sec | 21 sec |
| 162 | <10.0 sec | 17 sec |
| 163 | <10.0 sec | 13.8 sec |
| 164 | <10.0 sec | 11.2 sec |
| 165 | <10.0 sec | <10.0 sec |

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

----- fat%=4 -----

| Temperature F | time for Chicken unit | time for Turkey unit |
|------------------|--------------------------|-------------------------|
| 136 | 67 min | 64.9 min |
| 137 | 53.2 min | 52.8 min |
| 138 | 42.2 min | 43 min |
| 139 | 33.6 min | 35.1 min |
| 140 | 26.8 min | 28.7 min |
| 141 | 21.5 min | 23.5 min |
| 142 | 17.2 min | 19.3 min |
| 143 | 13.8 min | 15.9 min |
| 144 | 11.1 min | 13 min |
| 145 | 8.9 min | 10.7 min |
| 146 | 7.2 min | 8.8 min |
| 147 | 5.7 min | 7.2 min |
| 148 | 4.5 min | 5.8 min |
| 149 | 3.6 min | 4.7 min |
| 150 | 2.7 min | 3.7 min |
| 151 | 2.1 min | 2.9 min |
| 152 | 1.6 min | 2.3 min |
| 153 | 1.2 min | 1.9 min |
| 154 | 59.1 sec | 1.5 min |
| 155 | 46.8 sec | 1.2 min |
| 156 | 37 sec | 59.8 sec |
| 157 | 29.3 sec | 48.5 sec |
| 158 | 23.2 sec | 39.4 sec |
| 159 | 18.3 sec | 32 sec |
| 160 | 14.5 sec | 26 sec |
| 161 | 11.5 sec | 21.1 sec |
| 162 | <10.0 sec | 17.1 sec |
| 163 | <10.0 sec | 13.9 sec |
| 164 | <10.0 sec | 11.3 sec |
| 165 | <10.0 sec | <10.0 sec |

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

----- fat%=5 -----

| Temperature F | time for Chicken | unit | time for Turkey | unit |
|------------------|---------------------|------|--------------------|------|
| 136 | 68.4 | min | 65.3 | min |
| 137 | 54.3 | min | 53.2 | min |
| 138 | 43.2 | min | 43.4 | min |
| 139 | 34.4 | min | 35.4 | min |
| 140 | 27.5 | min | 29 | min |
| 141 | 22 | min | 23.8 | min |
| 142 | 17.6 | min | 19.5 | min |
| 143 | 14.2 | min | 16.1 | min |
| 144 | 11.4 | min | 13.2 | min |
| 145 | 9.2 | min | 10.8 | min |
| 146 | 7.4 | min | 8.9 | min |
| 147 | 5.9 | min | 7.3 | min |
| 148 | 4.7 | min | 5.9 | min |
| 149 | 3.6 | min | 4.7 | min |
| 150 | 2.8 | min | 3.7 | min |
| 151 | 2.1 | min | 2.9 | min |
| 152 | 1.6 | min | 2.3 | min |
| 153 | 1.3 | min | 1.9 | min |
| 154 | 1 | min | 1.5 | min |
| 155 | 47.7 | sec | 1.2 | min |
| 156 | 37.7 | sec | 1 | min |
| 157 | 29.8 | sec | 48.8 | sec |
| 158 | 23.6 | sec | 39.6 | sec |
| 159 | 18.7 | sec | 32.1 | sec |
| 160 | 14.8 | sec | 26.1 | sec |
| 161 | 11.7 | sec | 21.2 | sec |
| 162 | <10.0 | sec | 17.2 | sec |
| 163 | <10.0 | sec | 13.9 | sec |
| 164 | <10.0 | sec | 11.3 | sec |
| 165 | <10.0 | sec | <10.0 | sec |

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

----- fat%=6 -----

| Temperature F | time for Chicken unit | time for Turkey unit |
|------------------|--------------------------|-------------------------|
| 136 | 69.9 min | 65.8 min |
| 137 | 55.5 min | 53.6 min |
| 138 | 44.2 min | 43.8 min |
| 139 | 35.2 min | 35.8 min |
| 140 | 28.2 min | 29.3 min |
| 141 | 22.6 min | 24.1 min |
| 142 | 18.1 min | 19.8 min |
| 143 | 14.6 min | 16.3 min |
| 144 | 11.8 min | 13.4 min |
| 145 | 9.5 min | 11 min |
| 146 | 7.6 min | 9 min |
| 147 | 6.1 min | 7.4 min |
| 148 | 4.8 min | 6 min |
| 149 | 3.8 min | 4.8 min |
| 150 | 2.9 min | 3.8 min |
| 151 | 2.1 min | 2.9 min |
| 152 | 1.6 min | 2.3 min |
| 153 | 1.3 min | 1.9 min |
| 154 | 1 min | 1.5 min |
| 155 | 48.6 sec | 1.2 min |
| 156 | 38.4 sec | 1 min |
| 157 | 30.4 sec | 49 sec |
| 158 | 24 sec | 39.8 sec |
| 159 | 19 sec | 32.3 sec |
| 160 | 15 sec | 26.2 sec |
| 161 | 11.9 sec | 21.3 sec |
| 162 | <10.0 sec | 17.3 sec |
| 163 | <10.0 sec | 14 sec |
| 164 | <10.0 sec | 11.4 sec |
| 165 | <10.0 sec | <10.0 sec |

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

----- fat%=7 -----

| Temperature F | time for Chicken unit | time for Turkey unit |
|------------------|--------------------------|-------------------------|
| 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 |

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

----- fat%=8 -----

| Temperature F | time for Chicken unit | time for Turkey unit |
|------------------|--------------------------|-------------------------|
| 136 | 73 min | 66.9 min |
| 137 | 58.2 min | 54.7 min |
| 138 | 46.4 min | 44.8 min |
| 139 | 37.2 min | 36.7 min |
| 140 | 29.8 min | 30.2 min |
| 141 | 24 min | 24.9 min |
| 142 | 19.4 min | 20.5 min |
| 143 | 15.6 min | 17 min |
| 144 | 12.6 min | 14 min |
| 145 | 10.2 min | 11.5 min |
| 146 | 8.2 min | 9.5 min |
| 147 | 6.6 min | 7.7 min |
| 148 | 5.2 min | 6.3 min |
| 149 | 4.1 min | 5 min |
| 150 | 3.1 min | 4 min |
| 151 | 2.3 min | 3.1 min |
| 152 | 1.7 min | 2.3 min |
| 153 | 1.3 min | 1.9 min |
| 154 | 1.1 min | 1.5 min |
| 155 | 50.4 sec | 1.3 min |
| 156 | 39.9 sec | 1 min |
| 157 | 31.6 sec | 49.5 sec |
| 158 | 25 sec | 40.1 sec |
| 159 | 19.8 sec | 32.6 sec |
| 160 | 15.6 sec | 26.4 sec |
| 161 | 12.4 sec | 21.5 sec |
| 162 | 9.8 sec | 17.4 sec |
| 163 | <10.0 sec | 14.1 sec |
| 164 | <10.0 sec | 11.5 sec |
| 165 | <10.0 sec | <10.0 sec |

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

----- fat%=9 -----

| Temperature F | time for Chicken unit | time for Turkey unit |
|------------------|--------------------------|-------------------------|
| 136 | 74.8 min | 67.6 min |
| 137 | 59.7 min | 55.3 min |
| 138 | 47.7 min | 45.4 min |
| 139 | 38.3 min | 37.3 min |
| 140 | 30.8 min | 30.8 min |
| 141 | 24.9 min | 25.5 min |
| 142 | 20.1 min | 21.1 min |
| 143 | 16.3 min | 17.4 min |
| 144 | 13.2 min | 14.4 min |
| 145 | 10.7 min | 11.9 min |
| 146 | 8.6 min | 9.8 min |
| 147 | 6.9 min | 8 min |
| 148 | 5.5 min | 6.5 min |
| 149 | 4.3 min | 5.2 min |
| 150 | 3.3 min | 4.1 min |
| 151 | 2.5 min | 3.2 min |
| 152 | 1.8 min | 2.4 min |
| 153 | 1.4 min | 1.9 min |
| 154 | 1.1 min | 1.5 min |
| 155 | 51.4 sec | 1.3 min |
| 156 | 40.7 sec | 1 min |
| 157 | 32.2 sec | 49.7 sec |
| 158 | 25.4 sec | 40.3 sec |
| 159 | 20.1 sec | 32.7 sec |
| 160 | 15.9 sec | 26.6 sec |
| 161 | 12.6 sec | 21.6 sec |
| 162 | 10 sec | 17.5 sec |
| 163 | <10.0 sec | 14.2 sec |
| 164 | <10.0 sec | 11.5 sec |
| 165 | <10.0 sec | <10.0 sec |

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

----- fat%=10 -----

| Temperature F | time for Chicken | unit | time for Turkey | unit |
|------------------|---------------------|------|--------------------|------|
| 136 | 76.7 | min | 68.4 | min |
| 137 | 61.4 | min | 56.2 | min |
| 138 | 49.2 | min | 46.2 | min |
| 139 | 39.6 | min | 38.1 | min |
| 140 | 32 | min | 31.5 | min |
| 141 | 25.9 | min | 26.2 | min |
| 142 | 21 | min | 21.7 | min |
| 143 | 17.1 | min | 18 | min |
| 144 | 13.9 | min | 15 | min |
| 145 | 11.3 | min | 12.4 | min |
| 146 | 9.1 | min | 10.2 | min |
| 147 | 7.4 | min | 8.4 | min |
| 148 | 5.8 | min | 6.8 | min |
| 149 | 4.6 | min | 5.4 | min |
| 150 | 3.5 | min | 4.3 | min |
| 151 | 2.6 | min | 3.3 | min |
| 152 | 1.9 | min | 2.5 | min |
| 153 | 1.4 | min | 1.9 | min |
| 154 | 1.1 | min | 1.6 | min |
| 155 | 52.4 | sec | 1.3 | min |
| 156 | 41.4 | sec | 1 | min |
| 157 | 32.8 | sec | 49.9 | sec |
| 158 | 25.9 | sec | 40.5 | sec |
| 159 | 20.5 | sec | 32.9 | sec |
| 160 | 16.2 | sec | 26.7 | sec |
| 161 | 12.8 | sec | 21.7 | sec |
| 162 | 10.2 | sec | 17.6 | sec |
| 163 | <10.0 | sec | 14.3 | sec |
| 164 | <10.0 | sec | 11.6 | sec |
| 165 | <10.0 | sec | <10.0 | sec |

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

----- fat%=11 -----

| Temperature F | time for Chicken unit | time for Turkey unit |
|------------------|--------------------------|-------------------------|
| 136 | 78.9 min | 69.5 min |
| 137 | 63.3 min | 57.2 min |
| 138 | 50.9 min | 47.2 min |
| 139 | 41.1 min | 39.1 min |
| 140 | 33.4 min | 32.5 min |
| 141 | 27.1 min | 27.1 min |
| 142 | 22.1 min | 22.6 min |
| 143 | 18.1 min | 18.8 min |
| 144 | 14.8 min | 15.7 min |
| 145 | 12.1 min | 13 min |
| 146 | 9.8 min | 10.8 min |
| 147 | 7.9 min | 8.8 min |
| 148 | 6.3 min | 7.2 min |
| 149 | 4.9 min | 5.8 min |
| 150 | 3.8 min | 4.5 min |
| 151 | 2.9 min | 3.5 min |
| 152 | 2.1 min | 2.7 min |
| 153 | 1.4 min | 1.9 min |
| 154 | 1.1 min | 1.6 min |
| 155 | 53.4 sec | 1.3 min |
| 156 | 42.2 sec | 1 min |
| 157 | 33.4 sec | 50.2 sec |
| 158 | 26.4 sec | 40.7 sec |
| 159 | 20.9 sec | 33 sec |
| 160 | 16.5 sec | 26.8 sec |
| 161 | 13.1 sec | 21.8 sec |
| 162 | 10.3 sec | 17.7 sec |
| 163 | <10.0 sec | 14.3 sec |
| 164 | <10.0 sec | 11.6 sec |
| 165 | <10.0 sec | <10.0 sec |

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

----- fat%=12 -----

| Temperature F | time for Chicken unit | time for Turkey unit |
|------------------|-----------------------------|----------------------------|
| 136 | 81.4 min | 70.8 min |
| 137 | 65.5 min | 58.5 min |
| 138 | 52.9 min | 48.5 min |
| 139 | 43 min | 40.4 min |
| 140 | 35 min | 33.7 min |
| 141 | 28.7 min | 28.2 min |
| 142 | 23.5 min | 23.7 min |
| 143 | 19.3 min | 19.8 min |
| 144 | 15.9 min | 16.6 min |
| 145 | 13 min | 13.8 min |
| 146 | 10.6 min | 11.5 min |
| 147 | 8.6 min | 9.4 min |
| 148 | 6.8 min | 7.7 min |
| 149 | 5.4 min | 6.2 min |
| 150 | 4.2 min | 4.9 min |
| 151 | 3.1 min | 3.8 min |
| 152 | 2.3 min | 2.8 min |
| 153 | 1.6 min | 2.1 min |
| 154 | 1.1 min | 1.6 min |
| 155 | 54.4 sec | 1.3 min |
| 156 | 43 sec | 1 min |
| 157 | 34 sec | 50.4 sec |
| 158 | 26.9 sec | 40.9 sec |
| 159 | 21.3 sec | 33.2 sec |
| 160 | 16.9 sec | 26.9 sec |
| 161 | 13.3 sec | 21.9 sec |
| 162 | 10.5 sec | 17.7 sec |
| 163 | <10.0 sec | 14.4 sec |
| 164 | <10.0 sec | 11.7 sec |
| 165 | <10.0 sec | <10.0 sec |

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

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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. In addition, 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 lethality performance standards: 6.5₁₀ log of Salmonella in ready-to-eat *meat* products and 7 log₁₀ 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 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 microbiological laboratory methods used in salmonella 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.

