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

FSIS DIRECTIVE

7111.1 | 3-3-99

PERFORMANCE STANDARDS FOR THE PRODUCTION OF CERTAIN MEAT AND POULTRY PRODUCTS

I. PURPOSE

This directive provides inspection program personnel with instructions for verifying that fully and partially cooked uncured meat patties, cooked beef, roast beef, and cooked corned beef products, fully cooked poultry products and partially cooked poultry breakfast strips meet the applicable performance standard requirements and are processed according to procedures on file at the establishment.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

9 CFR 301.2, 317.2, 318.17, 318.23, 320.1, 320.4
9 CFR 381.1, 381.125, 381.150
FSIS Directive 5000.1, dated 11/21/97
FSIS Directive 5400.5, dated 11/21/97
FSIS Directive 7110.3, Revision 1, dated 1/24/89
FSIS Directive 7221.1, Amendment 1, dated 8/19/96
FSIS Directive 7235.1, Revision 1, dated 5/11/94
FSIS Directive 7370.1, Amendment 2, dated 4/26/94
FSIS Directive 7370.2, dated 6/28/95
FSIS Directive 8820.1, Revision 2, dated 9/6/96

V. BACKGROUND

A. Prior to January 6, 1999, the meat and poultry products inspection regulations governing the production of cooked beef, roast beef, and cooked corned beef products, fully and partially cooked uncured meat patties, and certain fully and partially cooked poultry products required that these products meet time/temperature requirements, which resulted in a certain pathogenic reduction or control being achieved. (9 CFR 301.2, 317.2,

318.17, 318.23, 320.1, 320.4, 381.1, 381.125 and 381.150.) Inspection program personnel performed tasks to ensure that establishments were meeting these regulatory time/temperature requirements.

B. On January 6, 1999, FSIS converted the above regulations (see Attachment 1) into performance standards. The performance standards do not prescribe the means by which the pathogenic reduction or control is achieved. Establishments must address how they will achieve the kill in either a process schedule (for non-HACCP establishments) or a HACCP plan (for HACCP establishments). A process schedule is a written description of processing procedures consisting of any number of specific, sequential operations, directly under the control of the establishment, that are employed in the manufacture of a specific product, including the control, monitoring, verification, validation, and corrective action activities associated with production.

C. Establishments that have not developed and implemented a HACCP plan must develop and maintain on file a documented process schedule that has either been approved by a process authority for safety and efficacy or that incorporates the previous regulatory requirements (see section V.D. below). A process authority is a person or organization with expert knowledge in meat or poultry process control and relevant regulations. The process authority should have access to the establishment's facilities to evaluate and approve the safety and efficacy of the establishment's process schedule. Inspection program personnel should not evaluate process authority-approved procedures for efficacy. Establishments operating under HACCP are not required to develop a process schedule. They must, however, develop hazard analyzes and HACCP plans that address measures the establishment will take to meet the applicable performance standard.

D. Establishments that do not wish to change their processing practices may continue following the previous regulatory requirements for these products. The previous regulatory requirements have been published in two booklets titled "Compliance Guidelines for Meeting Lethality Performance Standards for Ready-to-Eat Meat and Poultry Products" and "Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization)." These two booklets will be referred to as "Compliance Guidelines" throughout this directive. Compliance guidelines must be incorporated into a process schedule or HACCP plan if an establishment wishes to use them instead of developing new processing practices.

VI. CONDUCTING INSPECTION SYSTEM GUIDE (ISG) TASKS IN NON-HACCP ESTABLISHMENTS

A. INITIAL COMPLIANCE

1. Inspection program personnel verify that:

a. The establishment has a documented process schedule, which may consist of Compliance Guidelines, that is maintained on file in the establishment and is available to FSIS.

b. The process schedule has been approved in writing by a process authority for safety and efficacy. **Note**: FSIS considers the information in the FSIS Compliance Guidelines and previously approved procedures developed under the old regulations in 318.17 already to be validated as effective. If the establishment follows these guidelines or procedures, a process authority's review and signature is not necessary.

c. The operations specified in the process schedule comply with applicable meat and poultry products inspection regulations. If inspection program personnel doubt the efficacy of what the establishment proposed, they should discuss any concerns with establishment management. If establishment management is unable to resolve those concerns, inspection program personnel should contact the next level of supervision or, for technical questions, the Technical Service Center.