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 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 in-going 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 and salt, 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-log₁₀ 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.

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.

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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 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

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- The re-cooking procedure can achieve a final internal product temperature of at least 149°F (65°C) for two minutes. Subsequent to re-cooking, the product must be cooled in strict conformance to existing guidelines. When the product is to be reworked with another raw product, the re-cooking 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 re-cooking, 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

COMPLIANCE GUIDELINES FOR FERMENTED PRODUCTS

The proposed performance standards for lethality of fermented RTE products require a 6.5 log₁₀ reduction of *Salmonella* throughout the finished meat product and a 7.0 log₁₀ reduction of *Salmonella* throughout the finished poultry product. In addition, FSIS has proposed to require a 5 log₁₀ reduction of *E. coli* O157:H7 in fermented products containing beef. .

Some of the procedures suggested for these compliance guidelines achieve both a 7.0 log₁₀ reduction of *Salmonella* and a 5 log₁₀ reduction of *E. coli* O157:H7. These are for meat products containing beef. Some of the guidelines meet the requirements only for 5 log₁₀ reduction of *E. coli* O157:H7. For these processes, establishments have to additionally address the hazards for *Salmonella*.

Lebanon bologna

Process to achieve a 7-log₁₀ reduction of *Salmonella* and *E. coli* O157:H7

Lebanon bologna mix
boneless lean beef – 10% fat
salt – 3.5%
potassium nitrate – 12 ppm

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sodium nitrite – 200 ppm

- a) fermentation – 12 hrs at 80°F then 100°F until pH of 4.7 or 5.2 is reached
- b) heat – 110°F for 20 hrs; OR,
115°F for 10 hrs; OR,
120°F for 3 hrs

Reference: Ellajosyula, K.E., S. Doores, E.W. Mills. R.A. Wilson, R.C. Anantheswaran, and S.J. Knabel. 1998. Destruction of *Escherichia coli* O157:H7 and *Salmonella typhimurium* in Lebanon bologna by interaction of fermentation, pH, heating temperature, and time. J. Food Prot. 61(2):152-7.

Dry and Semidry Fermented Sausages

These guidelines are adapted from Blue Ribbon Task Force report “Dry Fermented Sausage and *E. coli* O157:H7,” May 1996. The report, which is a result of cooperative effort among industry representatives, scientists, manufacturers, and USDA agencies, recommended five options resulting in validated manufacturing processes to ensure that RTE dry and semidry fermented sausages are safe from *Escherichia coli* O157:H7.

- 1) Processes to achieve a 6.5-log₁₀ reduction of Salmonella and 5-log₁₀ reduction of *E. coli* O157:H7 (formerly Option 1).

For fermented sausages containing beef or beef and pork, heat according to the following:

Guidelines for Cooked Beef, Roast Beef, and Cooked Corned Beef in Appendix A—Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products (FR Vol. 64 No. 3, January 6, 1999)

For fermented sausages containing poultry, heat according to the following:

Guidelines for Cooked Poultry Rolls and Other Cooked Poultry Products in Appendix A—Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products (FR Vol. 64 No. 3, January 6, 1999)

- 2) Processes to achieve a 5-log₁₀ reduction or equivalent reduction of *E. coli* O157:H7 only (does not apply to *Salmonella*)
 - a) Validated processes for a 5-log₁₀ reduction of *E. coli* O157:H7 (formerly Option 2) – adapted from Table 6 of the Blue Ribbon Task Force report

| Fermentation Temp °F | pH | Process | Casing |
|-------------------------|-------|--------------------|--------|
| 70 | > 5.0 | Heat [*] | Small |
| 90 | ≤ 4.6 | Hold ^{**} | Small |
| 90 | ≤ 4.6 | Heat | Small |
| 90 | ≤ 4.6 | Heat | Large |
| 90 | > 5.0 | Heat | Large |
| 110 | ≤ 4.6 | Hold | Small |

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| | | | |
|-----|-------|------|-------|
| 110 | ≤ 4.6 | Hold | Large |
| 110 | > 5.0 | Hold | Large |

* Small Casing (55 mm) – 1 hour at 100°F followed by 6 hours at 125°F

Large Casing (105 mm)– 1 hour at 100°F, 1 hour at 110°F, 1 hour at 120°F, and ending with 7 hours at 125°F

** Hold at the indicated temperature for at least 7 days

b) No *E. coli* O157:H7 detected in raw product and a validated 2D, 2-log reduction, process (formerly Option 5)

i. Requirements for testing of raw product

- ◆ An analytical method equivalent to that used by USDA/FSIS must be implemented in the raw batter testing.
- ◆ The sample size and compositing procedure must ensure a detection level of 1 CFU/gram. Fifteen samples must be taken across the lot. These could then be composited into five 75-gram samples.
- ◆ The definition of a “lot” for the purposes of sampling must be statistically sound.
- ◆ GMPs must be applied.

ii. alternatively, the establishment could obtain a Letter of Guaranty from its supplier that the product was free of *E. coli* O157:H7

iii. apply one of the following validated processes for a 2D or greater process between stuffing and shipping

- ◆ use one of the processes above for a 5-log₁₀ or greater reduction of *E. coli* O157:H7
- ◆ use one of the following processes from the Blue Ribbon Task Force report that achieves at least a 2-log₁₀, but less than 5-log₁₀, reduction of *E. coli* O157:H7

| Fermentation Temp °F | pH | Process | Casing |
|----------------------|-------|---------|--------|
| 70 | > 5.0 | Heat* | Large |
| 90 | ≤ 4.6 | Hold** | Large |
| 90 | > 5.0 | Hold | Large |
| 110 | > 5.0 | Hold | Small |

* Small Casing (55 mm)– 1 hour at 100°F followed by 6 hours at 125°F

Large Casing (105 mm)– 1 hour at 100°F, 1 hour at 110°F, 1 hour at 120°F, and ending with 7 hours at 125°F

** Hold at the indicated temperature for at least 7 days

3) processes that achieve at least a 5-log₁₀ reduction of *E. coli* O157:H7 in specific products

a) soudjouk (soudjuk, soudjouck, surugu, sucuk)

ingredients –

- ground beef (20% fat or less)
- NaCl 1.9%
- sodium nitrite 0.25% or 156ppm
- starter culture Bactoferm LCP or equivalent – 8.0 log₁₀ cfu/gm of batter
- dextrose 1.5%

fermenting and drying

3 days at 75.2°F (24°C) with 90-95% relative humidity (RH), then
3 days at 71.6°F (22°C) with 80-85% RH until moisture is about 40%, then
heat at 120°F (48.8°C) with 70% RH for 1 hour, then at
130°F (54.4°C) with 70% RH until product internal temperature reaches 130°F

Reference: Calicioglu, M, N.G. Faith, D.R. Buege, and J.B. Luchansky. 2001. Viability of *E. coli* O157:H7 in Turkish-style soudjouk. Submitted for publication.

b) pepperoni

ingredients – 75% pork, 25% beef with 32% fat
dextrose – 0.63%
2% cure
pediococcal starter culture – 8.0 log₁₀ cfu/gm of batter

fermentation – 96.8°F (36°C) with 90% RH to pH 4.8
drying – 55.4°F (13°C) with 65% RH for 18 days to MPR ≤1:6.1
slicing – 1.9 gm/slice
storage – packed in air – 28 days at 69.8°F (21°C)
packed under vacuum – 60 days at 69.8°F (21°C)

Reference: Faith, N.G., N. Parniere, T. Larson, T.D. Lorang, and J.B. Luchansky. 1997. Viability of *E. coli* O157:H7 in pepperoni during the manufacture of sticks and the subsequent storage of slices at 21, 4 and –20°C under air, vacuum and CO₂. *Int. J. Food Microbiol.* 37:47-54.

c) pepperoni

ingredients – 75% pork, 25% beef with 32% fat
dextrose – 0.63%
2% cure
pediococcal starter culture – 8.0 log₁₀ cfu/gm of batter

fermentation – 96°F (36°C) with 85-90% RH until a pH ≤ 5.0
heat process – 145°F (63°C) instantaneous, or
128°F (53°C) for 60 minutes

cold showered to internal temperature of ≤ 80°F (27°C)

drying at 55°F (13°C) and 65% RH [wet bulb 50°F (10°C), dry bulb 55°F (13°C)] to MRP 1:6.1 (ca. 15 to 21 days)

Reference: Hinkens, J.C., N.G. Faith, T.D. Lorang, P. Bailey, D. Buege, C. Kaspar and J.B. Luchansky. 1996. Validation of pepperoni processes for control of *E. coli* O157:H7. *J. Food Prot.* 59(12):1260-66.

d) summer sausage

ingredients – beef with 11% fat
salt – 2.5%
curing salt – 0.26%
pediococcal starter culture -- 8.0 log₁₀ cfu/gm of batter
glucose – 1% for target pH 4.6
0.3% for target pH 5.0

fermentation at constant 80% RH – 1 hour at 85°F (29.4°C)
1 hour at 90°F (32.2°C)
1 hour at 95°F (35°C)
1 hour at 100°F (37.8°C)
8 hours at 105°F (40.6°C) until pH 4.6 or 5.0

summer sausage fermented to pH 4.6

heat to internal temperature of 130°F (54.4°C) with 60% RH – achieves a 7-log₁₀ reduction of *E. coli* O157:H7

summer sausage fermented to pH 5.0

heat to internal temperature of 130°F (54.4°C) with 60% RH for 30 minutes – achieves the minimum 5-log₁₀ of *E. coli* O157:H7

heat to internal temperature of 130°F (54.4°C) with 60% RH for 60 minutes – achieves a 7-log₁₀ of *E. coli* O157:H7

Reference: Calicioglu, M., N.G. Faith, D.R. Buege and J.B. Luchansky. 1997. Viability of *E. coli* O157:H7 in fermented semidry low-temperature-cooked beef summer sausage. *J. Food Prot.* 60(10):1158-62.

Compliance Guidelines for Dried Meat and Poultry Products

A study on beef jerky was done using meat strips and challenged with three pathogens, *Salmonella typhimurium*, *Escherichia coli* O157:H7, and *Listeria monocytogenes*. The hazards from these three pathogens are already addressed in this study. The times and temperatures used for each stage, including storage should be followed to achieve a 6.5 log₁₀ reduction of *Salmonella* in meat products. The hazards from *Staphylococcus aureus* and if pork is used, *Trichinella spiralis*, may also need to be addressed.

Beef Jerky Strips

1. Cut meat to approximately 15 X 1.5 X 1.5 cm pieces.
2. Cover meat strips with jerky marinade and let stand at 4°C for 1 hour.
2. Put strips in a shallow pan, covered with jerky marinade* and heat to 71.1°C (160°F).
3. Cool strips for 15 minutes.
4. Dry strips at 60°C (140°F) for 10 hours.
5. Store for 8 weeks at 25°C.

*Jerky marinade may consist of any of the following: salt, sugar, spices, seasonings, nitrates, nitrites.

REFERENCE: Harrison, J. A. and Harrison, M. A. 1996. Fate of *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella typhimurium* during preparation and storage of beef jerky. J. Food Protection. 59:(12):1336-1338.

Compliance Guidelines for Salt-Cured Meat and Poultry Products

This dry cured ham study used the three pathogens, *Salmonella typhimurium*, *Escherichia coli* O157:H7, *Listeria monocytogenes* for challenge, and the USDA procedure for country ham to treat *Trichinella spiralis*. Therefore hazards from all these four pathogens are addressed in this procedure. However, the hazard from *Staphylococcus aureus* may need to be additionally addressed. The times and temperature for dry cure, salt equalization, drying and storage must be closely followed, to achieve a 6.5 log reduction of *Salmonella* in a salt-cured meat product

Dry Cured Ham

1. Two cure mix formulations can be used:
 - a) 3.63 kg salt, 454 g sugar, 14.2 g sodium nitrite, 56.7 g sodium nitrate
 - b) 3.63 kg salt, 454 g sugar (no nitrites)
2. Apply 42.53 g of cure per 0.45 kg of ham by rubbing at day 0 and day 10.
3. Dry cure at 4.4°C for 35 days.
4. Brush excess salt, without adding water.
5. Place hams in stockettes and hold at 4.4°C for 14 days for salt equalization.
6. Age hams for 20 days at 29.4°C (65 % relative humidity).
7. Store hams in ambient storage through day 120.

REFERENCE: Reynolds, A. E., M. A. Harrison, R. Rose –Morrow, and C. E. Lyon. 2001. Fate of microorganisms on dry cured ham. **Accepted for publication, Journal of Food Science.**

Compliance Guidelines for *Listeria* Testing of Food Contact Surfaces

The proposed rule would require that establishments that produce RTE meat and poultry products conduct environmental testing of food contact surfaces for *Listeria* spp. after lethality treatment and before final product packaging. This testing is not required if establishments have identified *L. monocytogenes* as a hazard reasonably likely to occur and have incorporated into their HACCP systems one or more controls validated to eliminate the pathogen from their products.

The agency published the document, *Listeria* Guidelines for Industry, in May 1999. This document provides guidelines for environmental testing of both non-contact and contact surfaces. It includes guidance on sample sites, methods, follow-up of positive samples, and examples. These guidelines were gathered from guidelines prepared by industry organizations. For the proposed rule, guidelines for testing food contact surfaces are derived from this document and the FSIS Guidelines for Environmental and Chill Water/Brine Sampling for *Listeria*, March 2000. These documents can be accessed from the following site:
www.fsis.usda.gen/OA/topics/lm/htm

Sample Sites and Frequency

Selection of sample sites and sampling frequency for product contact surfaces depends on establishment features such as plant layout, overhead structures, number of production lines/products, location of processing equipment, and product flow. A sampling protocol should include the sample sites, sample area size, sampling frequency and sample collection techniques. In general, samples sites should be selected randomly. However, some sites may be designated for sampling on a regular basis based on the hazard analysis. For purposes of the compliance guidelines, sample sites for testing product contact surfaces should include equipment used after lethality treatment and before packaging. Product contact surfaces to be sampled may include but not necessarily limited to the following:

1. conveyor belts that contact unpackaged post-process product
2. table and counter tops that contact unpackaged post-process product
3. peeler apparatus
4. slicing equipment
5. packaging equipment
6. chill water or brines that directly contact unpackaged product. Non-chlorinated chill water/brine is more likely to be contaminated by *Listeria* spp. than chlorinated water/brine.
7. Any difficult-to-clean product contact surface areas along the line
8. Product contact surface sites soiled by food residue

Sample size can be determined based on the nature of equipment or surfaces, e.g. flat surfaces, inside of equipment, etc. The plan should also detail appropriate, progressive actions the establishment will take as positive samples are found.

Methods

Environmental samples, including swabs and sponges, should be placed in a neutralizing medium immediately after collection, in order to neutralize any residual disinfectants that may be picked up from equipment or other environmental sampling sites. Samples should be stored and shipped to laboratories using standardized procedures. A reputable laboratory should analyze samples. The establishment is responsible for determining the competency of the laboratory used. The laboratory conducting the sample analyses should have properly trained personnel, suitable facilities and equipment, a written quality assurance program that is available to all

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personnel, and reporting and record keeping capabilities. . Laboratories can use published methods after validation. Laboratories can also use FSIS' *L. monocytogenes* method published in the Microbiology Laboratory Guidebook, 3rd edition (Chapter 8, Revision #2, 11/8/99). FSIS updates its methods as new methods are developed, so it is advisable to periodically check the FSIS web site.

An establishment may choose to perform its own indicator organism testing using a screening test. Such tests are available but should be validated as part of the HACCP plan.

Record Keeping

The results of environmental sampling are not available until after products are produced. Therefore, adequate and accurate records are essential because the environmental sampling program is of retrospective value only. For example, identification of the site sampled (conveyor # 1 in peeling room) and the visible condition of the site (clean, smooth surface) is necessary to effectively utilize the sampling results.

Results and Follow-up: Product contact surfaces

If positive samples are found on product contact surfaces, different follow up actions should be taken, including follow up sampling of product produced on that line, as follows:

1. Once the product contact surface is found to be positive for the number of samples indicated in the HACCP plan for *Listeria spp.*, the next lot of product produced from the line should be sampled and tested for *L. monocytogenes*.
2. Minimum production time prior to sampling should be determined by the plant and followed. The time may depend on individual line configuration, clean up, and sanitizing procedures. The testing plan should include variations in the time of sampling to detect the increase in *Listeria* that could occur during the production shift.
3. After product sampling, the line may need to be cleaned and/or operational procedures reviewed, before production of the next lot.
4. The product lot sampled may be held, pending laboratory results.
5. If a sampled lot is found to be positive for *L. monocytogenes*, and is already in commerce, it will be subject to recall.
6. Product sampling may be intensified, such as testing several consecutive lots. All product produced on positive lines may be held pending laboratory results.
7. After the predetermined number of lots has tested negative for *L. monocytogenes*, the plant may resume its regular regime of environmental and product sampling.
8. The establishment should document the reason for contamination and steps taken to prevent future incidents.

Flow Chart

Environmental Sampling for *Listeria spp.*

Sampling product contact surfaces for *Listeria spp.**

Negative Results

Resume regularly
scheduled sampling
program

Negative Results***

Positive Results

Follow up actions per
HACCP plan (continue)**

Sample product for
L. monocytogenes+

Positive results++

Follow up actions per
HACCP plan+++

- * Between post lethality and packaging steps
- ** May include thorough cleaning of suspect areas/equipment with intensified/expanded sampling
- *** Predetermined lots have tested negative for *Listeria monocytogenes*
- + Product produced on positive lines may be held pending lab results
- ++ Product lot(s) sampled may be held pending lab results
- +++ Product in commerce subject to recall- FSIS may be involved

Guidelines for Thermally-Processed, Commercially Sterile Meat and Poultry Products

(This guidance is taken directly from the current regulatory requirements. FSIS has retained the regulatory numbering and cross-references).

SECTION: 300 – Definitions .

- (a) Abnormal container. A container with any sign of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled.
- (b) Acidified low acid product. A canned product which has been formulated or treated so that every component of the finished product has a pH of 4.6 or lower within 24 hours after the completion of the thermal process unless data are available from the establishment's processing authority demonstrating that a longer time period is safe.
- (c) Bleeders. Small orifices on a retort through which steam, other gasses, and condensate are emitted from the retort throughout the entire thermal process.
- (d) Canned product. A meat food product with a water activity above 0.85 that receives a thermal process either before or after being packed in a hermetically sealed container. Unless otherwise specified, the term “product” means “canned product.”
- (e) Closure technician. The individual(s) identified by the establishment as being trained to perform specific container integrity examinations as required by this subpart and designated by the establishment to perform such examinations.
- (f) Code lot. All production of a particular product in a specific size container marked with a specific container code.
- (g) Come-up time. The elapsed time, including venting time (if applicable), between the introduction of the heating medium into a closed retort and the start of process timing.
- (h) Critical factor. Any characteristic, condition or aspect of a product, container, or procedure that affects the adequacy of the process schedule. Critical factors are established by processing authorities.
- (i) Headspace. That portion of a container not occupied by the product.
 - (1) Gross headspace. The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (i.e., the flange of an unsealed can, the top of the double seam on a sealed can, or the top edge of an unsealed jar).
 - (2) Net headspace. The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the inside surface of the lid.
- (j) Hermetically sealed containers. Air-tight containers that are designed and intended to protect the contents against the entry of microorganisms during and after thermal processing.
 - (1) Rigid container. A container, the shape or contour of which, when filled and sealed, is neither affected by the enclosed product nor deformed by external mechanical pressure of up to 10 pounds per square inch gauge (0.7 kg/cm²) (i.e., normal firm finger pressure).
 - (2) Semirigid container. A container, the shape or contour of which, when filled and sealed, is not significantly affected by the enclosed product under normal atmospheric temperature and pressure, but can be deformed by external mechanical pressure of less than 10 pounds per square inch gauge (0.7 kg/cm²) (i.e., normal firm finger pressure).
 - (3) Flexible container. A container, the shape or contour of which, when filled and sealed, is significantly affected by the enclosed product.

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- (k) Initial temperature. The temperature, determined at the initiation of a thermal process cycle, of the contents of the coldest container to be processed.
- (l) Low acid product. A canned product in which any component has a pH value above 4.6.
- (m) Process schedule. The thermal process and any specified critical factors for a given canned product required to achieve shelf stability.
- (n) Process temperature. The minimum temperature(s) of the heating medium to be maintained as specified in the process schedule.
- (o) Process time. The intended time(s) a container is to be exposed to the heating medium while the heating medium is at or above the process temperature(s).
- (p) Processing authority. The person(s) or organization(s) having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions as indicated in this subpart.
- (q) Program employee. Any inspector or other individual employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the Program (the organizational unit within the Department having the responsibility for carrying out the provisions of the Act).
- (r) Retort. A pressure vessel designed for thermal processing of product packed in hermetically sealed containers.
- (s) Seals. Those parts of a semirigid container and lid or of a flexible container that are fused together in order to hermetically close the container.
- (t) Shelf stability. The condition achieved by application of heat, sufficient, alone or in combination with other ingredients and/or treatments, to render the product free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50 degrees F or 10 degrees C) at which the product is intended to be held during distribution and storage. Shelf stability and shelf stable are synonymous with commercial sterility and commercially sterile, respectively.
- (u) Thermal process. The heat treatment necessary to achieve shelf stability as determined by the establishment's processing authority. It is quantified in terms of:
 - (1) Time(s) and temperature(s); or
 - (2) Minimum product temperature.
- (v) Venting. The removal of air from a retort before the start of process timing.
- (w) Water activity. The ratio of the water vapor pressure of the product to the vapor pressure of pure water at the same temperature.

301 – Containers and closures.

- (a) Examination and handling of product containers prior to use.
 - Packaging materials, including closures and rollstock films, used to create hermetically-sealed product containers should be:
 - (1) Evaluated by the establishment prior to use to ensure that they are clean and free of damage and structural defects that may affect product or container integrity; and
 - (2) Stored, handled, and conveyed in a manner that will preclude soiling and damage that could result in product adulteration or affect the hermetic condition of the sealed container.
- (b) Closure examinations and tests.
 - (1) Visual examinations of containers equipped with double seams.
 - A closure technician should visually examine the double seams formed by each closing machine head. When seam defects are observed, necessary corrective actions should be taken and the observations,

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along with any corrective actions taken, should be promptly recorded. In addition the entire container should be examined for product leakage or obvious defects. Visual examinations should be conducted with sufficient frequency to ensure proper closure and container integrity.

(2) Teardown examinations of double seams.

A closure technician should perform teardown examinations of the double seams formed by each closing machine head. When seam defects are observed, necessary corrective actions should be taken and the observations, along with any corrective actions taken, should be promptly recorded. Teardown examinations should be performed at a frequency sufficient to ensure proper closure. At least one container from each closing head should be examined on the packer's end during each regular examination period. The establishment should have container specification guidelines for double seam integrity on file and available for review by Program employees.

A teardown examination of the can maker's end should be performed on at least one container selected from each closing machine during each examination period except when teardown examinations are made on incoming empty containers or when, in the case of self-manufactured containers, the containers are made in the vicinity of the establishment and the container plant records are made available to Program employees.

(i) Required double seam dimensional measurements and examinations.

(a) When a micrometer is used, the following dimensions should be measured:

Double seam length (width, height);

Double seam thickness;

Body hook length; and

Cover hook length.

(b) When a seamscope or seam projector is used, the required measurements include:

Body hook;

Overlap; and

Seam thickness (by micrometer).

(c) Maximum and minimum values for each dimensional measurement should be recorded.

(d) Seam tightness. Regardless of the method used to measure seam dimensions, the seam examined should be stripped to assess the degree of wrinkling.

(e) Side seam juncture rating. Regardless of the method used to measure seam dimensions, the cover hook should be stripped to examine the cover hook droop at the juncture for containers having soldered side seams.

(3) Visual examinations of glass containers.

A closure technician should visually assess the adequacy of the closures formed by each closing machine. When closure defects are observed, necessary corrective actions should be taken and promptly recorded. In addition to the closures, the entire container should be examined for defects. Visual examinations should be made with sufficient frequency to ensure proper closure.

(4) Closure examinations and tests on glass containers.

As appropriate for the container and closure, tests should be performed by the closure technician at a frequency sufficient to ensure proper closure. At least one container from each closing station should be examined during each regular examination period. Examination results, along with any corrective actions taken, should be promptly recorded. The establishment should have specification guidelines for closure integrity on file and available for review by Program employees.

(5) Visual examinations of flexible and semirigid containers.

A closure technician should visually examine the seals formed by each sealing machine. When sealing defects are observed, necessary corrective actions should be taken and recorded. In addition to examining the heat seals, the entire container should be examined for product leakage and obvious

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defects. Visual examinations should be performed before and after the thermal processing operation and with sufficient frequency to ensure proper closure. All defects noted and corrective actions taken should be promptly recorded.