2. **Deficiencies.** Inspection program personnel should document regulatory noncompliances on FSIS Form 8820-2, Process Deficiency Record (PDR) and take action as directed by FSIS Directive 8820.1, Rev. 2. **Note**: If establishments fail to meet the requirement in paragraph 1 above, inspection personnel should document this as a "major" deficiency. They do not have to take an official control action unless they determine that product is adulterated. If they determine such, the deficiency is "Critical" and a control action should be taken.

B. ONGOING COMPLIANCE

1. Inspection program personnel will verify that an establishment is producing product in accordance with its process schedule and meeting the regulatory performance standards by performing the appropriate ISG task.

2. **Deficiencies.** If an establishment fails to meet one or more of the ongoing regulatory compliance requirements, inspection program personnel should document the regulatory noncompliance on a PDR and take action as directed by FSIS Directive 8820.1, Rev. 2.

NOTE: Inspectors should not consider deviations from an establishment's process schedule to be noncompliances, in and of themselves, unless they may lead to product that does not meet regulatory performance standards. Questions should be referred to the Technical Service Center.

C. USING ALTERNATIVE LETHALITIES IN NON-HACCP ESTABLISHMENTS

In non-HACCP establishments producing products using alternative lethalities, inspection program personnel verify that the establishment has documentation demonstrating, within its validated process schedule, that its process yields finished, ready-to-eat meat or poultry products with reductions of Salmonella equivalent to the required reductions complying with the lethality performance standards explicitly provided for in the meat and poultry products inspection regulations. Inspection program personnel should follow the instructions contained in paragraph A.1. above for initial compliance or paragraph B.1. above for ongoing compliance. **Note**: The information in the FSIS compliance guidelines would not be sufficient.

D. USING COMBINATIONS OF TREATMENTS IN NON-HACCP ESTABLISHMENTS

In non-HACCP establishments using a combination of treatments (e.g., acidification to achieve partial reduction of Salmonella, followed by heat to achieve, in combination, the total reduction of Salmonella specified in the performance standard), inspection program personnel verify that the establishment has documentation demonstrating that it is meeting the required lethality performance standard by following the instructions contained in paragraph A.1. above for initial compliance or paragraph B.1. above for ongoing compliance. **Note**: The information in the FSIS compliance guidelines would not be sufficient.

VII. CONDUCTING PROCEDURES IN HACCP ESTABLISHMENTS

A. INITIAL COMPLIANCE

Under the appropriate ISP code, inspection program personnel will:

1. Review the establishment's Hazard Analysis and HACCP plan to verify that documentation, as required in section 417.5(a) of the HACCP

regulations, is included that addresses measures the establishment will take to meet the applicable performance standard. Note: establishments may incorporate the information in FSIS's compliance guidelines to meet the performance standard. If inspection program personnel doubt the efficacy of the establishment's measures to meet the performance standard, they should discuss any concerns with establishment management. If establishment management is unable to resolve those concerns, inspection program personnel should contact the next level of supervision or, for technical questions, the Technical Service Center.

2. Verify that the updated HACCP plan was signed and dated by are responsible establishment official.

3. Document findings of noncompliance as directed by FSIS Directive 5400.5.

B. COMPLIANCE/NONCOMPLIANCE—OTHER REQUIREMENTS

Inspection program personnel:

1. Verify that the establishment is adhering to its HACCP plan so that it is achieving the appropriate performance standards by performing the appropriate procedure(s).

2. Document findings of noncompliance as directed by FSIS Directive 5400.5.

C. USING ALTERNATIVE LETHALITIES IN HACCP ESTABLISHMENTS

In HACCP establishments producing products using alternative lethalities, inspection program personnel verify that the establishment has documentation demonstrating, within its validated HACCP plan, that its process yields finished, ready-to-eat meat or poultry products with reductions of Salmonella equivalent to the mandated reductions by complying with the lethality performance standards explicitly provided for in the meat and poultry products inspection regulations. Inspection program personnel should follow the instructions contained in paragraph A.1. above for initial compliance or paragraph B.1. above for ongoing compliance. **Note**: The information in the FSIS compliance guidelines would not be sufficient.