(6) Physical tests on flexible and semirigid containers.

Tests determined by the establishment as necessary to assess container integrity should be conducted by the closure technician at a frequency sufficient to ensure proper closure. These tests should be performed after the thermal processing operation. The establishment's acceptance guidelines for each test procedure should be on file and available for review by Program employees. Test results, along with any corrective actions taken, should be promptly recorded.

(c) Container coding.

Each product container should be marked with a permanent, legible, identifying code mark. The code mark should, at a minimum, identify the product (unless the product name lithographed or otherwise permanently affixed elsewhere on the container) and the day and year the product was packed.

(d) Handling of containers after closure.

(1) Filled and sealed product containers should be protected from damage which may cause defects that are likely to affect the hermetic condition of the containers or closures.

(2) The time lapse between closing and initiation of the thermal process should be controlled to minimize the growth of microorganisms and to preclude the production of microbial toxins. When deemed necessary to ensure product safety and stability, the processing authority may specify a maximum time that filled and sealed containers may be held.

302 – Thermal Processing.

(a) Process schedules.

Prior to processing of a given product for distribution in commerce, an establishment should have a process schedule that is adequate under the conditions of manufacture of such product to achieve commercial sterility.

(1) Process schedules used by an establishment should be developed or determined by a processing authority.

(2) Any change in product formulation, ingredients, or treatments that is not already incorporated in a process schedule and that may adversely affect either the product heat penetration profile or sterilization value requirements should be evaluated by a processing authority. If it is determined that any such change adversely affects the adequacy of the process schedule, the processing authority should amend the process schedule accordingly.

(b) Availability of process schedule information.

(1) Letters or other written communications from a processing authority recommending all process schedules should be maintained on file by the establishment. The establishment should make such written communications (or copies thereof) available to Program employees upon request.

(2) Critical factors.

(i) Critical factors specified in a process schedule should be controlled to ensure that they remain within the limits specified in the process schedule.

(ii) Examples of factors that are critical to process schedule adequacy may include:

(a) General

(i) Maximum fill-in weight or drained weight;

(ii) Arrangement of pieces in the container;

(iii) Container orientation during thermal processing;

(iv) Product formulation;

(v) Particle size;

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- (vi) Maximum thickness for flexible, and to some extent semirigid, containers during thermal processing;
 - (vii) Maximum pH;
 - (viii) Percent salt;
 - (ix) Ingoing (or formulated) nitrite level (ppm);
 - (x) Maximum water activity; and
 - (xi) Product consistency or viscosity.
- (b) Continuous rotary and batch agitating retorts.
 - (i) Minimum headspace; and
 - (ii) Retort reel speed.
 - (c) Hydrostatic retorts.
 - (i) Chain or conveyor speed.
 - (d) Steam/air retorts.
 - (i) Steam/air ratio; and
 - (ii) Heating medium flow rate.
- (ii) Written procedures for controlling each factor should be maintained at the establishment and be made available to Program employees upon request. Such procedures should include critical factor measurements (including frequency) and the recording of the measurements to document control.

303 – Operations in the thermal processing area.

- (a) Posting of processes.

Process schedules (or operating process schedules) for daily production, including minimum initial temperatures and operating procedures for thermal processing equipment, should be posted in a conspicuous place near the thermal processing equipment.
- (b) Process indicators and product traffic control.

A control system should be established to prevent containers of unprocessed product from bypassing the thermal processing operation. Each basket, crate or similar vehicle, should be plainly and conspicuously marked with a heat sensitive indicator that will visually indicate whether such unit has been thermally processed.
- (c) Initial temperature.
 - (1) When a process schedule specifies a product initial temperature (IT), the establishment should ensure that the temperature of the contents of the coldest container to be thermally processed is not lower than the specified IT. Product IT should be determined and recorded at the time the processing cycle begins.
 - (2) Thermal processing systems which subject filled and sealed containers to water at any time before process timing begins should be operated so the water will not lower the product temperature below the IT specified in the process schedule.
- (d) Timing devices.
 - (1) Devices used to time critical thermal processing functions and events should be accurate to assure that all such functions and events are achieved.
 - (2) Acceptable devices include analog and digital clocks; however, if seconds are not displayed, all required timed functions or events should have at least a 1-minute safety factor over the specified thermal processing operation times.
 - (3) Pocket watches and wristwatches should not be used to time critical thermal processing functions and events.

304 – Equipment and procedures for thermal processing systems.

- (a) Instruments and controls for retorts and other thermal processing systems
- (1) Indicating temperature devices. Each retort should be equipped with at least one indicating temperature device. An acceptable indicating temperature device, such as a mercury-in-glass (MIG) thermometer, should be used as the reference instrument to indicate the actual temperature within the retort.
 - (i) MIG thermometers should have divisions that are readable to 1 F degree (or 0.5 C degree) with not more than 17 F degrees/inch (or 4.0 C degrees/cm) of graduated scale. A MIG thermometer that has a divided mercury column or that cannot be adjusted to the standard should be repaired and tested for accuracy before further use, or replaced.
 - (ii) Other devices. In lieu of MIG thermometers, other indicating temperature devices, such as resistance temperature detectors, may be used provided that the accuracy and reliability of the device has been tested and verified to be comparable to that of the MIG thermometer. Such data should be maintained on file by the establishment and made available to Program employees.
 - (iii) Each indicating temperature device should, upon installation and at least once a year thereafter, be tested for accuracy against a known accurate standard. Records that specify the date, standard used, test method, and the person or organization performing the test should be maintained on file at the establishment and made available to Program employees.
 - (2) Temperature/time recording devices. Each thermal processing unit should be equipped with at least one temperature/time recording device to provide a permanent record of temperatures within the unit. This recording device may be combined with a steam controller; i.e., a recording/controlling instrument. When compared to the known accurate indicating temperature device, the recording accuracy should be equal to or better than 1 F degree (or 0.5 C degree) at the process temperature. The temperature recording chart should be adjusted to agree with, but should never be higher than, the known accurate indicating temperature device. The recorder timing mechanism should be accurate. Each chart should have a working scale of not more than 55 F degrees/inch (or 12 C degrees/cm) within a range of 20 F degrees (or 11 C degrees) of the process temperature. Chart graduations should not exceed 2 F degrees (or 1 C degree) within a range of 10 F degrees (or 5 C degrees) of the process temperature. Multipoint plotting chart-type devices should print temperature readings at intervals that will assure that the parameters of the process time and process temperature have been met.
 - (3) External wells. Bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices should be installed either within the retort shell or in external wells attached to the retort. An external well on a steam retort should be equipped with a bleeder sized and located to provide a constant flow of steam past the length of the bulb or probe; such bleeders should emit steam continuously during the entire thermal processing period.
 - (4) Steam controllers. Each retort should be equipped with an automatic steam controller to maintain the process temperature. The controller may be combined with a temperature/time recording device; i.e., a recording/controlling instrument.
 - (5) Air lines. Air lines connected to steam retorts should be installed, operated and maintained in a manner that will prevent leakage of air into the retort during the process cycle.
 - (6) Water lines. Retort water lines that are intended to be closed during a process cycle should be installed, operated and maintained in a manner that will prevent leakage of water into the retort.
 - (7) Bleeders on steam retorts. Bleeders should be wide open during the entire process, including the come-up time. All bleeders should be arranged in a way that enables the retort operator to observe that they are functioning properly. Vertical retorts should have at least one bleeder opening located in the portion of the retort opposite the steam inlet. In retorts having a steam inlet above the level of the lowest container, a bleeder should be installed in the bottom of the retort to remove condensate. The

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condensate bleeder should be located where the retort operator can observe that it is functioning properly, and it should be checked with sufficient frequency to ensure adequate removal of condensate and the results recorded. Intermittent condensate removal systems should be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system should be tested at the beginning of each shift for proper functioning and the results recorded. A retort with a malfunctioning alarm system should not be used.

(8) Vents on steam retorts.

- (i) Vents should be located opposite the steam inlet and should be controlled by a gate, plug cock, or other full-flow valve which should be fully opened to permit rapid air removal during the venting period.
- (ii) Vents should not be connected to a closed drain system without an atmospheric break in the line. Where a retort manifold connects several pipes from a single retort, the manifold should be controlled by a full-flow valve and the manifold should be of a size such that the cross-sectional area of the manifold is larger than the total cross-sectional area of all connecting vents. The discharge should not be connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts should lead to the atmosphere. The manifold header should not be controlled by a valve and should be of a size such that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from the maximum number of retorts to be vented simultaneously.

(9) Bleeder and vent mufflers.

- (i) If mufflers are used on bleeders or vent systems, the establishment should have on file documentation that the mufflers do not impede the removal of air from the retort.
- (ii) The documentation should consist of either heat distribution data or documentation from the muffler manufacturer or processing authority and be made available to the Program employee for review.

(b) Pressure processing in steam. The air in the retort should be removed before processing is started. Heat distribution data and other documentation from the manufacturer or from the processing authority who developed the venting procedure should be kept on file by the establishment and made available to the Program employees for review.

(1) Batch still retorts.

- (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a)(1) and (2) of this section.
- (ii) Steam controllers are required as described in paragraph (a)(4) of this section.
- (iii) Crate supports. Vertical still retorts with bottom steam entry should employ bottom retort crate supports. Baffle plates should not be used in the bottom of retorts.
- (iv) Steam spreader. Perforated steam spreaders, if used, should be maintained to ensure they are not blocked or otherwise inoperative.
- (v) Bleeders and condensate removal. The basic requirements for bleeders and condensate removal are described in paragraph (a)(7) of this section.
- (vi) Vents and venting. The basic requirements for vents and venting are described in paragraph (a)(8) of this section.
- (vii) Bleeder and vent mufflers. The basic requirements for bleeder and vent mufflers are described in paragraph (a)(9) of this section.

(2) Batch agitating retorts.

- (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section.
- (ii) Steam controllers are required as described in paragraph (a)(4) of this section.

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- (iii) Bleeders and condensate removal. The basic requirements for bleeders and condensate removal are described in paragraph (a)(7) of this section.
 - (iv) Vents and venting. The basic requirements for vents and venting are described in paragraph (a)(8) of this section.
 - (v) Retort or reel speed timing. The retort or reel speed should be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed should be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer should be determined and recorded at least once per shift by checking the retort or reel speed using an accurate stopwatch.
 - (vi) Bleeder and vent mufflers. The basic requirements for bleeder and vent mufflers are described in paragraph (a)(9) of this section.
- (3) Continuous rotary retorts.
- (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section.
 - (ii) Steam controllers are required as described in paragraph (a)(4) of this section.
 - (iii) Bleeders and condensate removal. The basic requirements for bleeders and condensate removal are described in paragraph (a)(7) of this section.
 - (iv) Vents and venting. The basic requirements for vents and venting are described in paragraph (a)(8) of this section.
 - (v) Retort speed timing. The rotational speed of the retort should be specified in the process schedule. The speed should be adjusted as specified, and recorded by the establishment when the retort is started, and checked and recorded with sufficient frequency to ensure that the correct retort speed is maintained. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. If a recording tachometer is used, the speed should be manually checked against an accurate stopwatch at least once per shift and the results recorded.
 - (vi) Bleeder and vent mufflers. The basic requirements for bleeder and vent mufflers are described in paragraph (a)(9) of this section.
- (4) Hydrostatic retorts.
- (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, an indicating temperature device should be located in the steam dome near the steam/water interface. Where the process schedule specifies maintenance of particular water temperatures in the hydrostatic water legs, at least one indicating temperature device should be located in each hydrostatic water leg so that it can accurately measure water temperature and be easily read. Additional temperature/time recorder probes should be installed in the hydrostatic water legs if the process schedule specifies maintenance of particular temperatures in these water legs.
 - (ii) Steam controllers are required as described in paragraph (a)(4) of this section.
 - (iii) Bleeders. The basic requirements for bleeders are described in paragraph (a)(7) of this section.
 - (iv) Vents and venting. The basic requirements for vents and venting are described in paragraph (a)(8) of this section.
 - (v) Conveyor speed. The conveyor speed should be checked and recorded with sufficient frequency to ensure that the speed necessary to obtain the required process time is maintained. When a recording device is used, the conveyor speed should be manually checked against an accurate stopwatch at least once per shift by the establishment.
 - (vi) Bleeders and vent mufflers. The basic requirements for bleeder and vent mufflers are described in paragraph (a)(9) of this section.

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- (c) Pressure processing in water. Documentation from the equipment manufacturer or a processing authority, demonstrating uniform heat distribution within the retort vessel, should be kept on file by the establishment and made available to Program employees for review.
- (1) Batch still retorts.
- (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, the indicating temperature device bulb or probe should extend directly into the water without a separable well or sleeve. The recorder/controller probe should be located in such a position that steam does not strike it directly.
 - (ii) Pressure recording device. Each retort should be equipped with a pressure recording device which may be combined with a pressure controller.
 - (iii) Steam controllers are required as described in paragraph (a)(4) of this section.
 - (iv) Crate supports. A bottom crate support should be used in vertical retorts. Baffle plates should not be used in the bottom of the retort.
 - (v) Stacking equipment. For filled flexible containers and, where applicable, semirigid containers, stacking equipment should be designed to ensure that the thickness of the filled containers does not exceed that specified in the process schedule and that the containers do not become displaced and overlap or rest on one another during the thermal process.
 - (vi) Drain valve. A nonclogging, water-tight drain valve should be used.
 - (vii) Water level. There should be a means of determining the water level in the retort during operation (i.e., by using a gauge, electronic sensor, or sight glass indicator). For retorts requiring complete immersion of containers, water should cover the top layer of containers during the entire come-up time and thermal processing periods. For retorts using cascading water or water sprays, the water level should be maintained within the range specified by the retort manufacturer or processing authority during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods should be provided. The retort operator should check and record the water level at intervals sufficient to ensure it meets the specified processing parameters.
 - (viii) Air supply and controls. Overriding air or steam pressure should be maintained continuously during the come-up, thermal processing, and cooling periods. The introduction of compressed air or steam into the retort should be controlled by an automatic pressure control unit. A nonreturn valve should be provided in the air supply line to prevent water from entering the system. If air is used to promote circulation, it should be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort.
 - (ix) Water recirculation. If a water recirculation system is used for heat distribution, suction outlets should be protected with screens to keep debris from entering the recirculation system. The pump should be equipped with a pilot light or a similar device to warn the operator when it is not running, and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation.
- (2) Batch agitating retorts.
- (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, the indicating temperature device bulb or probe should extend directly into the water without a separable well or sleeve. The recorder/controller probe should be located in such a position that steam does not strike it directly.
 - (ii) Pressure recording device. Each retort should be equipped with a pressure recording device which may be combined with a pressure controller.
 - (iii) Steam controllers are required as described in paragraph (a)(4) of this section.
 - (iv) Drain valve. A nonclogging, water-tight drain valve should be used.

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- (v) Water level. There should be a means of determining the water level in the retort during operation (i.e., by using a gauge, electronic sensor, or sight glass indicator). For retorts requiring complete immersion of containers, water should cover the top layer of containers during the entire come-up time and thermal processing periods. For retorts using cascading water or water sprays, the water level should be maintained within the range specified by the retort manufacturer or processing authority during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods should be provided. The retort operator should check and record the water level at intervals sufficient to ensure it meets the specified processing parameters.
 - (vi) Air supply and controls. Overriding air or steam pressure should be maintained continuously during the come-up, thermal processing, and cooling periods. The introduction of compressed air or steam into the retort should be controlled by an automatic pressure control unit. A nonreturn valve should be provided in the air supply line to prevent water from entering the system. If air is used to promote circulation, it should be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort.
 - (vii) Retort or reel speed timing. The retort or reel speed timing should be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed should be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer should be determined and recorded at least once per shift by the establishment by checking the retort or reel speed using an accurate stopwatch.
 - (viii) Water recirculation. If a water recirculation system is used for heat distribution, the suction outlets should be protected with screens to keep debris from entering the recirculation system. The pump should be equipped with a pilot light or a similar device to warn the operator when it is not running and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation.
- (d) Pressure processing with steam/air mixtures in batch retorts. Documentation from the equipment manufacturer or a processing authority, demonstrating the uniform distribution of heat within the retort vessel during processing, should be kept on file by the establishment and made available to Program employees for review.
- (1) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes for indicating temperature devices and temperature/time recording devices or controller probes should be inserted directly into the retort shell in such a position that steam does not strike them directly.
 - (2) Steam controllers are required as described in paragraph (a)(4) of this section.
 - (3) Recording pressure controller. A recording pressure controller should be used to control the air inlet and the steam/air mixture outlet.
 - (4) Circulation of steam/air mixtures. A means should be provided for the circulation of the steam/air mixture to prevent formation of low-temperature pockets. The circulation system should be checked to ensure its proper functioning and should be equipped with a pilot light or a similar device to warn the operator when it is not functioning.
- (e) Atmospheric cookers.
- (1) Temperature/time recording device. Each atmospheric cooker (e.g., hot water bath) should be equipped with at least one temperature/time recording device in accordance with the basic requirements described in paragraph (a)(2) of this section.

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- (2) Heat distribution. Documentation from the equipment manufacturer or a processing authority, demonstrating uniform heat distribution within the cooker, should be kept on file by the establishment and made available to Program employees for review.
- (f) Other systems. All other systems not specifically delineated in this section and used for the thermal processing of canned product should conform to the applicable requirements of this part and the methods and controls used for the manufacture, processing, and packing of these foods should be as established in the process schedule. These systems should be operated and administered in a manner adequate to produce commercially sterile products consistently and uniformly.
- (g) Equipment maintenance
 - (1) Upon installation, all instrumentation and controls should be checked by the establishment for proper functioning and accuracy and, thereafter, at any time their functioning or accuracy is suspect.
 - (2) At least once a year each thermal processing system should be examined by an individual not directly involved in daily operations to ensure the proper functioning of the system as well as all auxiliary equipment and instrumentation. In addition, each thermal processing system should be examined before the resumption of operation following an extended shutdown.
 - (3) Records should be kept on all maintenance items that could affect the adequacy of the thermal process. Records should include the date and type of maintenance performed and the person conducting the maintenance.
- (h) Container cooling and cooling water.
 - (1) Potable water should be used for cooling except as provided for in paragraphs (h) (2) and (3) of this section.
 - (2) Cooling canal water should be chlorinated or treated with a chemical approved by the Administrator as having a bactericidal effect equivalent to chlorination. There should be a measurable residual of the sanitizer in the water at the discharge point of the canal. Cooling canals should be cleaned and replenished with potable water to prevent the buildup of organic matter and other materials.
 - (3) Container cooling waters that are recycled or reused should be handled in systems that are so designed, operated, and maintained so there is no buildup of microorganisms, organic matter, and other materials in the systems and in the waters. System equipment, such as pipelines, holding tanks and cooling towers, should be constructed and installed so that they can be cleaned and inspected. In addition, the establishment should maintain, and make available to Program employees for review, information on at least the following:
 - (i) System design and construction;
 - (ii) System operation including the rates of renewal with fresh, potable water and the means for treating the water so that there is a measurable residual of an acceptable sanitizer, per paragraph (h)(2) of this section, in the water at the point where the water exits the container cooling vessel;
 - (iii) System maintenance including procedures for the periodic cleaning and sanitizing of the entire system; and
 - (iv) Water quality standards, such as microbiological, chemical and physical, monitoring procedures including the frequency and site(s) of sampling, and the corrective actions taken when water quality standards are not met.
- (i) Post-process handling of containers. Containers should be handled in a manner that will prevent damage to the hermetic seal area.

305 – Processing and production records .

At least the following processing and production information should be recorded by the establishment: date of production; product name and style; container code; container size and type; and the intended process

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schedule. Measurements made to control critical factors should be recorded. In addition, where applicable, the following information and data should be recorded:

- (a) Processing in steam
 - (1) Batch still retorts. For each retort batch, record the retort number or other designation, the approximate number of containers or the number of retort crates, product initial temperature, time steam on, the time and temperature vent closed, the start of process timing, time steam off, and the actual processing time. The indicating temperature device and the temperature recorder should be read at the same time at least once during process timing and the observed temperatures recorded.
 - (2) Batch agitating retorts. In addition to recording the information required for batch, still steam retorts in paragraph (a)(1) of this section, record the functioning of the condensate bleeder(s) and the rotational speed.
 - (3) Continuous rotary retorts. Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, the time and temperature vent closed, time process temperature reached, the time the first can enters and the time the last can exits the retort. The retort or reel speed should be determined and recorded with sufficient frequency to ensure compliance with the process schedule. Readings of the indicating temperature device(s) and temperature recorder(s) should be made and recorded at the time the first container enters the retort and thereafter with sufficient frequency to ensure compliance with the process schedule. Functioning of the condensate bleeder(s) should be observed and recorded at the time the first container enters the retort and thereafter with sufficient frequency to ensure adequate condensate removal.
 - (4) Hydrostatic retorts. For each identified retorting unit, record the retort system number, the approximate total number of containers retorted, product initial temperatures, time steam on, the time and temperature vent(s) closed, time process temperature reached, time first containers enter the retort, time last containers exit the retort, and, if specified in the process schedule, measurements of temperatures in the hydrostatic water legs. Readings of the temperature indicating device and the temperature recording device should be observed and the temperatures recorded at the time the first containers enter the steam dome. Thereafter, these instruments should be read and the temperatures recorded with sufficient frequency to ensure compliance with the temperature specified in the process schedule. Container conveyor speed, and for agitating hydrostatic retorts, the rotative chain speed, should be determined and recorded at intervals of sufficient frequency to ensure compliance with the process schedule.
- (b) Processing in water
 - (1) Batch still retorts. For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, the start of process timing, water level, water recirculation rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder should be read at the same time at least once during process timing and the observed temperatures recorded.
 - (2) Batch agitating retorts. In addition to recording the information required in paragraph (b)(1) of this section, record the retort or reel speed.
- (c) Processing in steam/air mixtures. For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, venting procedure, if applicable, the start of process timing, maintenance of circulation of the steam/air mixture, air flow rate or forced recirculation flow rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder should be read at the same time at least once during process timing and the observed temperatures recorded.
- (d) Atmospheric cookers

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- (1) Batch-type systems. For each cooker batch, record the cooker number or other designation and the approximate number of containers and all critical factors of the process schedule.
- (2) Continuous-type systems. Record the cooker number or other designation, the time the first containers enter and the last containers exit a cooker, and the approximate total number of containers processed and all critical factors of the process schedule.

306 – Record review and maintenance.

- (a) Process records.

Charts from recording devices should be identified as necessary to enable correlation with the records required in ' 305. Each entry on a record should be made at the time the specific event occurs, and the recording individual should sign or initial each record form. No later than 1 working day after the actual process, the establishment should review all processing and production records to ensure completeness and to determine if all product received the process schedule. All records, including charts and critical factor control records, should be signed or initialed and dated by the person conducting the review.

- (b) Automated process monitoring and recordkeeping.

Automated process monitoring and recordkeeping systems, alone or in combination with written records, should be designed and operated in a manner which will ensure compliance with the applicable requirements of ' 305.

- (c) Container closure records.

Written records of all container closure examinations should include any corrective actions taken. Records should be signed or initialed by the container closure technician and should be reviewed and signed by the establishment within 1 working day after the actual production to ensure that the records are complete and that the closing operations have been properly controlled.

- (d) Distribution of product.

Records should be maintained by the establishment identifying initial distribution of the finished product.

307 -- Process Deviations.

- (a) Whenever the actual process is less than the process schedule recommended by a processing authority or when any critical factor does not comply with the requirements for that factor as specified in the process schedule, it should be considered a process deviation and the establishment should:

(1) Fully reprocess that portion of the production involved, using a process schedule appropriate for reprocessing, provided such process schedule has been established in accordance with ' 302(a) and is filed with the inspector in accordance with ' 302(b); or

(2) Set aside that portion of the production involved for further evaluation as to safety and shelf stability (commercial sterility). Such evaluation should be made by a processing authority and should be in accordance with procedures recognized by processing authorities as being adequate to assess the significance of the deviant process. A record should be made of the evaluation procedures used and the results.

- (i) If this evaluation demonstrates that the affected production received a process that rendered it shelf stable (commercially sterile), the product can be shipped from the establishment provided all other requirements of this subpart have been met.
- (ii) If the evaluation demonstrates the product is not commercially sterile, but there is no evidence of a potential public health hazard, an examination adequate to ensure the affected production consists of only sound, normal-appearing containers should be performed.
- (iii) If the evaluation reveals a potential public health hazard, the affected production should either be fully reprocessed to render it commercially sterile or be destroyed.

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- (b) Deviations identified in-process. If a deviation is noted at any time before the completion of the recommended process schedule, the establishment should, depending on the circumstances, carry out one of the following actions:
 - (1) Immediately reapply the full, recommended process schedule.
 - (2) Use an alternate process schedule provided the alternate schedule was established in accordance with ' 302(a) and is filed with the inspector in accordance with ' 302(b).
 - (3) Hold the affected production pending an evaluation of the deviation in accordance with paragraph (a)(2) of this section.
- (c) When a deviation identified in-process is handled by the application of an alternate process schedule not filed with the inspector or through some arbitrary action, the affected production should be held pending an evaluation in accordance with paragraph (a)(2) of this section.
- (d) The establishment should maintain full records regarding the handling of each deviation. Such records should include, at a minimum, the appropriate processing and production records, a full description of the corrective actions taken, the evaluation procedures and results, and the disposition of the affected product. Such records should be maintained in a separate file or in a log that contains the appropriate information.

SECTION: 308 Examination of finished product.

- (a) Normal containers.
 - (1) A written plan to assess the condition of finished product lots prior to shipment should be developed and maintained by the establishment.
 - (2) The establishment should examine finished product lots according to the plan and maintain complete records of all examinations.
- (b) Abnormal containers.