D. USING COMBINATIONS OF TREATMENTS IN HACCP ESTABLISHMENTS

In HACCP establishments using a combination of treatments, inspection program personnel verify that the establishment has documentation demonstrating that it is meeting the required lethality performance standard by following the instructions contained in paragraph A.1. above for initial compliance or paragraph B.1. above for ongoing compliance. **Note**: The information in the FSIS compliance guidelines would not be sufficient.

Any questions regarding these instructions should be directed to the next level of supervision or the Technical Service Center.

/s/ Philip S. Derfler

Deputy Administrator
Office of Policy, Program Development
and Evaluation

PERFORMANCE STANDARD REQUIREMENTS

All products covered under this directive must meet lethality (**except** for uncured meat patties) and stabilization performance standards.

A. Lethality. To meet the lethality performance standard, establishments must treat the following ready-to-eat products so as to ensure a specific reduction (i.e., an "x-$\log_{10}$" reduction) in the number of Salmonella microorganisms, thereby eliminating or adequately reducing it and other pathogens and their toxins or toxic metabolites from or on the product. An "x-$\log_{10}$" reduction means that the number of organisms in the product would be expected to be reduced by a factor of 10^x. The lethality process must also include a cooking step.

1. **Alternative lethalities.** Establishments may produce products using lethalities ("x-$\log_{10}$" reductions) different than those contained in the performance standard regulations. However, any alternative lethality must achieve an equivalent probability that no viable Salmonella organisms or other pathogens of concern remain in the finished product as when the prescribed lethality is used.

2. **Combination of treatments.** Establishments may use a combination of treatments to meet the required performance standards for lethality, so long as a cooking step is included and a knowledgeable processing authority has validated the process schedules.

B. Stabilization. To meet the stabilization performance standard, establishments must prevent the growth of spore-forming bacteria capable of producing toxins either in the product or in the human intestine after consumption.

1. **Cooked beef, roast beef and cooked corned beef products** must be produced using processes ensuring that the products meet the following performance standards:

i. Lethality. Establishments must treat these ready-to-eat products so as to ensure that a 6.5-$\log_{10}$ reduction of Salmonella (or an alternative lethality that achieves an equivalent probability that no viable Salmonella organisms remain in the finished product) is achieved throughout the product.

ii. Stabilization. Establishments must prevent the multiplication of microorganisms such as Clostridium botulinum, and may allow no more than a 1-$\log_{10}$ multiplication of Clostridium perfringens within the product.

2. **Uncured meat patties** must be produced using one of the heat-processing procedures listed in §318.23. They must also be produced using a process ensuring that the product meets the following stabilization performance standard: no multiplication of organisms such as Clostridium botulinum, and no more than a 1-$\log_{10}$ multiplication of Clostridium perfringens within the product is allowed.

3. **Fully cooked poultry products** must be produced using processes ensuring that the products meet the following performance standards:

i. Lethality. Establishments must treat ready-to-eat product so as to ensure that a 7-$\log_{10}$ reduction of Salmonella (or an alternative lethality that achieves an equivalent probability that no viable Salmonella organisms remain in the finished product) is achieved throughout the product.

ii. Stabilization. Establishments must prevent the multiplication of microorganisms such as Clostridium botulinum, and allow no more than a 1-$\log_{10}$ multiplication of Clostridium perfringens within the product.

4. **Partially cooked poultry breakfast strips** must be produced using processes ensuring that the products meet the stabilization performance standard listed in paragraph VI.B.3.ii, above.

The performance standards regulations as published in the Federal Register are as follows:

PART 301--DEFINITIONS

1. The authority citation for part 301 is revised to read as

follows:

Authority: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

2. Section 301.2 is amended by removing the paragraph designations (a) through (yyy) and adding, in alphabetical order, new definitions for ``Process authority'' and ``Process schedule,'' to read as follows:

Sec. 301.2 Definitions.

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Process authority. A person or organization with expert knowledge in meat production process control and relevant regulations. This definition does not apply to subpart G of part 318.