- (1) When abnormal containers are detected, the affected code lot (or portions thereof) should not be shipped until the establishment has determined that the product is safe and stable. Such a determination should take into account the cause and level of abnormalities in the affected lot as well as any product disposition actions taken by the establishment.
- (2) When the abnormal condition is found to be the result of microbial spoilage that represents a potential health hazard, the establishment should immediately inform the Agency.

309 -- Recall procedure.

Establishments should prepare and maintain a current procedure for the recall of all canned product covered by this subpart. Upon request, the recall procedure should **be made** available to Program employees

Guidelines for Treatment of Trichina (*Trichinella spiralis*)

FSIS has proposed to remove the regulations that require treatment of pork and products containing pork to destroy trichina. These prescribed trichina treatments will be unnecessary because compliance with the specified lethality performance standards should render most RTE products free from trichina. However, establishments producing RTE or not-RTE products containing pork should assess if trichina is a hazard reasonably likely to occur in their processes. If it is a hazard, they should include control procedures for trichina in their HACCP plan. These treatments are sufficient for destroying trichina but may not be sufficiently lethal for the other more prevalent and resistant bacterial pathogens often found in raw pork. The establishment also may need to address these other hazards in its HACCP plan.

The procedures reproduced here are treatments for trichina that are in 9 CFR 318.10 and 319.106. Since these were required by the Agency for effective trichina treatments, these can be used as compliance guidelines by establishments that need to control the hazard from trichina. Trichina treatment should consist of heating, refrigerating, or curing.

HEATING

1. All parts of the pork muscle tissue should be heated according to one of the time and temperature combinations in the following table:

| Minimum internal temperature | | Minimum time |
|------------------------------|-----------|--------------|
| Degrees F | Degrees C | |
| 120 | 49.0 | 21 hours |
| 122 | 50.0 | 9.5 hours |
| 124 | 51.1 | 4.5 hours |
| 126 | 52.2 | 2.0 hours |
| 128 | 53.4 | 1.0 hour |
| 130 | 54.5 | 30 minutes |
| 132 | 55.6 | 15 minutes |
| 134 | 56.7 | 6 minutes |
| 136 | 57.8 | 3 minutes |
| 138 | 58.9 | 2 minutes |
| 140 | 60.0 | 1 minute |
| 142 | 61.1 | 1 minute |
| 144 | 62.2 | Instant |

2. Time and temperature should be monitored by a calibrated recording instrument that meets the requirements provided in the section on General Instructions. *of paragraph (d) of this section, except for paragraph (c)(1)(iv).*

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3. The time to raise product temperature from 60 ° F. to 120 ° F should not exceed 2 hours unless the product is cured or fermented.
4. Time, in combination with temperatures of 138 ° F to 143 ° F, need not be monitored if the product's minimum thickness exceeds 2 inches (5.1 cm) and refrigeration of the product does not begin within 5 minutes of attaining 138 ° F (58.9 ° C).
5. The establishment should use procedures, which insure the proper heating of all parts of the product. It is important that each piece of sausage, each ham, and other product treated by heating in water be kept entirely submerged throughout the heating period; and that the largest pieces in a lot, the innermost links of bunched sausage or other massed articles, and pieces placed in the coolest part of a heating cabinet or compartment or vat be included in the temperature tests.

REFRIGERATING

At any stage of preparation and after preparatory chilling to a temperature of not above 40 °F or preparatory freezing, all parts of the muscle tissue of pork or product containing such tissue should be subjected continuously to a temperature not higher than one of those specified in Table 1, the duration of such refrigeration at the specified temperature being dependent on the thickness of the meat or inside dimensions of the container.

TABLE 1-REQUIRED PERIOD OF FREEZING AT TEMPERATURE INDICATED

| Temperature °F. | Group 1 (Days) | Group 2 (Days) |
|------------------------|-----------------------|-----------------------|
| 5 | 20 | 30 |
| -10 | 10 | 20 |
| -20 | 6 | 12 |

1. Group 1 comprises product in separate pieces not exceeding 6 inches in thickness, or arranged on separate racks with the layers not exceeding 6 inches in depth, or stored in crates or boxes not exceeding 6 inches in depth, or stored as solidly frozen blocks not exceeding 6 inches in thickness.
2. Group 2 comprises product in pieces, layers, or within containers, the thickness of which exceeds 6 inches but not 27 inches, and product in containers including tierces, barrels, kegs, and cartons having a thickness not exceeding 27 inches.
3. The product undergoing such refrigeration or the containers thereof should be so spaced while in the freezer as will insure a free circulation of air between the pieces of meat, layers, blocks, boxes, barrels, and tierces in order that the temperature of the meat throughout will be promptly reduced to not higher than 5 °F., -10 °F., or -20 °F., as the case may be.
4. In lieu of the methods prescribed in Table 1, the treatment may consist of commercial freeze-drying or controlled freezing, at the center of the meat pieces, in accordance with the times and temperatures specified in Table 2.

TABLE 2-ALTERNATE PERIODS OF FREEZING AT TEMPERATURES INDICATED

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| Maximum internal temperature | | Minimum Time | |
|-------------------------------------|------------------|---------------------|-----|
| Degrees F | Degrees C | | |
| 0 | -17.8 | 106 hours | |
| -5 | -20.6 | 82 hours | |
| -10 | -23.3 | 63 hours. | |
| -15 | -26.1 | 48 hours | |
| -20 | -28.9 | 35 hours. | |
| -25 | -31.7 | 22 hours | -- |
| -30 | -34.5 | 8 hours | --- |
| -35 | -37.2 | 1/2 hour | |

6. During the period of refrigeration the product should be kept separate from other products in rooms or compartments equipped and made secure with a lock or seal. The rooms or compartments containing product undergoing freezing should be equipped with accurate thermometers placed at or above the highest level at which the product undergoing treatment is stored and away from refrigerating coils. After completion of the prescribed freezing of pork to be used in the preparation of product, the pork should be kept under close supervision of a QC supervisor until it is prepared in finished form or until it is transferred to another official establishment for preparation in such finished form.

7. Pork which has been refrigerated as specified in this subparagraph may be transferred in sealed railroad cars, sealed motor trucks, sealed trailers, or sealed closed containers to another official establishment at the same or another location, for use in the preparation of product. Such vehicles and containers should be sealed and transported between official establishments in accordance with 9 CFR 325.7.

CURING

1. Sausage

The sausage may be stuffed in animal casings, hydrocellulose casings, or cloth bags. During any stage of treating the sausage for the destruction of live trichinae, except as provided in Method 5, these coverings should not be coated with paraffin or like substance, nor should any sausage be washed during any prescribed period of drying. In the preparation of sausage, one of the following methods may be used:

Method No. 1. The meat should be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry curing mixture containing not less than 3 1/3 pounds of salt to each hundredweight of the unstuffed sausage should be thoroughly mixed with the ground or chopped meat. After being stuffed, sausage having a diameter not exceeding 3 1/2 inches, measured at the time of stuffing, should be held in a drying room not less than 20 days at a temperature not lower than 45 °F., except that in sausage of the variety known as pepperoni, if in casings not exceeding 1 3/8 inches in diameter measured at the time of stuffing, the period of drying may be reduced to 15 days. In no case, however, should the sausage be released from the drying room in less than 25 days from the time the curing materials are added, except that sausage of the variety known as

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pepperoni, if in casings not exceeding the size specified, may be released at the expiration of 20 days from the time the curing materials are added. Sausage in casings exceeding 3 1/2 inches, but not exceeding 4 inches, in diameter at the time of stuffing, should be held in a drying room not less than 35 days at a temperature not lower than 45 °F., and in no case should the sausage be released from the drying room in less than 40 days from the time the curing materials are added to the meat.

Method No. 2. The meat should be ground or chopped into pieces not exceeding three fourths of an inch in diameter. A dry curing mixture containing not less than 3 1/3 pounds of salt to each hundredweight of the unstuffed sausage should be thoroughly mixed with the ground or chopped meat. After being stuffed, sausage having a diameter not exceeding 3 1/2 inches, measured at the time of stuffing, should be smoked not less than 40 hours at a temperature not lower than 80 °F., and finally held in a drying room not less than 10 days at a temperature not lower than 45 °F. In no case, however, should the sausage be released from the drying room in less than 18 days from the time the curing materials are added to the meat. Sausage exceeding 3 1/2 inches, but not exceeding 4 inches, in diameter at the time of stuffing, should be held in a drying room, following smoking as above indicated, not less than 25 days at a temperature not lower than 45 °F., but in no case should the sausage be released from the drying room in less than 33 days from the time the curing materials are added to the meat.

Method No. 3. The meat should be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry-curing mixture containing not less than 3 1/3 pounds of salt to each hundredweight of the unstuffed sausage should be thoroughly mixed with the ground or chopped meat. After admixture with the salt and other curing materials and before stuffing, the ground or chopped meat should be held at a temperature not lower than 34 °F. for not less than 36 hours. After being stuffed, the sausage should be held at a temperature not lower than 34 °F. for an additional period of time sufficient to make a total of not less than 144 hours from the time the curing materials are added to the meat, or the sausage should be held for the time specified in a pickle curing medium of not less than 50° strength (salometer reading) at a temperature not lower than 44 °F. Finally, sausage having a diameter not exceeding 3 1/2 inches, measured at the time of stuffing, should be smoked for not less than 12 hours. The temperature of the smokehouse during this period at no time should be lower than 90 °F.; and for 4 consecutive hours of this period the smokehouse should be maintained at a temperature not lower than 128 °F. Sausage exceeding 3 1/2 inches, but not exceeding 4 inches, in diameter at the time of stuffing should be smoked, following the prescribed curing, for not less than 15 hours. The temperature of the smokehouse during the 15-hour period should at no time be lower than 90 °F., and for 7 consecutive hours of this period the smokehouse should be maintained at a temperature not lower than 128 °F. In regulating the temperature of the smokehouse for the treatment of sausage under this method, the temperature of 128 °F. should be attained gradually during a period of not less than 4 hours.

Method No. 4. The meat should be ground or chopped into pieces not exceeding one-fourth of an inch in diameter. A dry curing mixture containing not less than 2 1/2 pounds

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of salt to each hundredweight of the unstuffed sausage should be thoroughly mixed with the ground or chopped meat. After admixture with the salt and other curing materials and before stuffing, the ground or chopped sausage should be held as a compact mass, not more than 6 inches in depth, at a temperature not lower than 36 °F. for not less than 10 days. At the termination of the holding period, the sausage should be stuffed in casings or cloth bags not exceeding 3 1/3 inches in diameter, measured at the time of stuffing. After being stuffed, the sausage should be held in a drying room at a temperature not lower than 45 °F for the remainder of a 35-day period, measured from the time the curing materials are added to the meat. At any time after stuffing, if the establishment operator deems it desirable, the product may be heated in a water bath for a period not to exceed 3 hours at a temperature not lower than 85 °F., or subjected to smoking at a temperature not lower than 80 °F., or the product may be both heated and smoked as specified. The time consumed in heating and smoking, however, should be in addition to the 35-day holding period specified.

Method No. 5. The meat should be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry curing mixture containing not less than 3 1/3 pounds of salt to each hundredweight of the unstuffed sausage should be thoroughly mixed with the ground or chopped meat. After being stuffed, the sausage should be held for not less than 65 days at a temperature not lower than 45 °F. The coverings for sausage prepared according to this method may be coated at any stage of the preparation before or during the holding period with paraffin or other substance approved by the Administrator.

Method No. 6.

(A) Basic requirements. The meat should be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry-curing mixture containing not less than 3.33 pounds of salt to each hundred-weight of the unstuffed sausage, excluding the weight of dry ingredients, should be thoroughly mixed with the ground or chopped meat. After the curing mixture has been added, the sausage should be held for two time periods, a holding period and a drying period. The holding period will be for a minimum of 48 hours at a room temperature not lower than 35 ° F. This holding period requirement may be fulfilled totally or in part before the drying period and then the remainder, if any, after the drying period or as an extension of the drying period. During the drying period, the sausage should be held in a drying room at a temperature not lower than 50 ° F. (10.0 ° C) for a period of time determined by Tables 3A, 3B, and 4. The length of the drying period, established in Method No.6 (A) may be modified as provided in Method No.6 (B) or (C)

TABLE 3A-SAUSAGE DRYING ROOM TIMES BY METHOD NO. 6

| Diameter of casing at time of stuffing¹ | Days in drying room² |
|---|--|
| Up to: | |
| 1 inches | 14 |
| 1 1/2 inches | 15 |
| 2 inches | 16 |
| 2 1/2 inches | 18 |
| 3 inches | 20 |

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| | |
|--------------|----|
| 3 1/2 inches | 23 |
| 4 inches | 25 |
| 4 1/2 inches | 30 |
| 5 inches | 35 |
| 5 1/2 inches | 43 |
| 6 inches | 50 |

¹ The drying room times for flattened or oval sausages should use a diameter derived by measuring the circumference and dividing by 3.14 (pi).

² Drying room time may be modified as set forth in Tables 3B and 4.

(B) Reduction in Drying Room Time. During the holding period, the sausage may be smoked or fermented. If the temperature is increased to 70 ° F. (21.1 ° C) or higher, while the sausage is being held after adding curing materials but before the drying period, the subsequent drying room times prescribed for this method may be reduced according to the schedule in Table 3B. No interpolation of values is permissible.

TABLE 3B-PERCENTAGE REDUCTION IN DRYING ROOM TIME (TABLE 3A) PERMITTED BY HOLDING TIMES AND TEMPERATURES PRIOR TO DRYING¹

| Minimum Temperature ² | Minimum Time (hours) | | | | |
|----------------------------------|----------------------|------------------|------------------|-----|------------------|
| | 24 | 48 | 72 | 96 | 120 |
| 70 ° F (21.1 ° C) | 4 | 9 | 14 | 19 | 24 |
| 75 ° F (23.9 ° C) | 5 | 12 | 19 | 26 | 33 |
| 80 ° F (26.7 ° C) | 8 | 18 | 28 | 38 | 48 |
| 85 ° F (29.5 ° C) | 10 | 25 | 39 | 53 | 67 |
| 90 ° F (32.2 ° C) | 15 | 35 | 55 | 75 | 95 |
| 95 ° F (35.0 ° C) | 23 | 49 | 74 | 98 | 100 ³ |
| 100 ° F (37.9 ° C) | 37 | 88 | 100 ³ | 100 | 100 |
| 105 ° F (40.6 ° C) | 57 | 100 ³ | 100 | 100 | 100 |
| 110 ° F (43.3 ° C) | 90 | 100 ³ | 100 | 100 | 100 |
| 120 ° F (48.9 ° C) | 100 ³ | 100 | 100 | 100 | 100 |

¹ In computing the days to be deducted, the number with any fraction should be rounded to the next lower whole number and should be deducted from the required total drying time. Example: Sausage stuffed in 3 inch diameter casing requires 20 days in the drying room (from Drying Room Times, Table 3A). If allowed to ferment, after addition of curing materials, at 80 ° F. for 48 hours, the 20 day drying time may be reduced 18% (from Table 3B). Eighteen percent of 20 day equals 3.6 days. Twenty days minus 3 days equals 17 days. The total drying time required in the drying room, therefore, will be 17 days.

² Either room temperature or internal product temperature should be used for sausages that will be subsequently dried to a moisture-protein ratio of 2.3: 1 or less. Internal product temperature should be used for all other sausages.

³ Trichinae will be destroyed during fermentation or smoking at the temperature and length of time indicated. Therefore, no drying room period is required for products so treated.

(C) Reduced Salt Content-Drying Room Times. Salt content of less than 3.33 pounds for each hundredweight of sausage formulation, excluding dry ingredients, (such as salts,

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sugars, and spices), may be permitted provided the drying time is increased according to the schedule contained in Table 4.

TRICHINA TREATMENT OF SAUSAGE BY METHOD NO. 6

TABLE 4-REDUCED SALT CONTENT-DRYING ROOM TIMES
[Required percentage increase in drying room time (Table 3A) for added salt of less than 3.33 pounds per hundredweight of sausage]

| Minimum pounds of salt added to sausage ¹ | Increase in drying room time ² |
|--|---|
| 3.3 | 1 |
| 3.2 | 4 |
| 3.1 | 7 |
| 3.0 | 10 |
| 2.9 | 13 |
| 2.8 | 16 |
| 2.7 | 19 |
| 2.6 | 22 |
| 2.5 | 25 |
| 2.4 | 28 |
| 2.3 | 31 |
| 2.2 | 34 |
| 2.1 | 37 |
| 2.0 | 40 |

¹Calculate the salt content for column 1 as follows: Multiply the pounds of salt in the sausage formulation by 100. Then divide this number by the total weight of sausage formulation minus the weight of dry ingredients and round down to the next lowest 0.1%. Percents may be substituted for pounds.

Example: 120 lbs. pork, 3.56 lbs. salt, 2 lbs. spices, 0.5 lbs. wine, 1 lb. water and starter culture, 0.8 lbs. sugar, .012 lbs. sodium nitrite total weight is 127.872 lbs.

$$(3.56 \times 100) / (127.872 - 3.56 - 2 - 0.8 - 0.012) = 356 / 121.5 = 2.93$$

Therefore, the sausage drying time must be increased by 13 percent.

²In computing the days to be added to the required total drying time, fractions should be rounded to the next higher whole number and added to the required total drying time. Example: Sausage stuffed in 3 1/2 inch diameter casing requires 23 days in the drying room (from Drying Room Times). If the quantity of salt added per hundredweight of sausage is 2 pounds instead of 3.33 pounds, the drying room time must be increased by 40 percent (from Reduced Salt Content-Drying Room Times), or 9.2 days. The 9.2 is rounded up to 10 days and is added to the 23 days to equal 33 days. The total drying time required in the drying room, therefore, will be 33 days.

Method No. 7

Dry Sausages. (A) General Requirements. The establishment should use meat particles reduced in size to no more than 1/4 inch in diameter. The establishment should add a curing mixture containing no less than 2.7 pounds of salt per hundred pounds of meat and mix it uniformly throughout the product. The establishment should hold, heat, and dry the product according to paragraph (B) or (C) below.

(B) Holding, Heating, and Drying Treatment, Large Sausages. Except as permitted in (C) below, the establishment should subject sausages in casings not exceeding 105 mm in diameter, at the time of stuffing, to all of the following minimum chamber temperatures and time periods.

**TREATMENT SCHEDULE FOR SAUSAGES 105 MIL-LIMETERS (4 1/8
INCHES) OR LESS IN DIAMETER**

| Minimum chamber temperature | | Minimum time (hours) |
|-----------------------------|------|----------------------|
| (°F) | (°C) | |
| 50 | 10 | 12 |
| 90 | 32.2 | 1 |
| 100 | 37.8 | 1 |
| 110 | 43.3 | 1 |
| 120 | 48.9 | 1 |
| 125 | 51.7 | 7 |

Following the preceding treatment, the establishment should dry the sausages at a temperature not lower than 50 °F (10 °C) for not less than 7 days.

(C) Heating and Drying Treatment, Small Sausages. Alternatively, the establishment may subject sausages in casings not exceeding 55 mm in diameter, at the time of stuffing, to all of the following minimum chamber temperatures and time periods.

**TREATMENT SCHEDULE FOR SAUSAGES 55 MILLIMETERS (2 1/8 INCHES)
OR LESS IN DIAMETER**

| Minimum chamber temperature | | Minimum time (hours) |
|-----------------------------|------|----------------------|
| (°F) | (°C) | |
| 50 | 10 | 12 |
| 100 | 37.8 | 1 |
| 125 | 51.7 | 6 |

Following the preceding heat treatment, the establishment should dry the sausages at a temperature not lower than 50 °F (10 °C) for not less than 4 days.

2. Capocollo (capicola, capicola)

Boneless pork butts for *capocollo* should be cured in a dry curing mixture containing not less than 4 1/2 pounds of salt per hundredweight of meat for a period of not less than 25 days at a temperature not lower than 36 °F. If the curing materials are applied to the butts by the process known as churning, a small quantity of pickle may be added. During the curing period the butts may be overhauled according to any of the usual processes of overhauling, including the addition of pickle or dry salt if desired. The butts should not be subjected during or after curing to any treatment designed to remove salt from the meat, except that superficial washing may be allowed. After being stuffed, the product should be smoked for a period of not less than 30 hours at a temperature not lower than 80 °F., and should finally be held in a drying room not less than 20 days at a temperature not lower than 45 °F.

3. Coppa

Boneless pork butts for coppa should be cured in a dry curing mixture containing not less than 4 1/2 pounds of salt per hundredweight of meat for a period of not less than 18 days at a temperature not lower than 36 °F. If the curing mixture is applied to the butts by the

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process known as churning, a small quantity of pickle may be added. During the curing period the butts may be overhauled according to any of the usual processes of overhauling, including the addition of pickle or dry salt if desired. The butts should not be subjected during or after curing to any treatment designed to remove salt from the meat, except that superficial washing may be allowed. After being stuffed, the product should be held in a drying room not less than 35 days at a temperature not lower than 45 °F.

4. Hams and pork shoulder picnics.

In the curing of hams and pork shoulder picnics, one of the methods below should be used. For calculating days per pound, the establishment should use the weight of the heaviest ham or picnic in the lot.

Method No. 1. The hams and pork shoulder picnics should be cured by a dry salt curing process not less than 40 days at a temperature no lower than 36 °F. The products should be laid down in salt, not less than 4 pounds to each hundredweight of product, the salt being applied in a thorough manner to the lean meat of each item. When placed in cure, the products may be pumped with pickle if desired. At least once during the curing process, the products should be overhauled (turned over for the application of additional cure) and additional salt applied, if necessary, so that the lean meat of each item is thoroughly covered. After removal from cure, the products may be soaked in water at a temperature not higher than 70 °F for not more than 15 hours, during which time the water may be changed once, but they should not be subjected to any other treatment designed to remove salt from the meat except that superficial washing may be allowed. The products should finally be dried or smoked at a time and temperature not less than a combination prescribed in Table 5 of Method No. 3.

Method No. 3.

- (A) Curing. (Other than bag curing): Establishments should cure hams and shoulders by using a cure mixture containing not less than 70 percent salt by weight to cover all exposed muscle tissue and to pack the hock region. Total curing time consists of a mandatory cure contact time and an optional equalization time.
- (B) Cure Contact Time. This is the cure contact period, during which the establishment should keep exposed muscle tissue coated with the cure mixture at least 28 days but for no less than 1.5 days per pound of ham or shoulder. Overhaul is optional so long as the exposed muscle tissue remains coated with curing mixture.
- (C) Equalization. The establishment may provide an equalization period after the minimum cure contact period in (B) above to permit the absorbed salt to permeate the product's inner tissues. Equalization is the time after the excess cure has been removed from the product at the end of the cure contact period until the product is placed in the drying room and the drying period begins. The total curing time (equalization plus cure contact) should be at least 40 days and in no case less than 2 days per pound of an uncured ham or shoulder.
- (D) Removing Excess Cure. After the required cure contact period, the establishment may remove excess cure mixture from the product's surface mechanically or by rinsing up to 1 minute with water, but not by soaking.

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- (E) **Bag Curing.** Bag curing is a traditional ham curing technique in which the manufacturer wraps the ham and all of the cure mixture together in Kraft paper then hangs them individually. The paper keeps the extra cure mixture in close contact with the product making reapplication of salt unnecessary, and it protects the product from mites and insects. Establishments may employ the bag curing method as an alternative to (A) through (D) above. An establishment which elects to use the bag curing method should apply a cure mixture containing at least 6 pounds of salt per 100 pounds of uncured product. The establishment should rub the curing mixture into the exposed muscle tissue, pack the hock region with the curing mixture, and use uncoated wrapping paper to wrap the product together with any remaining curing mixture. The bag-cured product should remain wrapped throughout the curing period and may or may not remain wrapped during the drying period. In any case, the curing period should be at least 40 days but not less than 2 days per pound of an uncured ham or shoulder. After curing, the cured product should be exposed to a drying time and temperature prescribed in Table 5.
- (F) **Curing Temperature.** During the curing period the establishment should use one of the following procedures: (1) The establishment should control the room temperature at not less than 35 ° F (1.7 ° C) nor greater than 45 ° F (7.2 ° C) for the first 1.5 days per pound of an uncured ham or shoulder, and not less than 35 ° F (1.7 ° C) nor greater than 60 ° F (15.6 ° C) for the remainder of the curing period. (2) The establishment should monitor and record daily product temperature. The room temperature need not be controlled but days on which the product temperature drops below 35 ° F (1.7 ° C) should not be counted as curing time. If the product temperature exceeds 45 ° F (7.2 ° C) within the first period of 1.5 days per pound of an uncured ham or shoulder or if it exceeds 60 ° F (15.6 ° C) for the remainder of the curing period, the establishment should cool the product back to the 45 ° F (7.2 ° C) maximum during the first period or 55 ° F (12.8 ° C) maximum during the remainder of the period. (3) The establishment should begin curing product only between the dates of December 1 and February 13. The room temperature need not be controlled, but the establishment should monitor and record daily room temperatures, and days in which the room temperature drops below 35 ° F (1.7 ° C) should not be counted as curing time.
- (G) **Drying.** After the curing period, establishments should use one of three procedures for drying: (1) The establishment should subject the product to a controlled room temperature for a minimum time and minimum temperature combination prescribed in Table 5 or for a set of such combinations in which the total of the fractional periods (in column 4 of Table 5) exceeds 1.5. (2) Establishments using uncontrolled room temperatures should monitor and record the internal product temperature. The drying period should be complete when, from the days which can be counted as curing time, one of the time/temperature combinations of Table 5 is satisfied or when the total of the fractional values for the combinations exceeds 1.5. (3) Establishments using uncontrolled room temperatures should dry the product for a minimum of 160 days including the entire months of June, July, and August. This procedure is obviously dependent on local climatic conditions and no problem exists with respect to current producers who use this procedure. Future applicants should demonstrate that their local monthly average temperatures and the local monthly minimum

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temperatures are equal to or warmer than the normal average temperatures and normal minimum temperatures compiled by the National Oceanic and Atmospheric Administration for Boone, North Carolina, station 31-0977, 1951 through 1980.