Process schedule. A written description of processing procedures, consisting of any number of specific, sequential operations directly under the control of the establishment employed in the manufacture of a specific product, including the control, monitoring, verification, validation, and corrective action activities associated with production. This definition does not apply to subpart G of part 318.

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PART 317--LABELING, MARKING DEVICES, AND CONTAINERS

3. The authority citation for part 317 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

4. In Sec. 317.2, paragraph (l) introductory text is revised to read as follows:

Sec. 317.2 Labels: definition; required features.

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(1) Safe handling instructions shall be provided for: All meat and meat products of cattle, swine, sheep, goat, horse, other equine that do not meet the requirements contained in Sec. 318.17, or that have not undergone other processing that would render them ready-to-eat; and all comminuted meat patties not heat processed in a manner that conforms to the time and temperature combinations in the Table for Permitted Heat-

Processing Temperature/Time Combinations For Fully-Cooked Patties in Sec. 318.23, except as exempted under paragraph (l)(4) of this section.

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5. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 138f, 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

6. Section 318.17 is revised to read as follows:

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

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

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

(2) Stabilization. There can be no multiplication of toxigenic microorganisms such as Clostridium botulinum, and no more than 1-log<INF>10</INF> multiplication of Clostridium perfringens within the product.

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

(c) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically

supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

7. Section 318.23 is revised to read as follows:

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

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

(1) Patty. A shaped and formed, comminuted, flattened cake of meat food product.

(2) Comminuted. A processing term describing the reduction in size of pieces of meat, including chopping, flaking, grinding, or mincing, but not including chunking or sectioning.

(3) Partially-cooked patties. Meat patties that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.

(4) Char-marked patties. Meat patties that have been marked by a heat source and that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.

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

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

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

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

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

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

(c) Stabilization. (1) Fully cooked, partially cooked, and char-marked meat patties must be produced using processes ensuring no multiplication of toxigenic microorganisms such as Clostridium botulinum, and no more than a 1 log<INF>10</INF> multiplication of Clostridium perfringens, within the product.

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

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

by challenge studies conducted outside the plant.

(4) Partially cooked patties must bear the labeling statement ``Partially cooked: For Safety Cook Until Well Done (Internal Meat Temperature 160 degrees F.).'' The labeling statement must be adjacent to the product name, and prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

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

PART 320--RECORDS, REGISTRATION, AND REPORTS

8. The authority citation for part 320 is revised to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

Sec. 320.1 [Amended]

9. In Sec. 320.1, paragraph (b)(4) is removed and reserved.

320.4 [Amended]

10. In Sec. 320.4, the first sentence is amended by adding the phrase ``process schedules,'' immediately before the phrase ``facilities and inventory.''

PART 381--POULTRY PRODUCTS INSPECTION REGULATIONS

11. The authority citation for part 381 is revised to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451-470; 7 CFR 2.18,

2.53.

12. Section 381.1 is amended by removing the paragraph designations (b)(1) through (62) and adding, in alphabetical order, within paragraph (b), new definitions for ``Process authority'' and ``Process schedule,'' to read as follows:

381.1 Definitions.

* * * * *

(b) * * *

Process authority. A person or organization with expert knowledge in poultry production process control and relevant regulations.

Process schedule. A written description of processing procedures, consisting of any number of specific, distinct, and ordered operations directly under control of the establishment employed in the manufacture of a specific product, including the control, monitoring, verification, validation, and corrective action activities associated with production.

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Sec. 381.125 [Amended]

13. In Sec. 381.125, the introductory text of paragraph (b) is amended by removing the word ``heat''; by removing the phrase ``Sec. 381.150(b)'' and by adding the phrase ``Sec. 381.150(a)'' in its place; and by removing the word ``further''.

14. Section 381.150 is revised to read as follows:

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

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

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

(2) Stabilization. There can be no multiplication of toxigenic microorganisms such as Clostridium botulinum, and no more than a 1 log<INF>10</INF> multiplication of Clostridium perfringens within the product.

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

(c) For each product produced using a process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file, available to FSIS, a process schedule, as defined in Sec. 381.1(b). Each process schedule must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to an establishment in order to evaluate and approve the safety and efficacy of each process schedule.

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