(Should we update these temperatures?)

MONTHLY TEMPERATURES (° F) FOR BOONE NC, 1951-1980

| Jan. | Feb. | Mar. | Apr. | May | June | July | Aug. | Sep. |
|-----------------------------|------|------|------|------|------|------|------|------|
| Normal average temperatures | | | | | | | | |
| 32.2 | 34.1 | 41.3 | 51.2 | 59.1 | 65.1 | 68.3 | 67.5 | 61.6 |
| Normal minimum temperatures | | | | | | | | |
| 22.8 | 24.2 | 30.8 | 39.6 | 48.1 | 54.7 | 58.5 | 57.6 | 51.6 |

Drying Times and Temperatures for Trichina Inactivation in Hams and Shoulders

TABLE 5. MINIMUM DRYING DAYS AT A MINIMUM TEMPERATURE*

| Minimum Drying Temperature | | Minimum days at drying temperature | Fractional period for one day of drying |
|----------------------------|-----------|------------------------------------|---|
| Degrees F | Degrees C | | |
| 130 | 54.4 | 1.5 | .67 |
| 125 | 51.7 | 2 | .50 |
| 120 | 48.9 | 3 | .33 |
| 115 | 46.1 | 4 | .25 |
| 110 | 43.3 | 5 | .20 |
| 105 | 40.6 | 6 | .17 |
| 100 | 37.8 | 7 | .14 |
| 95 | 35.0 | 9 | .11 |
| 90 | 32.2 | 11 | .091 |
| 85 | 29.4 | 18 | .056 |
| 80 | 26.7 | 25 | .040 |
| 75 | 23.9 | 35 | .029 |

* Interpolation of these times or temperatures is not acceptable; establishments wishing to use temperatures or times not in this Table should first validate their efficacy.

Method No. 4.

- (A) Cure: Establishments should cure hams and shoulders by using a cure mixture containing not less than 71.5 percent salt by weight to cover all exposed muscle tissue and to pack the hock region. Establishments may substitute potassium chloride (KCl) for up to half of the required salt on an equal weight basis.
- (B) Curing. Establishments should apply the cure at a rate not less than 5.72 pounds of salt and KCl per hundred pounds of fresh meat. The cure should be applied in either three or four approximately equal amounts (two or three overhauls) at separate times during the first 14 days of curing.

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- (C) Cure Contact Time. Establishments should keep the product in contact with the cure mixture for no less than 2 days per pound of an uncured ham or shoulder but for at least 30 days. Establishments should maintain the curing temperature at no less than 35° F (1.7° C) during the cure contact time.
- (D) Equalization. After the cure contact period, establishments should provide an added equalization period of no less than 1 day per pound of an uncured ham or shoulder but at least 14 days. Equalization is the time after the excess cure has been removed from the product, the end of the cure contact period, and before the drying period begins. Establishments may substitute additional cure contact days for an equal number of equalization days.
- (E) Removing Excess Cure. After the required cure contact period, the establishment may remove excess cure mixture from the product's surface mechanically or by rinsing up to 1 minute with water, but not by soaking.
- (F) Drying. After the curing period, establishments should use one of the controlled temperature methods for drying listed in Method No. 3 of this subparagraph.

Method No. 5

- (A) Curing. The establishment should cure the ham to a minimum brine concentration of 6 percent by the end of the drying period. Brine concentration is calculated as 100 times the salt concentration divided by the sum of the salt and water concentrations.
$$\text{Percent brine} = 100 \times \frac{[\text{salt}]}{([\text{salt}] + [\text{water}])}$$
The Agency will accept the brine concentration in the biceps femoris as a reasonable estimate of the minimum brine concentration in the ham.
- (B) Drying and Total Process Times. The establishment should dry the cured ham at a minimum temperature of 55 °F (13 °C) for at least 150 days. The total time of drying plus curing should be at least 206 days.
- (C) Ensuring an Acceptable Internal Brine Concentration. (1) To establish compliance, the establishment should take product samples from the first 12 lots of production as follows: From each lot, (i) One sample should be taken from each of 5 or more hams; (ii) Each sample should be taken from the biceps femoris. As an alternative to the use of the biceps femoris, the Agency should consider other method (s) of sampling the dry cured hams to determine the minimum internal brine concentration, as long as the establishment proposes it and submits data and other information to establish its sufficiency to the processing authority; (iii) Each sample should weigh no less than 100 grams; (iv) The samples should be combined as one composite sample and sealed in a water vapor proof container; (v) The composite sample should be submitted to a laboratory accredited under the provisions of 9 CFR 318.21 (Accreditation of Chemistry Labs) to be analyzed for salt and water content using methods from the `` Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC), " 15th Edition, 1990, Section 983.18 (page 931) and Section 971.19 (page 933) which are incorporated by reference. If the time between sampling and submittal of the composite sample to the accredited laboratory will exceed 8 hours, then the establishment should freeze the composite sample immediately after the samples are combined; (vi) Once the laboratory results for the composite sample are received, the manufacturer should calculate the internal brine concentration by multiplying the salt

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concentration by 100 and then dividing that figure by the sum of the salt and water concentrations; (vii) Compliance is established when the samples from the first 12 lots of production have a minimum internal brine concentration of 6 percent. Lots being tested to establish compliance should be held until the internal brine concentration has been determined and found to be at least 6 percent. If the minimum internal brine concentration is less than 6 percent, the lot being tested should be held until the establishment brings the lot into compliance by further processing. (2) To maintain compliance, the establishment should take samples, have the samples analyzed, and perform the brine calculations as set forth above from one lot every 13 weeks. Lots being tested to maintain compliance should not be held. If the minimum internal brine concentration is less than 6 percent in a lot being tested to maintain compliance, the establishment should develop and propose steps acceptable to FSIS to ensure that the process is corrected. (3) Accredited laboratory results and the brine calculations should be placed on file at the establishment and available for review.

Method No. 6

- (A) Curing. The establishment should cure the ham to a minimum brine concentration of 6 percent by the end of the drying period. Brine concentration is calculated as 100 times the salt concentration divided by the sum of the salt and water concentrations. Percent brine = $100 \times [\text{salt}] / ([\text{salt}] + [\text{water}])$ The Agency will accept the brine concentration in the biceps femoris as a reasonable estimate of the minimum brine concentration.
- (B) Drying and Total Process Times. The establishment should dry the cured ham at a minimum temperature of 110 ° F (43 ° C) for at least 4 days. The total time of drying plus curing should be at least 34 days.
- (C) Ensuring an Acceptable Internal Brine Concentration. (1) To establish compliance the establishment should take product samples from the first 12 lots of production as follows: From each lot, (i) One sample should be taken from each of 5 or more hams; (ii) Each sample should be taken from the biceps femoris. As an alternative to the use of the biceps femoris, the Agency will consider other methods of sampling the dry cured hams to determine internal brine concentration, as long as the establishment validates the process. (iii) Each sample should weigh no less than 100 grams; (iv) The samples should be combined as one composite sample and sealed in a water vapor proof container; (v) The composite sample should be submitted to an accredited laboratory to be analyzed for salt and water content using methods from the “Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC)”, 15th Edition, 1990, section 983.18 (page 931) and section 971.19 (page 933) which are incorporated by reference. If the time between sampling and submittal of the composite sample to the accredited laboratory will exceed 8 hours, then the establishment should freeze the composite sample immediately after the samples are combined; (vi) Compliance is established when the samples from the first 12 lots of production have a minimum internal brine concentration of 6 percent. Lots being tested to establish compliance should be held until the internal brine concentration has been determined and found to be at least 6 percent. If the minimum internal brine concentration is less than 6 percent, the lot being tested should be held

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until the establishment brings the lot into compliance by further processing. (2) To maintain compliance, the establishment should take samples, have the samples analyzed, and perform the brine calculations as set forth above from one lot every 13 weeks. Lots being tested to maintain compliance should not be held. If the minimum internal brine concentration is less than 6 percent in a lot being tested to maintain compliance, the establishment should develop and propose steps acceptable to FSIS to ensure that the process is corrected. (3) Accredited laboratory results and the brine calculations should be placed on file in the establishment and available to Program employees for review.

5. Boneless pork loins and loin ends.

In lieu of heating or refrigerating to destroy possible live trichinae in boneless loins, the loins may be cured for a period of not less than 25 days at a temperature not lower than 36 °F. by the use of one of the following methods:

Method No. 1. Application of a dry salt curing mixture containing not less than 5 pounds of salt to each hundredweight of meats.

Method No. 2. Application of a pickle solution of not less than 80° strength (salometer) on the basis of not less than 60 pounds of pickle to each hundredweight of meat.

Method No. 3. Application of a pickle solution added to the dry salt cure prescribed as Method No. 1 in this subdivision (v) provided the pickle solution is not less than 80° strength (salometer). After removal from cure, the loins may be soaked in water for not more than 1 hour at a temperature not higher than 70 °F. or washed under a spray but should not be subjected, during or after the curing process, to any other treatment designed to remove salt. Following curing, the loins should be smoked for not less than 12 hours. The minimum temperature of the smokehouse during this period at no time should be lower than 100 °F., and for 4 consecutive hours of this period the smokehouse should be maintained at a temperature not lower than 125 °F. Finally, the product should be held in a drying room for a period of not less than 12 days at a temperature not lower than 45 °F.

General Instructions

When necessary to comply with the requirements of this section, the smokehouses, drying rooms, and other compartments used in the treatment of pork to destroy possible live trichinae should be suitably equipped, by the operator of the official establishment, with accurate automatic recording thermometers. *Equipment such as automatic recording thermometers or any thermometers used in drying rooms, and other compartments should be checked periodically to make sure they are functioning accurately.*

The requirements for using the pooled sample digestion technique to analyze pork for the presence of trichina cysts are: (1) *The establishment should include in its HACCP plan its proposed procedure for identifying and pooling carcasses, collecting and pooling samples, testing samples (including the name and address of the laboratory),*

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communicating test results, retesting individual carcasses, and maintaining positive identification and clear separation of pork found to be trichina-free from untested pork or trichina-positive pork. (2) *The establishment should use the services of an accredited laboratory for all required testing. Such accredited laboratories should show adequacy of facilities, reagents, and equipment, and demonstration of continuing competency and reliability in performing the pooled sample digestion technique for trichinae.* (3) The establishment should sample no less than 5 grams of diaphragm muscle or tongue tissue from each carcass or no less than 10 grams of other muscle tissue. Samples may be pooled but a pool should not consist of more than 100 grams of sample. Sampling and sample preparation are subject to inspection supervision. (4) Pork or products made from tested pork should not be released as trichina free from the official establishment without treatment until the inspector in charge receives a laboratory report that the tested pork is free of trichina cysts. (f) Use of other tests for trichinosis in pork. Any additional analytical method for trichina testing *may be used upon the determination that it will detect at least 98 percent of swine bearing cysts present at a tissue density equal to or less than one cyst per gram of muscle from the diaphragm pillars at a 95 percent confidence level. Any such method should be supported by any data and other needed information.*

“Country Ham”, “Country Style Ham”, “Dry Cured Ham”, “Country Pork Shoulder”, “Country Style Pork Shoulder”, and “Dry Cured Pork Shoulder”.

Country Ham, Country Style Ham, or Dry Cured Ham, and Country Pork Shoulder, Country Style Pork Shoulder, or Dry Cured Pork Shoulder are the uncooked, cured, dried, smoked or unsmoked meat food products made respectively from a single piece of meat conforming to the definition of “ham”, or from a single piece of meat from a pork shoulder. The product must be treated for the destruction of possible live trichinae using tested and approved methods They are prepared by the dry application of salt (NaCl), or by the dry application of salt (NaCl) and one or more of the optional ingredients listed below. They may not be injected with curing solutions nor placed in curing solutions.

- (1) The entire exterior of the ham or pork shoulder should be coated by the dry application of salt or by the dry application of salt combined with other ingredients as permitted in paragraph (d) of this section.
- (2) Additional salt, or salt mixed with other permitted ingredients, may be re-applied to the product as necessary to insure complete penetration.
- (3) When sodium or potassium nitrate, or sodium or potassium nitrite, or a combination thereof, is used, the application of salt should be in sufficient quantity to insure that the finished product has an internal salt content of at least 4 percent.
- (4) When no sodium nitrate, potassium nitrate, sodium nitrite, potassium nitrite or a combination thereof is used, the application of salt should be in sufficient quantity to insure that the finished product has a brine concentration of not less than 10 percent or a water activity of not more than 0.92.

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The optional ingredients for these products are: (1) Nutritive sweeteners, spices, seasonings and flavorings. (2) Sodium or potassium nitrate and sodium or potassium nitrite.